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Presidential Documents

Title 3—

The President

Proclamation 8653 of April 11, 2011

National Equal Pay Day, 2011

By the President of the United States of America

A Proclamation

Generations of women have fought for the advancement of their sisters, daughters, and themselves in acts of great courage—reaching for and winning the right to vote, breaking barriers in America's universities and boardrooms, and flooding the modern workforce with skilled talent. While our Nation has come far, obstacles continue to exist for working women, who still earn less on average than working men. Each year, National Equal Pay Day reflects how far into the current year women must work to match what men earned in the previous year. On National Equal Pay Day, we rededicate ourselves to carrying forward the fight for true economic equality for all, regardless of gender.

When the Equal Pay Act was signed into law in 1963, women earned 59 cents for every dollar earned by men. Though women today are more likely than men to attend and graduate from college, women still earn an average of only about 77 cents for every dollar a man earns. Even when accounting for factors such as experience, education, industry, and hours, this wage gap persists. Over the course of her lifetime, this gap will cost a woman and her family lost wages, reduced pensions, and diminished Social Security benefits. Though we have made great strides, wage discrimination is real and women are still more likely to live in poverty. These inequities remind us to work even harder to close the gaps that still exist.

At a time when families across this country are struggling to make ends meet, National Equal Pay Day reminds us that achieving equal pay for equal work is not just a women's issue—it is a family issue. In today's world, women represent both powerful consumers and vital wage earners. Women make up nearly half of the labor force and mothers are the primary or co-breadwinners in two-thirds of families. When women are not paid fairly, the families that depend on their earnings suffer.

That is why one of my first acts as President was to sign the Lilly Ledbetter Fair Pay Act, a law that empowers women who have been discriminated against in their salaries to have their day in court to make it right. I established the National Equal Pay Enforcement Task Force to identify persistent challenges to equal pay enforcement and ensure equal pay laws are vigorously enforced throughout our country. My Administration also published *Women in America: Indicators of Social and Economic Well-Being*, the first comprehensive Federal report on the status of American women in almost 50 years, which documents that although women have higher graduation rates than men at all academic levels, the wage gap still persists. We are pursuing these efforts because of the simple fact that when women are paid fairly, our whole Nation will benefit.

Achieving equal pay for women is vital to strengthening the future prosperity of our country. For the sake of our daughters and granddaughters, we must renew our commitment to eliminating the barriers women face in the workforce and give both women and men the opportunity to reach greater heights.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 12, 2011, as National Equal Pay Day. I call upon all Americans to recognize the full value of women's skills and their significant contributions to the labor force, acknowledge the injustice of wage discrimination, and join efforts to achieve equal pay.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

[FR Doc. 2011–9349
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Presidential Documents

Proclamation 8654 of April 12, 2011

Civil War Sesquicentennial

By the President of the United States of America

A Proclamation

On April 12, 1861, artillery guns boomed across Charleston Harbor in an attack on Fort Sumter. These were the first shots of a civil war that would stretch across 4 years of tremendous sacrifice, with over 3 million Americans serving in battles whose names reach across our history. The meaning of freedom and the very soul of our Nation were contested in the hills of Gettysburg and the roads of Antietam, the fields of Manassas and the woods of the Wilderness. When the terrible and costly struggle was over, a new meaning was conferred on our country's name—the United States of America. We might be tested, but whatever our fate might be, it would be as one Nation.

The Civil War was a conflict characterized by legendary acts of bravery in the face of unprecedented carnage. Those who lived in these times—from the resolute African American soldier volunteering his life for the liberation of his fellow man to the determined President secure in the rightness of his cause—brought a new birth of freedom to a country still mending its divisions.

On this milestone in American history, we remember the great cost of the unity and liberty we now enjoy, causes for which so many have laid down their lives. Though America would struggle to extend equal rights to all our citizens and carry out the letter of our laws after the war, the sacrifices of soldiers, sailors, Marines, abolitionists, and countless other Americans would bring a renewed significance to the liberties established by our Founders. When the guns fell silent and the fate of our Nation was secured, blue and gray would unite under one flag and the institution of slavery would be forever abolished from our land.

As a result of the sacrifice of millions, we would extend the promise and freedom enshrined in our Constitution to all Americans. Through the 13th, 14th, and 15th Amendments, we would prohibit slavery and indentured servitude, establish equal protection under the law, and extend the right to vote to former slaves. We would reach for a more perfect Union together as Americans, bound by the collective threads of history and our common hopes for the future.

We are the United States of America—we have been tested, we have repaired our Union, and we have emerged stronger. As we respond to the critical challenges of our time, let us do so as adherents to the enduring values of our founding and stakeholders in the promise of a shared tomorrow.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 12, 2011, as the first day of the Civil War Sesquicentennial. I call upon all Americans to observe this Sesquicentennial with appropriate programs, ceremonies, and activities that honor the legacy of freedom and unity that the Civil War bestowed upon our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of April, in the year of our Lord two thousand eleven, and of the Independence of the United States of America the two hundred and thirty-fifth.

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Rules and Regulations

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DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 274a

[CIS No. 2441–08; Docket No. USCIS–2008–0001]

RIN 1615–AB69

Documents Acceptable for Employment Eligibility Verification

AGENCY: U.S. Citizenship and Immigration Services (USCIS), DHS.

ACTION: Final rule.

SUMMARY: This rule finalizes without change a 2008 interim final rule amending Department of Homeland Security (DHS) regulations governing the types of acceptable identity and employment authorization documents (EADs) and receipts that employees may present to employers for completion of Form I–9, Employment Eligibility Verification.

DATES: This final rule is effective May 16, 2011.

FOR FURTHER INFORMATION CONTACT: Letitia Coffin, Verification Division, U.S. Citizenship and Immigration Services, Department of Homeland Security, 131 M Street, NE., Suite 200, Washington, DC 20002, telephone (888) 464–4218 or e-mail at *Everify@dhs.gov.*

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I. Background

All employers, agricultural recruiters and referrers for a fee [1] (hereinafter collectively referred to as "employer(s)") are required to verify the identity and employment authorization of each individual they hire for employment in the United States, regardless of the individual's citizenship. *See* Immigration and Nationality Act (INA) section 274A(a)(1)(B), 8 U.S.C. 1324a(a)(1)(B). As part of the verification process, employers must complete Form I–9, "Employment Eligibility Verification," retain the form for a statutorily established period of time, and make the form available for inspection by certain government officials. *See* INA sec. 274A(b), 8 U.S.C. 1324a(b); 8 CFR 274a.2. On Form I–9, a newly hired employee must attest to being a U.S. citizen or national, a lawful permanent resident (LPR), or an alien authorized to work in the United States. The employee then must present to his or her employer a document or combination of documents designated by statute and regulation as acceptable for establishing identity and employment authorization. The employer must examine the document, record the document information on Form I–9, and attest that the document reasonably appears both to be genuine and to relate to the individual presenting it.

The Form I–9 has three categories of documents that employers may accept, alone or in combination, for employment authorization verification:

(1) *List A*—documents that establish both identity and employment authorization (e.g., U.S. passport; Form I–551, "Permanent Resident Card;" or Form I–766, "Employment Authorization Document");

(2) *List B*—documents that establish only identity (e.g., State-issued driver's license or identification card); and

(3) *List C*—documents that establish only employment authorization (*e.g.,* State-issued birth certificate or an unrestricted Social Security Account Number card).

See INA section 274A(b)(1)(B), (C) and (D), 8 U.S.C. 1324a(b)(1)(B), (C), and (D); 8 CFR 274a.2(b)(1)(v)(A), (B) and (C). An individual must present to his or her employer either one document from List A or one document each from List B and List C. The employer may not specify a document or combination of documents that the employee must present. *See* INA section 274B(a)(6), 8 U.S.C. 1324b(a)(6); 8 CFR 274a.1(l)(2).

If the employee cannot present an acceptable document from one of the three lists, he or she may present an acceptable substitute document, referred to as a "receipt." *See* 8 CFR 274a.2(b)(1)(vi) (commonly referred to as "the receipt rule"). The receipt satisfies the document presentation requirement for a short period of time, at the end of which the employee must present the actual document or other documents specified in the regulations as acceptable to present. An employer may accept a receipt, however, only under specific circumstances prescribed under 8 CFR 274a.2(b)(1)(vi). For example, if a document acceptable under Lists A, B, or C is stolen or lost, the new hire may provide a receipt for the application for the replacement document, in lieu of the actual document, as long as he or she provides the replacement document within 90 days of hire. If the individual employee is an alien whose employment authorization or employment authorization documentation expires, the employer must reverify the employee's continued employment authorization by the expiration date by reviewing any acceptable List A or List C document.[2] *See* 8 CFR 274a.2(b)(1)(vii).

[1] Title 8 CFR 274a.2(a)(1) provides that "[f]or purposes of complying with section 274A(b) of the [INA] and this section, all references to recruiters and referrers for a fee are limited to a person or entity who is either an agricultural association, agricultural employer, or farm labor contractor (as defined in section 3 of the Migrant and Seasonal Agricultural Worker Protection Act, Pub. L. 97–470)."

[2] Note that an expiration date on Form I–551 does not trigger the reverification requirement. *See* "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 01/05/11), *http://www.uscis.gov,* ("Handbook for Employers"), pages 9 and 39.

A. Interim Rule

On December 17, 2008, DHS published an interim rule amending DHS regulations governing the Form I–9 process. *See* 73 FR 76505. The interim rule became effective on April 3, 2009.[3] DHS improved the integrity of the Form I–9 process by:

- Prohibiting employers from accepting expired documents. Expired documents may not demonstrate the correct status of the bearer; are prone to tampering and fraudulent use; and may create confusion among employers. This change is intended to ensure that the documents accepted by employers as evidence of an employee's identity and employment authorization are valid and reliable;
- Removing Form I–688, "Temporary Resident Card," and Forms I–688A and I–688B, "Employment Authorization Cards," from the Lists of Acceptable Documents because USCIS no longer issues these documents and any such documents in possession of an employee would now have expired;
- Adding to the List of Acceptable Documents on List A of Form I–9: (1) The new U.S. passport card and (2) the temporary Form I–551, "Permanent Resident Card," with a printed notation on a machine-readable immigrant visa;
- Adding documentation for certain citizens of the Federated States of Micronesia (FSM) and the Republic of the Marshall Islands (RMI) to List A to more accurately reflect their status under the Compacts of Free Association.

In addition to the amendments made by the 2008 interim rule, USCIS issued an amended Form I–9 which clarified changes, such as providing a separate box for noncitizen nationals to clearly delineate U.S. citizens from noncitizen nationals, and making minor format changes that make the form easier to use.

On January 16, 2009, DHS published a correction to the interim rule to remove extraneous language from two paragraphs of the regulation that describe a type of receipt that can be presented by lawful permanent residents to their employers in lieu of the Form I–551, "Permanent Resident Card," for completion of Form I–9. *See* 74 FR 2838.

On February 3, 2009, DHS extended the comment period for the interim rule to March 4, 2009. *See* 74 FR 5899.[4]

[3] On February 3, 2009, DHS delayed the effective date of the December 17, 2008, interim rule to April 3, 2009 to provide DHS with an opportunity for further consideration of the interim rule. The February 3, 2009 document also extended the public comment period until March 4, 2009. *See* 74 FR 5899.

[4] *See supra* footnote 3.

During the entire comment period, DHS received 75 comments. These comments came from a broad spectrum of individuals and organizations, including refugee and immigrant services advocacy organizations and public policy and advocacy groups. Many commenters addressed multiple issues and provided variations on the same substantive issues.

In preparing this final rule, DHS considered the comments that were received during the comment period and were within the scope of this rulemaking as well as the other materials contained in the docket. The final rule does not address comments seeking changes in United States statutes, changes in regulations or petitions unrelated to or not addressed by the interim rule, changes in procedures of other components within DHS or other agencies, or the resolution of any other issues not within the scope of the rulemaking or the authority of DHS.

All comments may be reviewed at the Federal Docket Management System (FDMS) at *http://www.regulations.gov,* docket number USCIS–2008–0001.

B. Final Rule

The final rule adopts, without change, all of the regulatory amendments set forth in the interim rule. The rationale for the interim rule and the reasoning provided in the preamble to the interim rule remain valid with respect to these regulatory amendments, and DHS adopts such reasoning in support of the promulgation of this final rule.

II. Public Comments on the Interim Rule

A. Summary of Comments

Many commenters supported the improvements to the Form I–9 process made in the interim rule, such as: Prohibiting employers from accepting expired documents; removing certain documents no longer issued by USCIS; adding two new documents to List A; adding documentation for certain citizens of the FSM and RMI to List A; and making clarifying changes to Form I–9, such as providing a separate box for noncitizen nationals. Most commenters discussed the prohibition on employers from accepting expired documents and supported the change because they believe that this change would prevent unauthorized aliens from obtaining employment in the United States by using expired documents which are more susceptible to fraud and counterfeiting than unexpired documents.

Although most commenters supported one or more changes to the Form I–9 process, several commenters opposed the prohibition on the use of expired documents because they believe that many employment-authorized individuals such as asylees, refugees, and conditional residents should not be required to present an unexpired document as evidence of employment authorization. The commenters were concerned that such employees will be unable to work if processing or issuance of a new document is delayed. Several commenters also opposed the prohibition on the use of expired documents because they believe that these changes will create additional burdens and costs for employers and employees. Some of the commenters who opposed the prohibition on the use of expired documents requested a delay in implementation of the interim rule. In response to public comments requesting an extension of the effective date, DHS delayed the effective date of the interim rule from February 2, 2009, to April 3, 2009. *See* 74 FR 5899.

Many commenters pointed out the need for comprehensive immigration reform including a thorough review of the Form I–9 process. Some commenters suggested improvements to the Form I–9 process such as: Biometrics; providing the public a truly electronic Form I–9; and detailed changes to the form. Other commenters discussed document reduction or suggested changes to the acceptability of specific document types such as: School IDs; U.S. Passports; State-issued drivers' licenses including enhanced drivers' licenses; voter registration cards; Native American tribal documents; and the Certificates of Citizenship and Naturalization.

Comments that were received are addressed below and are organized by subject area. Comments related to the economic burdens of this rule are addressed in the Executive Order 12866 and Regulatory Flexibility Act sections of part III of the Supplementary Information.

B. Requiring Unexpired Documents

DHS received 23 comments addressing the interim rule's requirement that all documents presented for Form I–9 be unexpired. Fifteen commenters supported the requirement and eight commenters opposed it. Most of the commenters who supported the requirement wrote that allowing employers to accept expired documents would lead to the inadvertent acceptance of fraudulent documents and, therefore, the employment of unauthorized aliens. Some commenters who supported the

requirement wrote that this change eliminates confusion in the Form I–9 process and that requiring unexpired documents provides benefits to law enforcement.

1. Continued Acceptance of Expired Documents

Eight commenters opposed the requirement that documents must be unexpired for Form I–9 and stated that employers should be able to continue to accept expired documents as permitted before the interim rule went into effect. Five of these commenters proposed the continued acceptance of expired documents for varying periods between 30 days and five years after expiration of the document. Two of these commenters wrote that the cost of obtaining replacement documents was too high. One commenter wrote that refugees and asylees should be excused from this requirement because these individuals are authorized for employment incident to their status.

DHS is retaining the requirement that documents be unexpired and is not adopting the commenters' suggestions to continue accepting expired documents. Concerns about document fraud were among the most important reasons for this rulemaking. Unexpired documents are more likely to contain up-to-date security features that make them less vulnerable to counterfeiting and fraud. Because expired documents may lack security features or may have outdated security features, these documents can more easily be counterfeited.

DHS disagrees with the commenters who wrote that expired documents should be allowed within specified parameters (e.g., 30 days after expiration). Establishing a requirement that all documents be unexpired sets a clear standard that is easy for U.S. employers to apply. Such a requirement honors the time limits of validity placed on documents by their issuing authorities. In addition, precluding employers from accepting expired documents alleviates confusion when determining whether documents are valid for Form I–9 and helps to ensure that the documents relate to the person presenting them. Moreover, disallowing the acceptance of expired documents reduces document fraud and may prevent unauthorized aliens, criminals and even terrorists from evading detection.

2. Refugees and Asylees

One commenter requested that DHS allow employers to accept Employment Authorization Documents (EADs) presented by refugees and asylees that have been expired no longer than 90 days. The commenter wrote that neither group requires an EAD because both are authorized to work incident to their lawful immigration status.

DHS has not adopted the commenter's request in this final rule. DHS is aware of the many difficulties that refugees and asylees face in adapting to a new life in the United States and has carefully considered those difficulties as they relate to employment authorization. However, permitting the use of expired documents for Form I–9, even for the limited period of 90 days as suggested by the commenter, introduces vulnerabilities into the verification process that undermine the purpose of the process as a whole. The EAD is not the only acceptable document that refugees and asylees may present for Form I–9 purposes. They may satisfy Form I–9 requirements by presenting a combination of a List B and a List C document, such as a State-issued driver's license and an unrestricted Social Security Account Number card. Many refugees and asylees instead choose to present an EAD because of the simplicity of having a List A document that meets identity and employment authorization requirements. DHS acknowledges the desire for simplicity on the part of both groups; however, permitting the use of expired EADs for only refugees and asylees and for only a 90-day period after a particular document's expiration conflicts with DHS' desire to provide a consistent rule prohibiting the use of expired documents.

3. Alleged Delays in the Issuance of Documents by USCIS

Five commenters wrote that expired documents should be acceptable because USCIS is unable to timely process applications for new documents demonstrating employment authorization.

DHS is not adopting the commenters' recommendations. DHS processes applications for renewal of immigration-related documents in a timely manner for applicants who apply to renew their immigration documents with sufficient planning in advance of expiration dates. In the event of a processing delay or unforeseen emergency, or for applications filed too close to the documents' expiration dates, applicants may request expedited processing. The regulations at 8 CFR 274a.13(d) impose a 90-day processing time for DHS to adjudicate applications for Form I–765, "Application for Employment Authorization Document," and to issue an EAD. DHS records indicate that the current average cycle time for Form I–765 processing was 1.9 months as of November 2008.[5] Aliens whose applications for employment authorization have been pending for more than 90 days may call USCIS to request expedited processing of their applications. Lawful permanent residents (LPRs) seeking to replace a Form I–551, "Permanent Resident Card," that has expired or has been lost, stolen, or mutilated can present other non-USCIS documents to meet Form I–9 requirements, such as a State-issued driver's license and an unrestricted Social Security Account Number card, until a new card can be issued. In the alternative, LPRs may request a temporary Form I–551 stamp in their passports or on Form I–94, "Arrival-Departure Record," that is evidence of LPR status while their renewal or replacement application is pending. Consequently, DHS does not adopt the commenters' recommendations.

Two of the five commenters also wrote that if USCIS precludes the use of expired documents, then USCIS should adopt a rule that permits employers to accept, in lieu of an acceptable Form I–9 document, a receipt for the application of replacement of an expired document, for a 240-day period. These two commenters also stated that the current 90-day period provides insufficient time to present proper documentation due to USCIS's processing delays.

DHS is not adopting the suggestion by the commenter to expand the period of time that a receipt for the application for a replacement document may be used in lieu of a document listed as acceptable for Form I–9. The commenter is referring to the "receipt rule" which allows employers to accept a document specified in the regulations as a "receipt" in lieu of a List A, B, or C document for a temporary period. Under the receipt rule, an employer may accept a receipt for the application for a replacement document for a 90-day period for Form I–9 if the List A, B, or C document that is being replaced has been lost, stolen, or damaged. *See* 8 CFR 274a.2(b)(1)(vi)(A). Because the receipt rule only applies if the List A, B, or C document has been lost, stolen, or damaged, and not when the document has expired, it is not relevant to DHS's preclusion of the use of expired documents.

Another commenter wrote that refugees should be permitted a grace

[5] *See* Memorandum by Michael Aytes, Former Acting Director, USCIS, *Response to Recommendation 35, Recommendations on USCIS Processing Delays for Employment Authorization Documents,* (Jan. 2, 2009) (available at *http://www.dhs.gov* (Citizenship and Immigration Services Ombudsman page)).

period of 90 days from the requirement that they present an unexpired document because refugees are employment-authorized incident to their status and may not receive an initial EAD from USCIS in a timely manner. The commenter also wrote that refugees may not be aware that expired documents are no longer acceptable.

DHS has not adopted the commenter's suggestions in this final rule. USCIS expedites applications for those refugees who choose to apply for an EAD. DHS records show that, in most instances, USCIS issues EADs to refugees within two weeks of their admission to the United States. In addition, current regulations already contain a "90-day grace period" for refugees. Until refugees receive their EADs, they may present Form I–94, "Arrival-Departure Record," with an unexpired refugee admission stamp as temporary proof of employment authorization. *See* 8 CFR 274a.2(b)(1)(vi)(C)(*1*). Refugees have 90 days from receipt of the admission stamp to present either an EAD or a combination of a List B and List C document. *See* 8 CFR 274a.2(b)(1)(vi)(C)(*2*).

4. Definition of an Unexpired Document

One commenter requested that DHS provide a definition of the term "unexpired." In general, DHS considers a document to be unexpired when the expiration date on the face of the document, if any, has not passed. DHS is not, however, including a formal definition of "unexpired" in this final rule. DHS has determined that, given the wide variety of documents acceptable for Form I–9 purposes, and the fact that the term has been present in the regulations for many years, it would not be appropriate or necessary to provide an all-encompassing definition of the term in this rulemaking. DHS will provide guidance to the public in response to specific questions concerning particular documents as appropriate.

C. Comprehensive Review of the Form I–9 Process

Six commenters expressed concerns about the entire Form I–9 employment verification process. Three of the six commenters requested that DHS conduct a comprehensive review of the entire Form I–9 process that carefully considers the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA).

DHS has not adopted these comments as they are outside the scope of the interim rule. The interim rule did not make changes to the verification process as a whole. Instead, the rule made limited changes to the types of documents that are acceptable for employment verification, such as eliminating outdated List A documents and precluding the presentation of expired documents. *See, e.g.,* 73 FR 76506–07. DHS regularly reviews and analyzes its programs for improvement and greater effectiveness and may consider changes to the employment verification process in a future rulemaking.

One of the commenters wrote that DHS has not removed enough documents from the Lists of Acceptable Documents on Form I–9 to fulfill its mandate under the authorizing statute. DHS assumes that the commenter is referring to the document reduction provision of IIRIRA. IIRIRA amended section 274A(b)(1) of the INA, 8 U.S.C. 1324a(b)(1), by removing several documents from List A (*e.g.*, certificate of naturalization) and List C (*e.g.,* birth certificate). However, IIRIRA retained the authority of the Attorney General (now the Secretary of Homeland Security) to designate additional documents within certain boundaries, including the requirement that the designated documents contain security features that make them resistant to tampering, counterfeiting, and fraudulent use. The former Immigration and Naturalization Service (INS) implemented the document reduction mandate of IIRIRA in its interim rulemaking at 62 FR 51001 (Sept. 30, 1997). DHS believes that the 1997 interim rulemaking met its statutory mandate to ensure that the documents remaining on List A and C contain certain minimum security features. Through this final rule, DHS is making additional changes to further secure the Form I–9 process.

One commenter suggested that Form I–9 is not an effective tool to discourage unauthorized employment because an employer can easily discard a Form I–9 after three years under certain circumstances. The same commenter also noted that an employee's departure from the United States is not confirmed after his or her employment authorization has expired.

DHS has not addressed Form I–9's effectiveness as a means of providing employment verification or reporting the departure of aliens previously authorized to work in this rulemaking. The Form I–9 retention requirement is statutory, and, therefore, is not within DHS's authority to change. The statute requires that employers retain completed Forms I–9 for all employees for three years after the date an employee is hired, or one year after the date employment is terminated, whichever is later. *See* INA section 274(b)(3), 8 U.S.C. 1324a(b)(3); 8 CFR 274a.2(b)(2)(i)(B). For more information on retention requirements, please refer to the Handbook.[6]

With respect to the commenter's suggestion that an employee's departure from the United States be noted on Form I–9, current rules only require reverification of employment authorization once the employment authorization noted on Form I–9 expires. *See* 8 CFR 274a.2(b)(1)(vii). The interim rule did not modify the reverification provision. Note that an individual whose employment authorization has expired may not necessarily be required to depart the United States if he or she remains lawfully present in the United States (*e.g.,* asylees) or has received a renewal of employment authorization.

Another commenter requested that the 2008 interim rule be withdrawn because of DHS's failure to perform a comprehensive review of the Form I–9 process, noting that time and resources could be better spent on a comprehensive review.

DHS is not withdrawing the 2008 interim rule for purposes of conducting a comprehensive review. The changes made in the interim rule will lead to significant administrative benefits by reducing employer confusion and increasing compliance. Moreover, to withdraw the rule and revert to the preceding Form I–9 also would result in considerable confusion among employers. DHS continually reviews and analyzes the employment eligibility verification process and considers changes to the process as appropriate. DHS may propose additional changes in the Form I–9 verification process in the future as needed.

D. The 1998 Notice of Proposed Rulemaking

Two commenters discussed the 1998 notice of proposed rulemaking found at 63 FR 5287. One commenter wrote that prior to the 2008 interim rule, the former INS last requested public comments in 1998 and has not published responses to those comments. The commenter added that DHS has not promulgated a rule in the **Federal Register** on one issue mentioned in the preamble to the 1998 proposed rule: The good faith defense against technical Form I–9 paper violations. The commenter also wrote that the failure to promulgate rules has denied employers

[6] Part Three, "Photocopying and Retaining Form I–9" "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 01/05/11), *http://www.uscis.gov,* pages 23–26.

a compliance standard and led to confusion.

DHS agrees with the commenter that the INS did not publish responses to the public comments received with respect to the 1998 proposed rule, and neither has DHS published responses to the comments. As stated in the Supplementary Information to the interim rule, however, the interim rule superseded the 1998 proposed rule, and the comments received as part of that rulemaking informed the development of the interim rule. DHS does not intend to publish responses to the public comments, given the time that has passed since the 1998 proposed rule. INS published a proposed rule in 1998 regarding the good faith defense against technical Form I–9 paper violations. *See* 63 FR 16909 (Apr. 7, 1998). DHS disagrees that employers have been operating without a compliance standard. The Handbook for Employers provides guidance for employers on Form I–9 compliance.[7]

E. Mistake in Interim Rule

One commenter alerted DHS that the interim rule erroneously added the language "with an unexpired passport" to the regulation found at 8 CFR 274a.2(b)(1)(vi)(B)(*1*). The commenter pointed out that the regulation in question describes a receipt for Form I–551, "Permanent Resident Card," (the arrival portion of Form I–94 with an unexpired temporary Form I–551 stamp and photograph of the individual) and that the interim rule had placed language in the wrong section.

DHS published a correction to 8 CFR 274a.2(b)(1)(vi)(B)(*1*) in the **Federal Register** on January 16, 2009 at 74 FR 2838 and deleted the erroneous language.

F. Delay in Effective Date of Interim Rule

Ten commenters requested a delay in implementation of the interim rule. DHS did delay the initial effective date, extending the date from February 2, 2009, to April 3, 2009. DHS determined that there was no basis for any further delay in the effective date for this rule.

G. Comments to the Form I–9

DHS received several comments regarding Form I–9 in response to the information collection published with the interim rule. These comments are addressed below.

1. Expiration Date of Form I–9

Eight commenters discussed the expiration date indicated on Form I–9. Six commenters were concerned that the revised Form I–9 (Rev. 02/02/09) might expire on June 30, 2009, as indicated on the form. Four commenters suggested that because the current Form I–9 bears an expiration date of June 30, 2009, employers should be allowed to continue using the preceding Form I–9 until that time, with its allowance for accepting expired documents. Three commenters noted that the gap between the implementation date of the new form and the expiration of the old form is confusing. One commenter argued that DHS should allow the use of either Form I–9 until June 30, 2009.

Employers may use either Form I–9 with the new revision date of 08/07/09 or Form I–9 with the 02/02/09 revision date. On April 28, 2009, DHS published a 30-day notice in the **Federal Register** at 74 FR 19233, extending the expiration date of Form I–9 (Rev. 02/02/09) beyond June 30, 2009. The expiration date is now August 31, 2012. Therefore, the commenters' concerns about whether to use Form I–9 (Rev. 02/02/09) are moot. DHS recognizes that the expiration date on Form I–9 may be confusing to some employers. The Office of Management and Budget (OMB) expiration date found on the front page of Form I–9 refers only to the control number assigned for the information collection requirements of the form, which must be updated and renewed periodically.

2. Adding Miscellaneous Instructions and Reorganizing Form I–9

Seven commenters recommended specific changes to Form I–9. Two commenters recommended that all acceptable documents and receipts be included on Lists A, B, and C. Another commenter requested that Part 8 of the Handbook be updated to include the current Lists of Acceptable Documents. One commenter requested that DHS provide guidance about List A, Item 5, the foreign passport with Form I–94 indicating:

- Nonimmigrant status,
- Work is authorized incident to status, and that
- Work is restricted for a specific employer.

While DHS appreciates the commenters' recommendations, DHS is not making further changes to Form I–9 beyond those made based on the interim rule. DHS may consider these recommendations when undertaking future revisions to Form I–9 and the Handbook.[8] Note that the Handbook contains a listing of all documents, including receipts, that are acceptable for Form I–9. DHS has also included a section in the Handbook that provides images of common documents acceptable as permanent or temporary proof of employment authorization.[9] The Handbook provides guidance on nonimmigrant aliens with temporary employment authorization who present List A, Item 5 documents.[10] DHS released a revised Handbook on January 5, 2011.

One commenter requested that instructions to Form I–9 be written in plain language. DHS promotes and supports the use of plain language and regrets that the commenter found the instructions difficult to understand. DHS will continue carefully to examine future changes to Form I–9 for plain language.

Another commenter recommended that the boxes to attest to U.S. citizenship and noncitizen national status should be separated on Form I–9. In the Form I–9 accompanying the interim rule, DHS added a separate check box for U.S. citizens and noncitizen nationals in the immigration/citizenship status attestation of Section 1 of Form I–9. DHS is retaining this change in Form I–9.

3. Public Access to New Forms I–9 Prior to Issuance

Two commenters requested that any future version of Form I–9 be made available at *http://www.uscis.gov* further in advance to allow the public time to prepare for changes.

DHS recognizes the need for employers and human resource professionals to have sufficient time to prepare for any changes to Form I–9. For this rulemaking, DHS made Form I–9 available to the public for informational

[7] Part Four, "Unlawful Discrimination and Penalties for Prohibited Practices," "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 01/05/11), *http://www.uscis.gov,* page 30. *See also* Part Four, "Unlawful Discrimination and Penalties for Prohibited Practices," "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 07/31/09) (no longer available online), p. 22. Part Four, "Unlawful Discrimination and Penalties for Prohibited Practices," "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 04/03/09) (no longer available online), p. 19; Part Four, "Unlawful Discrimination and Penalties for Prohibited Practices," "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 11/1/2007) (no longer available online), p. 17; and Part 5, "Penalties for Prohibited Practices," "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (11/1991) (no longer available online), p. 10.

[8] *Id.*

[9] Part Eight, "Acceptable Documents for Verifying Employment Authorization and Identity," in the "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 01/05/11), *http://www.uscis.gov,* pages 51–63.

[10] Part Two, "Completing Form I–9," "Handbook for Employers, Instructions for Completing Form I–9" (M–274) (Rev. 01/05/11), *http://www.uscis.gov,* pages 3–19.

purposes on December 17, 2008. DHS will make every effort to make any future version of Form I–9 available on USCIS's Web site at the earliest possible time.

4. Discretion in Use of Incorrect Form I–9 Due to Employer Confusion Following Implementation of the Interim Rule

One commenter requested that DHS exercise favorable discretion for employers who unintentionally used the wrong Form I–9 after the interim rule went into effect.

Beginning April 3, 2009, employers were required to use the Form I–9 (Rev. 02/02/09) containing the revisions based on the interim rule. A subsequent Form I–9 was made available on August 7, 2009 (Rev. 8/7/09). Employers may use either form. DHS may exercise favorable discretion if an employer unintentionally used the wrong Form I–9 due to confusion regarding which form to use between February 2009 and April 2009. Employers who used the wrong form during this time period are still expected to comply with all other Form I–9 regulations applicable to the preceding form.

5. Creating an Electronic Employment Eligibility Verification Process

Three commenters requested that DHS make an electronic Form I–9 available that could be used with human resources software. Another commenter requested specific technical improvements to create a solely electronic employment authorization verification process. Four commenters noted that the Form I–9 provided on the USCIS Web site was password-protected or had security settings that prohibited them from completing and saving the form electronically. These commenters also requested that DHS provide an electronic Form I–9 that can be completed, signed electronically and saved on their computer systems.

DHS appreciates the commenters' recommendations regarding requested enhancements in electronic completion and storage of the electronic Form I–9. These comments are technical in nature and outside the scope of the changes that DHS is making to Form I–9 through this rulemaking. Changes to Form I–9 are limited to amending the Lists of Acceptable Documents and making minor clarifications to the data elements on the form.

The revised Form I–9 that DHS posted on the USCIS Web site as of January 16, 2009, can be completed online but cannot be signed and stored electronically. As such, DHS must password-protect the form to prevent the public from making any changes to it. DHS recognizes the public's desire for an electronic Form I–9. DHS is continually evaluating possible improvements to the Form I–9 process so that it is more user-friendly.

H. Suggested Revisions to the Lists of Acceptable Documents

DHS received several suggested changes to the lists of documents acceptable for Form I–9. Suggested changes to List A documents include one commenter's proposal for DHS to rename the Native American tribal document and add it to List A because it is already acceptable as both a List B and List C document. Two commenters requested that Form I–797, "Notice of Action," be made an acceptable document for permanent residents who possess an expired Form I–551 and whose conditions on status have been removed. One commenter requested that Form I–797 serve as an acceptable receipt for a List A document until the initial Form I–551 is received in the mail. Four commenters requested that Certificates of Naturalization or Citizenship be added to List A of Form I–9. One commenter wrote that it is discriminatory to allow U.S. citizens to use certified copies of birth certificates but not allow Certificates of Naturalization or Citizenship for those born outside of the United States. Two commenters requested that enhanced State-issued drivers' licenses be added to the list of documents that establish both identity and employment authorization (List A).

Suggested changes to acceptable documents on List B of Form I–9 included one commenter's suggestion that Native American tribal documents meet the same minimum requirements as State-issued driver's licenses if they are included on List B. Two commenters wrote that school ID cards should meet the same minimum requirements as State-issued driver's licenses.

With respect to changes to acceptable documents on List C of Form I–9, one commenter proposed that voter registration cards, currently under List B, be made acceptable documents on List C because such documents evidence that the bearer is 18 or older and a U.S. citizen. Concerning all documents acceptable for Form I–9, two commenters suggested the addition of biometrics to Form I–9 documents. One of the two commenters suggested that the addition of biometrics would prevent identity fraud.

DHS appreciates these commenters' concerns and suggestions. However, these comments do not address the changes made in the interim rule to the Lists of Acceptable Documents for Form I–9 and, therefore, are outside the scope of this rulemaking. In considering any future changes to the Lists of Acceptable Documents, DHS may consider commenters' suggestions.

I. Standardizing State and Federal Document Requirements

One commenter suggested that all State and Federal agencies should accept the documents on Lists A, B, and C of Form I–9 as proof of entitlement to a benefit.

This suggestion is outside the scope of the interim rule, which is limited to documents used for the Form I–9 employment eligibility verification process. Moreover, DHS does not have the authority to mandate that State and Federal agencies accept Form I–9 documents as proof of entitlement to benefits.

J. Requests for Outreach and Guidance

DHS received several requests for additional outreach to the public and additional guidance on the Form I–9 process. Two commenters requested that DHS perform greater outreach to inform the public about their responsibilities concerning Form I–9. One of the two commenters indicated that special efforts should be made to reach refugees and asylees.

One commenter asked whether Forms I–9 that were completed a few days before the effective date of the revised Form I–9 still have to meet the requirements of the final rule.

Two commenters wrote that there is insufficient guidance for the many categories of aliens with temporary employment authorization. One commenter wrote that many of these aliens are at risk of losing or being denied employment because they are unable to meet the requirements of the interim rule. The first commenter wrote that since the notice of proposed rulemaking at 63 FR 5287 was published in 1998, Congress and USCIS have created a number of new categories of employment authorization, for which it provided only sporadic or no guidance. The first commenter also wrote that the 1997 interim rule that precedes this interim rule (*see* 62 FR 51001) provides no guidance for these categories. Both commenters, however, requested DHS guidance for the special categories of temporary employment authorization with varying validity periods, such as those with automatic extensions.

With respect to acceptable documents for Form I–9, one commenter requested that DHS provide examples of school ID cards acceptable as List B documents.

One commenter asked whether an employer can accept documents other than those the employee originally presented under the receipt rule and would like this clarification to be included in the Handbook.

With respect to completion of Form I–9, one commenter wanted to know whether a notary public can act on behalf of an employer.

Several commenters requested that DHS provide additional guidance for employers about reverification of an employee's continued employment authorization. Six commenters requested clarification on reverifying documents that have expired after the time of hire and after Form I–9 is completed. Four commenters asked if U.S. passports or State-issued drivers' licenses had to be reverified. One commenter requested that refugees and asylees not be required to be reverified once their EADs expire because both are authorized to work incident to status. One commenter wanted to know how to complete Form I–9 for employees who are rehired by the same employer and whose documents that were used to complete the original Form I–9 have expired. The commenter also questioned whether Section 3 of Form I–9 has sufficient room to reverify two documents. Two commenters asked if they were required to reverify expired passports from FSM or RMI that were not expired at the time Form I–9 was initially completed.

DHS appreciates the commenters' requests for outreach and further guidance on the Form I–9 process. In addition to multiple written resources, including the Handbook, USCIS continually provides individualized outreach to employers. USCIS regularly provides Web-based seminars on Form I–9 and E–Verify and conducts live presentations in several states. Employers may request these seminars and live presentations at the DHS Web site. USCIS also collaborates with U.S. Immigration and Customs Enforcement (ICE) to provide additional outreach to employers regarding employment authorization requirements. Employers with specific questions related to the Form I–9 process are encouraged to call the USCIS Verification Division at 1–888–464–4218.

K. Comprehensive Immigration Reform

Nineteen commenters requested that DHS conduct a comprehensive reform of current immigration policies. Thirteen of the 19 commenters expressed opposition to the displacement of U.S citizens and/or employment-authorized persons in the workforce by undocumented workers. Two of the 19 commenters supported the legalization of undocumented workers. Three of the 19 commenters opposed continued legal immigration to the United States. Six of the 19 commenters specifically supported the use of E-Verify, and five commenters specifically opposed it.

These comments are outside the scope of the interim rule which was limited to making discrete changes to the Lists of Acceptable Documents for Form I–9.

III. Regulatory Requirements

The interim rule published by DHS on December 17, 2008, contains a complete regulatory analysis for the changes implemented under that rule. *See* 73 FR 76505, 76507–10.

A. Executive Order 12866

This rule is a significant regulatory action under Executive Order 12866, section 3(f)(1), Regulatory Planning and Review. Accordingly, the Office of Management and Budget (OMB) has reviewed this rule.

DHS received three comments on the interim rule's estimated cost of renewing an expired document to comply with the rule. One commenter suggested that the costs may be too high for many individuals or may force an employee to get a new type of document. The commenter also wrote that the basis for the decision to remove expired documents is not supported by any study or statistic.

DHS appreciates the concerns of the commenters regarding the added costs that some individuals may bear to obtain unexpired documents to meet the new Form I–9 requirement. However, DHS has determined that any such costs are outweighed by the benefits of retaining the requirement that all documents be unexpired. Continuing to permit use of expired documents for Form I–9 would undermine the reliability of the verification process. Expired documents are subject to fraud. DHS experience indicates that:

- Older, invalid, expired documents are too easily converted to uses other than the purpose intended by their issuing authorities,
- Requiring documents to be unexpired establishes a clear standard for U.S. employers,
- Since an expired document is no longer useful for its original purpose as intended by the issuer, DHS should not impute validity to an expired document for purposes of Form I–9,
- As stated in the interim rule, once the transition to the new Form I–9 is complete, DHS anticipates that the costs incurred by employers will decrease because the updated Lists of Acceptable Documents, simplified design of the Form I–9, and more comprehensive instructions provided with the form, will make the verification process for employers easier than it is now.

DHS is not adopting the commenters' suggestions in this final rule.

Another commenter objected to the use of leisure time to calculate the cost of the time spent obtaining unexpired documents, noting that the time spent retrieving documents could be spent working. DHS agrees that it is possible that some of the opportunity costs associated with obtaining replacements for expired documents could be based on the value of time spent working and not solely the value of leisure time as the interim rule estimated. In the example that the commenter refers to, the interim rule stated that if 1.2 percent of the estimated 58 million annual new hires in the United States must obtain a new document, 696,000 people are affected. *See* 73 FR 76510. The example said that costs for an identification card was $14.40, and that each affected person would spend about 4 hours of personal time to obtain a new card at a cost per hour of $14.06. *Id.* If the interim rule had used the Bureau of Labor Statistics employer compensation costs for all civilian occupations of $28.11 per hour worked, instead of the value of leisure, the example would have estimated that a person could expend up to $14.40 in cash and $112.44 in opportunity costs, or total costs of $126.84, to obtain a State-issued identification card. Thus, using, as suggested by the commenter, the value of time spent working instead of the value of leisure, along with the 1.2 percent figure from the American University study cited in the interim rule,[11] the rule would have shown that the aggregate employee expense for obtaining an acceptable document could be as high as $88,280,640, instead of the $49,137,600 that was cited in the interim rule's example. It is likely that the time spent obtaining unexpired documents would be a mix of foregone leisure time and foregone work time and the actual cost would be within the range of the $49,137,000 cited in the interim rule and the $88,280,640 calculated above. DHS continues to believe these costs are outweighed by the benefits of retaining the requirement that all documents be unexpired.

[11] Robert Pastor, *et al.*, Voter IDs Are Not the Problem: A Survey of Three States (Center for Democracy and Election Management, American University, Washington, DC, Jan. 9, 2008). *http://www.american.edu/ia/cdem/pdfs/VoterIDFinalReport1-9-08.pdf.*

B. Regulatory Flexibility Act

As discussed in the interim rule, DHS determined that this regulatory action is exempt from notice and comment rulemaking pursuant to 5 U.S.C. 553(b)(B). Therefore, the interim rule was exempt from the provisions of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* Accordingly, USCIS has not prepared a regulatory flexibility analysis of this action.

IV. Paperwork Reduction Act (PRA)

In the December 17, 2008, interim rule DHS requested and received OMB approval to use the revised Form I–9 when the interim rule became effective until June 30, 2009. The interim rule also allowed the public to submit comments on the revised Form I–9 for 60 days. The comments to the revised Form I–9 have been addressed in the supplementary portion of this final rule, and DHS determined it would not make additional changes to Form I–9 at this time. On April 28, 2009, DHS published a 30-day notice in the **Federal Register** at 74 FR 19233 to extend the use of the revised Form I–9 past the June 30, 2009, expiration date. OMB approved the extension request on August 7, 2009. Form I–9 does not expire until August 31, 2012.

List of Subjects in 8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, the interim rule amending 8 CFR part 274a, which was published in the **Federal Register** at 73 FR 76505 on December 17, 2008, including the corrections to the interim rule which were published in the **Federal Register** on January 16, 2009, at 74 FR 2838 and March 11, 2009, at 74 FR 10455 are adopted as a final rule without change.

Janet Napolitano,

Secretary.

[FR Doc. 2011–9152 Filed 4–14–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30776; Amdt. No. 3420]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective April 15, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 15, 2011.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located;
3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or
4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit *http://www.nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Harry J. Hodges, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPS, Takeoff Minimums and/or ODPS. The complete regulators description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are FAA Forms 8260–3, 8260–4, 8260–5, 8260–15A, and 8260–15B when required by an entry on 8260–15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead refer to their depiction on charts printed by publishers of aeronautical materials. The advantages of incorporation by reference are realized and publication of the complete description of each SIAP, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the, associated Takeoff Minimums and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as contained in the transmittal. Some SIAP and Takeoff Minimums and

textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPS and Takeoff Minimums and ODPS, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPS contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPS and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedures before adopting these SIAPS, Takeoff Minimums and ODPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26,1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on April 1, 2011.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

** * * Effective 5 MAY 2011*

Deadhorse, AK, Deadhorse, RNAV (RNP) Z RWY 5, Orig
Deadhorse, AK, Deadhorse, RNAV (RNP) Z RWY 23, Orig
Fairhope, AL, H L Sonny Callahan, RNAV (GPS) RWY 1, Amdt 2
Fairhope, AL, H L Sonny Callahan, RNAV (GPS) RWY 19, Amdt 2
Fairhope, AL, H L Sonny Callahan, Takeoff Minimums and Obstacle DP, Amdt 1
Fairhope, AL, H L Sonny Callahan, VOR/DME–A, Amdt 7
Gulf Shores, AL, Jack Edwards, ILS OR LOC RWY 27, Amdt 1
Gulf Shores, AL, Jack Edwards, RNAV (GPS) RWY 9, Amdt 3
Gulf Shores, AL, Jack Edwards, RNAV (GPS) RWY 27, Amdt 2
Montgomery, AL, Montgomery Rgnl (Dannelly Field), ILS OR LOC RWY 28, Amdt 10
Montgomery, AL, Montgomery Rgnl (Dannelly Field), NDB RWY 10, Amdt 19
Montgomery, AL, Montgomery Rgnl (Dannelly Field), RADAR–1, Amdt 9
Montgomery, AL, Montgomery Rgnl (Dannelly Field), RNAV (GPS) RWY 3, Amdt 1
Montgomery, AL, Montgomery Rgnl (Dannelly Field), RNAV (GPS) RWY 10, Amdt 1
Montgomery, AL, Montgomery Rgnl (Dannelly Field), RNAV (GPS) RWY 28, Amdt 1
Montgomery, AL, Montgomery Rgnl (Dannelly Field), VOR–A, Amdt 4
Almyra, AR, Almyra Muni, VOR/DME–A, Amdt 6, CANCELLED
Corning, AR, Corning Muni, Takeoff Minimums and Obstacle DP, Orig
Jonesboro, AR, Jonesboro Muni, RNAV (GPS) RWY 5, Orig
Pine Bluff, AR, Grider Field, RNAV (GPS) RWY 18, Amdt 1
Pine Bluff, AR, Grider Field, RNAV (GPS) RWY 36, Amdt 1
Pine Bluff, AR, Grider Field, Takeoff Minimums and Obstacle DP, Orig
Hayward, CA, Hayward Executive, LOC/DME RWY 28L, Amdt 2
Hayward, CA, Hayward Executive, VOR/DME–B, Amdt 2
Napa, CA, Napa County, VOR RWY 6, Amdt 13
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS OR LOC RWY 10, ILS RWY 10 (SA CAT I), ILS RWY 10 (CAT II), ILS RWY 10 (CAT III), Amdt 2
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS OR LOC RWY 28, ILS RWY 28 (SA CAT I), ILS RWY 28 (CAT II), Amdt 2
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS PRM RWY 10, ILS RWY 10 (CAT II), ILS RWY 10 (CAT III), (Simultaneous Close Parallel), Amdt 2
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, ILS PRM RWY 28, ILS RWY 28 (CAT II), (Simultaneous Close Parallel), Amdt 2
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 10, Amdt 2
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (GPS) Y RWY 28, Amdt 2
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 10, Amdt 1
Atlanta, GA, Hartsfield-Jackson Atlanta Intl, RNAV (RNP) Z RWY 28, Amdt 1
Lawrenceville, GA, Gwinnett County-Briscoe Field, NDB RWY 25, Amdt 1
Lawrenceville, GA, Gwinnett County-Briscoe Field, VOR/DME RWY 7, Amdt 2
Macon, GA, Macon Downtown, LOC RWY 10, Amdt 7
Macon, GA, Macon Downtown, RNAV (GPS) RWY 10, Amdt 1
Macon, GA, Macon Downtown, RNAV (GPS) RWY 28, Amdt 1
Bloomington/Normal, IL, Central Il Rgnl Arpt at Bloomington-Normal, ILS OR LOC RWY 29, Amdt 10
Bloomington/Normal, IL, Central Il Rgnl Arpt at Bloomington-Normal, LOC BC RWY 11, Amdt 10
Larned, KS, Larned-Pawnee County, NDB RWY 17, Amdt 4
Larned, KS, Larned-Pawnee County, RNAV (GPS) RWY 17, Orig
Larned, KS, Larned-Pawnee County, RNAV (GPS) RWY 35, Orig
Marysville, KS, Marysville Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Patterson, LA, Harry P Williams Memorial, ILS OR LOC/DME RWY 24, Amdt 2
Patterson, LA, Harry P Williams Memorial, RNAV (GPS) RWY 24, Amdt 1
Vineyard Haven, MA, Marthas Vineyard, RNAV (GPS) RWY 6, Amdt 1
Sanford, ME, Sanford Rgnl, ILS OR LOC RWY 7, Amdt 4
Sanford, ME, Sanford Rgnl, RNAV (GPS) RWY 7, Orig
Sanford, ME, Sanford Rgnl, RNAV (GPS) RWY 25, Orig
Sanford, ME, Sanford Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3
Sanford, ME, Sanford Rgnl, VOR RWY 7, Amdt 4
Sanford, ME, Sanford Rgnl, VOR RWY 25, Amdt 14
Battle Creek, MI, W K Kellogg, Takeoff Minimums and Obstacle DP, Amdt 3
Niles, MI, Jerry Tyler Memorial, VOR OR GPS RWY 4, Amdt 7A CANCELLED
Niles, MI, Jerry Tyler Memorial, VOR OR GPS RWY 22, Amdt 3A CANCELLED
Buffalo, MN, Buffalo Muni, RNAV (GPS) RWY 36, Orig
Buffalo, MN, Buffalo Muni, VOR–A, Orig
Buffalo, MN, Buffalo Muni, VOR OR GPS–B, Amdt 4, CANCELLED
Hallock, MN, Hallock Muni, GPS RWY 31, Orig, CANCELLED

Hallock, MN, Hallock Muni, RNAV (GPS) RWY 31, Orig
Hallock, MN, Hallock Muni, Takeoff Minimums and Obstacle DP, Orig
Little Falls, MN, Little Falls/Morrison County-Lindbergh Fld, GPS RWY 31, Orig-A, CANCELLED
Little Falls, MN, Little Falls/Morrison County-Lindbergh Fld, RNAV (GPS) RWY 31, Orig
Marshall, MN, Southwest Minnesota Rgnl/Marshall/Ryan Fld, GPS RWY 30, Orig-A, CANCELLED
Marshall, MN, Southwest Minnesota Rgnl/Marshall/Ryan Fld, RNAV (GPS) RWY 30, Orig
St Paul, MN, Lake Elmo, NDB RWY 4, Amdt 5
St Paul, MN, Lake Elmo, RNAV (GPS) RWY 32, Amdt 1
Moberly, MO, Omar N Bradley, VOR/DME RNAV OR GPS RWY 13, Amdt 1, CANCELLED
Moberly, MO, Omar N Bradley, VOR/DME RNAV OR GPS RWY 31, Amdt 1, CANCELLED
Clarksdale, MS, Fletcher Field, RNAV (GPS) RWY 18, Amdt 1
Clarksdale, MS, Fletcher Field, RNAV (GPS) RWY 36, Amdt 1
Tunica, MS, Tunica Muni, ILS or LOC/DME RWY 35, Amdt 1
Tunica, MS, Tunica Muni, RNAV (GPS) RWY 17, Amdt 3
Tunica, MS, Tunica Muni, RNAV (GPS) RWY 35, Amdt 2
Tunica, MS, Tunica Muni, VOR/DME–A, Orig
Bismarck, ND, Bismarck Muni, ILS OR LOC RWY 13, Amdt 3
Bismarck, ND, Bismarck Muni, ILS OR LOC RWY 31, Amdt 33
Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 3, Amdt 2
Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 13, Orig
Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 21, Amdt 1
Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 31, Amdt 1
Bismarck, ND, Bismarck Muni, VOR–A, Amdt 21
Walhalla, ND, Walhalla Muni, Takeoff Minimums and Obstacle DP, Orig
Creighton, NE, Creighton Muni, RNAV (GPS) RWY 13, Orig
Creighton, NE, Creighton Muni, RNAV (GPS) RWY 31, Orig
Creighton, NE, Creighton Muni, Takeoff Minimums and Obstacle DP, Orig
Lincoln, NE, Lincoln, VOR RWY 17, Amdt 7
Lincoln, NE, Lincoln, VOR RWY 18, Amdt 13
Nashua, NH, Boire Field, RNAV (GPS) RWY 32, Orig-A
Poughkeepsie, NY, Dutchess County, ILS OR LOC RWY 6, Amdt 6A
Poughkeepsie, NY, Dutchess County, RNAV (GPS) RWY 6, Orig-A
Poughkeepsie, NY, Dutchess County, VOR/DME RWY 6, Amdt 6A
Watertown, NY, Watertown Intl, ILS OR LOC RWY 7, Amdt 7
Watertown, NY, Watertown Intl, RNAV (GPS) RWY 7, Amdt 2
Watertown, NY, Watertown Intl, VOR RWY 7, Amdt 14
White Plains, NY, Westchester County, ILS OR LOC RWY 16, Amdt 23A
Cadiz, OH, Harrison County, GPS RWY 13, Orig, CANCELLED
Cadiz, OH, Harrison County, GPS RWY 31, Orig, CANCELLED
Cadiz, OH, Harrison County, RNAV (GPS) RWY 13, Orig
Cadiz, OH, Harrison County, RNAV (GPS) RWY 31, Orig
Cadiz, OH, Harrison County, Takeoff Minimums and Obstacle DP, Amdt 3
Cleveland, OH, Cleveland-Hopkins Intl, CONVERGING ILS RWY 24R, Amdt 1
Cleveland, OH, Cleveland-Hopkins Intl, ILS OR LOC RWY 6R, ILS RWY 6R (SA CAT II), Amdt 21
Cleveland, OH, Cleveland-Hopkins Intl, ILS OR LOC RWY 24L, ILS RWY 24L (SA CAT II), Amdt 22
Cleveland, OH, Cleveland-Hopkins Intl, ILS OR LOC/DME RWY 24R, ILS RWY 24R (CAT II), ILS RWY 24R (CAT III), ILS RWY 24R (SA CAT I), Amdt 5
Cleveland, OH, Cleveland-Hopkins Intl, ILS PRM RWY 24R (Simultaneous Close Parallel), Amdt 1
Cleveland, OH, Cleveland-Hopkins Intl, RNAV (GPS) RWY 24L, Amdt 3
Cleveland, OH, Cleveland-Hopkins Intl, RNAV (GPS) RWY 24R, Amdt 3
Oklahoma City, OK, Wiley Post, ILS OR LOC RWY 35R, Orig
Scappoose, OR, Scappoose Industrial Airpark, RNAV (GPS) RWY 15, Orig
Scappoose, OR, Scappoose Industrial Airpark, VOR/DME–A, Amdt 3
St. George, SC, St George, VOR/DME–A, Amdt 2, CANCELLED
Dyersburg, TN, Dyersburg Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
Gallatin, TN, Summer County Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3
Charlottesville, VA, Charlottesville-Albemarle, ILS OR LOC RWY 3, Amdt 14, CANCELLED
Charlottesville, VA, Charlottesville-Albemarle, ILS OR LOC RWY 3, Orig
Burlington, VT, Burlington Intl, RNAV (GPS) RWY 33, Orig, CANCELLED
Burlington, VT, Burlington Intl, RNAV (GPS) Y RWY 33, Orig
Burlington, VT, Burlington Intl, RNAV (GPS) Z RWY 33, Orig
Amery, WI, Amery Muni, NDB RWY 18, Amdt 6A, CANCELLED
Madison, WI, Dane County Rgnl-Traux Field, RNAV (GPS) RWY 14, Amdt 2
Madison, WI, Dane County Rgnl-Traux Field, RNAV (GPS) RWY 32, Amdt 2
Madison, WI, Dane County Rgnl-Traux Field, Takeoff Minimums and Obstacle DP, Amdt 8
Madison, WI, Dane County Rgnl-Traux Field, VOR RWY 18, Amdt 1
Madison, WI, Dane County Rgnl-Traux Field, VOR RWY 32, Amdt 1
Middleton, WI, Middleton Muni-Morey Field, VOR RWY 10, Amdt 1
Mosinee, WI, Central Wisconsin, ILS OR LOC RWY 8, Amdt 13
Mosinee, WI, Central Wisconsin, ILS OR LOC RWY 35, Amdt 2
Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 8, Amdt 1
Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 17, Amdt 1
Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 26, Amdt 1
Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 35, Amdt 1
Mosinee, WI, Central Wisconsin, VOR/DME RWY 35, Amdt 9
Waupaca, WI, Waupaca Muni, RNAV (GPS) RWY 10, Amdt 1
Waupaca, WI, Waupaca Muni, RNAV (GPS) RWY 28, Amdt 1

On March 4, 2011 (76 FR 11944) the FAA published an Amendment in Docket No. 30770, Amdt 3414 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entries, published in TL 11–07 effective for 05 MAY 2011, are hereby *rescinded:*

Hartford, CT, Hartford-Brainard, LDA RWY 2, Amdt 1G
Hartford, CT, Hartford-Brainard, VOR OR GPS–A, Amdt 9C

On March 25, 2011 (76 FR 16690) the FAA published an Amendment in Docket No. 30772, Amdt 3416 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entry, published in TL 11–08 effective for 05 MAY 2011, is hereby *rescinded:*

Kamuela, HI, Waimea-Kohala, RNAV (GPS) RWY 4, Amdt 1

On March 25, 2011 (76 FR 16691) the FAA published an Amendment in Docket No. 30772, Amdt 3416 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entries, published in TL 11–08 effective for 05 MAY 2011, are hereby *rescinded:*

Kamuela, HI, Waimea-Kohala, VOR/DME RWY 4, Amdt 1
Niles, MI, Jerry Tyler Memorial, VOR OR GPS RWY 3, Amdt 7A, CANCELLED
Niles, MI, Jerry Tyler Memorial, VOR OR GPS RWY 21, Amdt 3A,CANCELLED

[FR Doc. 2011–8934 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30777; Amdt. No. 3421]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes

occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective April 15, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 15, 2011.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located;
3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or
4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Availability—All SIAPs are available online free of charge. Visit *http://nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Harry J. Hodges, Flight Procedure Standards Branch (AFS–420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on April 1, 2011.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
5–May–11	NE	Lincoln	Lincoln	1/0794	3/23/11	ILS OR LOC RWY 18, Amdt 6F
5–May–11	FL	Venice	Venice Muni	1/1934	3/23/11	Takeoff Minimums and Obstacle DP, Amdt 2
5–May–11	NC	Greenville	Pitt-Greenville	1/2023	3/23/11	RNAV (GPS) RWY 2, Orig
5–May–11	NY	Niagara Falls	Niagara Falls Intl	1/2456	3/23/11	NDB OR GPS RWY 28R, Amdt 16A
5–May–11	NC	Greenville	Pitt-Greenville	1/2789	3/23/11	ILS OR LOC RWY 20, Amdt 4
5–May–11	TX	Dallas	Dallas Love Field	1/3002	3/23/11	RNAV (GPS) Z RWY 13L, Orig-B
5–May–11	VA	Orange	Orange County	1/5119	3/4/11	VOR/DME OR GPS A, Amdt 2A
5–May–11	GA	Rome	Richard B Russell	1/5120	3/4/11	ILS/DME RWY 1, Orig-A
5–May–11	NJ	Linden	Linden	1/5393	3/7/11	Takeoff Minimums and Obstacle DP, Amdt 2
5–May–11	NJ	Newark	Newark Liberty Intl	1/5735	3/4/11	RNAV (RNP) Z RWY 29, Orig-A
5–May–11	MD	Cambridge	Cambridge-Dorchester	1/6177	3/1/11	NDB OR GPS RWY 34, Amdt 7
5–May–11	FL	Deland	Deland Muni-Sidney H Taylor Field.	1/6474	3/1/11	RNAV (GPS) RWY 5, Orig
5–May–11	FL	Panama City	Northwest Florida Beaches Intl	1/6475	3/1/11	RNAV (GPS) RWY 16, Orig-B
5–May–11	FL	Panama City	Northwest Florida Beaches Intl	1/6476	3/1/11	RNAV (GPS) RWY 34, Orig-B
5–May–11	WV	Charleston	Yeager	1/6478	3/1/11	Takeoff Minimums and Obstacle DP, Amdt 8
5–May–11	RI	Providence	Theodore Francis Green State	1/6567	3/1/11	ILS RWY 34, Amdt 10B
5–May–11	NJ	Newark	Newark Liberty Intl	1/6957	3/4/11	RNAV (RNP) Y RWY 29, Orig-A
5–May–11	CT	Groton (New London)	Groton-New London	1/7378	3/7/11	ILS OR LOC RWY 5, Amdt 11B
5–May–11	VT	Morrisville	Morrisville-Stowe State	1/7381	3/9/11	NDB OR GPS B, Amdt 1C
5–May–11	VT	Morrisville	Morrisville-Stowe State	1/7382	3/9/11	Takeoff Minimums and Obstacle DP, Amdt 2
5–May–11	MS	Starkville	George M Bryan	1/7383	3/14/11	LOC/DME RWY 36, Orig
5–May–11	FL	Lakeland	Lakeland Linder Rgnl	1/7480	3/7/11	RNAV (GPS) RWY 27, Orig
5–May–11	NY	White Plains	Westchester County	1/7527	3/7/11	RNAV (RNP) Z RWY 34, Orig
5–May–11	MA	Falmouth	Cape Cod Coast Guard Air Station.	1/7535	3/7/11	ILS OR LOC RWY 32, Orig
5–May–11	KY	Lexington	Blue Grass	1/7821	3/1/11	ILS OR LOC RWY 22, Amdt 20
5–May–11	AL	Auburn	Auburn University Rgnl	1/7887	3/7/11	RNAV (GPS) RWY 18, Orig
5–May–11	AL	Auburn	Auburn University Rgnl	1/7888	3/7/11	RNAV (GPS) RWY 11, Orig
5–May–11	NY	Poughkeepsie	Dutchess County	1/8102	3/9/11	Takeoff Minimums and Obstacle DP, Amdt 1
5–May–11	TN	Memphis	Memphis Intl	1/8162	3/7/11	RNAV (RNP) Y RWY 18R, Orig
5–May–11	TN	Memphis	Memphis Intl	1/8163	3/7/11	RNAV (RNP) X RWY 18L, Orig
5–May–11	TN	Memphis	Memphis Intl	1/8164	3/7/11	RNAV (RNP) Y RWY 18L, Orig
5–May–11	PA	Perkasie	Pennridge	1/8350	3/7/11	Takeoff Minimums and Obstacle DP, Orig
5–May–11	DC	Washington	Washington Dulles Intl	1/8351	3/7/11	RNAV (GPS) RWY 12, Amdt 1
5–May–11	DC	Washington	Washington Dulles Intl	1/8353	3/7/11	RNAV (GPS) RWY 1L, Orig
5–May–11	WI	Madison	Blackhawk Airfield	1/8455	3/9/11	VOR OR GPS A, Orig-C
5–May–11	AL	Lanett	Lanett Muni	1/8471	3/7/11	VOR/DME OR GPS A, Amdt 2A
5–May–11	IA	Keokuk	Keokuk Muni	1/8893	3/9/11	RNAV (GPS) RWY 14, Orig
5–May–11	IA	Keokuk	Keokuk Muni	1/8894	3/9/11	ILS OR LOC/DME RWY 26, Orig
5–May–11	IA	Keokuk	Keokuk Muni	1/8895	3/9/11	RNAV (GPS) RWY 26, Orig
5–May–11	IA	Keokuk	Keokuk Muni	1/8896	3/9/11	RNAV (GPS) RWY 8, Orig
5–May–11	NC	Goldsboro	Goldsboro-Wayne Muni	1/9054	3/7/11	VOR A, Amdt 5
5–May–11	NC	Goldsboro	Goldsboro-Wayne Muni	1/9055	3/7/11	RNAV (GPS) RWY 23, Orig
5–May–11	NC	Goldsboro	Goldsboro-Wayne Muni	1/9056	3/7/11	ILS OR LOC RWY 23, Amdt 1A
5–May–11	NY	Middletown	Randall	1/9081	3/4/11	NDB RWY 26, Amdt 1
5–May–11	VA	Marion/Wytheville	Mountain Empire	1/9082	3/4/11	RNAV (GPS) RWY 26, Orig
5–May–11	WV	Ravenswood	Jackson County	1/9088	3/4/11	Takeoff Minimums and Obstacle DP, Amdt 1
5–May–11	KS	Concordia	Blosser Muni	1/9097	3/9/11	GPS RWY 17, Orig-A
5–May–11	IL	Morris	Morris Muni-James R. Washburn.	1/9221	3/4/11	RNAV (GPS) RWY 18, Orig
5–May–11	VA	Martinsville	Blue Ridge	1/9234	3/4/11	LOC RWY 30, Amdt 1
5–May–11	NE	Lincoln	Lincoln	1/9352	3/23/11	ILS OR LOC RWY 36, Amdt 11E
5–May–11	IL	Peru	Illinois Valley Rgnl-Walter A Cuncan Field.	1/9358	3/9/11	LOC RWY 36, Amdt 3A
5–May–11	IL	Peru	Illinois Valley Rgnl-Walter A Cuncan Field.	1/9360	3/9/11	RNAV (GPS) RWY 18, Orig-A
5–May–11	IL	Peru	Illinois Valley Rgnl-Walter A Cuncan Field.	1/9362	3/9/11	RNAV (GPS) RWY 36, Orig-A
5–May–11	NY	New York	La Guardia	1/9829	3/9/11	RNAV (RNP) Z RWY 22, Orig
5–May–11	NY	Poughkeepsie	Dutchess County	1/9964	3/23/11	VOR A, Amdt 11
5–May–11	NY	Poughkeepsie	Dutchess County	1/9965	3/23/11	RNAV (GPS) RWY 24, Orig
5–May–11	NY	Poughkeepsie	Dutchess County	1/9966	3/23/11	VOR/DME RWY 24, Amdt 4A

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BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2011–N–0118]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Hemorrhoid Prevention Pressure Wedge

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the hemorrhoid prevention pressure wedge into class II (special controls). The special controls will apply to the device in order to provide a reasonable assurance of safety and effectiveness of the device. A hemorrhoid prevention pressure wedge provides support to the perianal region during the labor and delivery process.

DATES: This rule is effective May 16, 2011. The classification was applicable on January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Glenn Bell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G112, Silver Spring, MD 20993–0002, 301–796–6531.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C.360c(i)), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on August 5, 2009, classifying the Hem-Avert Perianal Stabilizer into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On August 17, 2009, Plexus Biomedical, Inc., submitted a petition requesting classification of the Hem-Avert Perianal Stabilizer under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II. (Ref. 1)

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name hemorrhoid prevention pressure wedge, and it is identified as a hemorrhoid prevention pressure wedge that provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

FDA has identified the following risks to health associated specifically with this type of device and the recommended measures to mitigate these risks.

TABLE 1—HEALTH RISKS AND MITIGATIONS

Identified risk	Mitigation measures
Skin/tissue trauma (*e.g.,* rectal and/or anal trauma, necrosis, thinning, abrasion, laceration to the perineum, vulvar hematoma, sloughing).	Nonclinical Analysis and Testing. Clinical Information. Labeling.
Device failure (*e.g.,* material failure, slippage)	Nonclinical Analysis and Testing. Labeling.
Device failure—obstruction to the treatment area caused by inability to remove the instrument quickly	Device Description. Labeling.
Infection.	Labeling.
Adverse tissue reaction	Biocompatibility.
Pain	Nonclinical Analysis and Testing. Biocompatibility.

FDA believes that the following special controls address the risks to health and provide reasonable assurance of the safety and effectiveness of the device: (1) The sale, distribution, and use of this device are restricted to

prescription use in accordance with 21 CFR 801.109; (2) the labeling should include specific instructions regarding the proper placement and use of the device; (3) the device should be demonstrated to be biocompatible; (4) mechanical bench testing of material strength should demonstrate that the device will withstand forces encountered during use; and (5) safety and effectiveness data should demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls. Therefore, on January 13, 2011 (corrected order sent to petitioner on February 1, 2011), FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 884.5200.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a hemorrhoid prevention pressure wedge will need to address the issues covered in the special controls.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the hemorrhoid prevention pressure wedge they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from or in addition to" certain Federal requirements applicable to devices. (21 U.S.C. 360k); *See Medtronic* v. *Lohr,* 518 U.S. 470 (1996); *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). The special controls established by this final rule create "requirements" to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors may have flexibility in how they meet these requirements. Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–42 (9th Cir. 1997).

V. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 32501–3520). The collections of information in part 807, regarding premarket notification submissions, have been approved under OMB control no. 0910–0120; the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control no. 0910–0485.

VI. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Plexus Biomedical, Inc., August 17, 2009.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 884.5200 is added to subpart F to read as follows:

§ 884.5200 Hemorrhoid prevention pressure wedge.

(a) *Identification.* A hemorrhoid prevention pressure wedge provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions regarding the proper placement and use of the device.

(3) The device must be demonstrated to be biocompatible.

(4) Mechanical bench testing of material strength must demonstrate that the device will withstand forces encountered during use.

(5) Safety and effectiveness data must demonstrate that the device prevents hemorrhoids in women undergoing spontaneous vaginal delivery, in addition to general controls.

Dated: April 11, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–9141 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

28 CFR Parts 0 and 51

[CRT Docket No. 120; AG Order No. 3262–2011]

Revision of Voting Rights Procedures

AGENCY: Civil Rights Division, Department of Justice.

ACTION: Final rule.

SUMMARY: The Attorney General finds it necessary to revise the Department of Justice's "Procedures for the Administration of section 5 of the Voting Rights Act of 1965." The revisions are needed to clarify the scope of section 5 review based on recent amendments to section 5, make technical clarifications and updates, and provide better guidance to covered jurisdictions and interested members of the public concerning current Department practices. Proposed revised Procedures were published for comment on June 11, 2010, and a 60-day comment period was provided.

DATES: The rule will be effective on April 15, 2011.

FOR FURTHER INFORMATION CONTACT: T. Christian Herren, Jr., Chief, Voting Section, Civil Rights Division, United States Department of Justice, Room 7254–NWB, 950 Pennsylvania Avenue, NW., Washington, DC 20530, or by telephone at (800) 253–3931.

SUPPLEMENTARY INFORMATION:

Discussion

Section 5 of the Voting Rights Act of 1965, as amended, 42 U.S.C. 1973c, requires certain jurisdictions (listed in the Appendix) to obtain "preclearance" from either the United States District Court for the District of Columbia or the United States Attorney General before implementing any new standard, practice, or procedure that affects voting.

Procedures for the Attorney General's Administration of section 5 were first published in 1971. Proposed Procedures were published for comment on May 28, 1971 (36 FR 9781), and the final Procedures were published on September 10, 1971 (36 FR 18186). As a result of the Department's experience under the 1971 Procedures, changes mandated by the 1975 Amendments to the Voting Rights Act, and interpretations of section 5 contained in judicial decisions, proposed revised Procedures were published for comment on March 21, 1980 (45 FR 18890), and final revised Procedures were published on January 5, 1981 (46 FR 870) (corrected at 46 FR 9571, Jan. 29, 1981). As a result of further experience under the 1981 Procedures, specifically with respect to redistricting plans adopted following the 1980 Census, changes mandated by the 1982 Amendments to the Voting Rights Act, and judicial decisions in cases involving section 5, revised Procedures were published for comment on May 6, 1985 (50 FR 19122), and final revised Procedures were published on January 6, 1987 (52 FR 486).

In the twenty-four years since the previous revisions became final, the Attorney General has had further experience in the consideration of voting changes; the courts have issued a number of important decisions in cases involving section 5, and Congress enacted the 2006 amendments to the Voting Rights Act. This new revision reflects these developments.

Comments

In response to the Notice of Proposed Rulemaking ("Notice") published on June 11, 2010 (75 FR 33205), we received comments from or on behalf of two national public interest organizations, one research and educational institution, one national political organization composed of attorneys, and one individual. All comments received are available for inspection and copying at www.regulations.gov and at the Voting Section, Civil Rights Division, Department of Justice, Washington DC 20530.

The comments received expressed diverse views and were of great assistance in the preparation of these final revisions to the Procedures. The final revised Procedures reflect our consideration of the comments as well as further consideration of sections or topics that were not the subject of comments.

Section 51.2 Definitions

The purpose of the revision to the definition of "change affecting voting" or "change" is to clarify the definition of the benchmark standard, practice, or procedure. One commenter recommended we revise this section to reflect that the benchmark is the standard, practice, or procedure in force or effect at the time of the submission or the last legally enforceable standard, practice, or procedure in force or effect in the jurisdiction. We have concluded that no further revision of this section is warranted. The Voting Section's practice is to compare the proposed standard, practice, or procedure to the benchmark. Generally, the benchmark is the standard, practice, or procedure that has been: (1) Unchanged since the jurisdiction's coverage date; or (2) if changed since that date, found to comply with section 5 and "in force or effect." *Riley* v. *Kennedy,* 553 U.S. 406, 421 (2008); Procedures for the Administration of Section 5 of the Voting Rights Act of 1965, 28 CFR 51.54. Where there is an unsubmitted intervening change, the Attorney General will make no determination concerning the submitted change because of the prior unsubmitted change. In such instances, it is our practice to inform the jurisdiction there is a prior related change that has not been submitted and that simultaneous review is required. A standard, practice, or procedure that has been reviewed and determined to meet section 5 standards is considered to be in force or effect, even if the jurisdiction never implements the change because the change is effective as a matter of federal law and was available for use.

Section 51.3 Delegation of Authority

The purpose of the revisions to the delegation of authority is to make technical corrections to the delegation of authority from the Attorney General to the Assistant Attorney General, and from the Chief of the Voting Section to supervisory attorneys within the Voting Section, and to conform the Procedures to other parts of Title 28. Two commenters objected to the revisions, expressing concern that the delegation of the functions of the Chief to supervisory attorneys in the Voting Section results in the delegation of section 5 legal review authority to non-politically appointed attorneys subordinate to the Section Chief.

The concerns of these commenters are unfounded. The delegation of authority in these Procedures is similar to existing delegations. For example, pursuant to the appendix to 28 CFR Part 0, Subpart J, the Chief may authorize the Deputy Chief to act on his or her behalf. Moreover, under the revised Procedures, the Chief needs the concurrence of the Assistant Attorney General, who is a presidential appointee, to designate supervisory attorneys to perform section 5 functions. Accordingly, we decline to revise the section further.

Section 51.9 Computation of Time

The purpose of the revisions to this section is to clarify that the review period commences when a submission is received by the Department officials responsible for conducting section 5 reviews and to clarify the date of the response.

One commenter objected to the commencement of the 60-day review period upon receipt of the submission by the Voting Section or the Office of the Assistant Attorney General of the Civil Rights Division as an unwarranted extension of the 60-day review period. The Federal Rules of Civil Procedure provide for the designation of a Department clerical employee to receive summonses on behalf of the Attorney General. Fed. R. Civ. P. 4(i)(1)(A)(i). Similarly, and for the same purpose of prompt and efficient routing, the Attorney General has designated both the Voting Section and the Office of the Assistant Attorney General of the Civil Rights Division as the proper recipients for section 5 submissions.

The Department has made one additional edit to this section. As set forth in the Notice and as described below, a second paragraph is being added to § 51.37 (Obtaining information from the submitting authority). To ensure consistency, the reference to § 51.37, contained in previous versions of the Procedures, is amended to § 51.37(b),

Section 51.13 Examples of Changes

The purpose of this revision is to clarify that the dissolution or merger of voting districts, de facto elimination of an elected office, and reallocations of authority to adopt or administer voting practices or procedures are all subject to section 5 review.

One commenter suggested that we add the extension of a term of office for an elected official as an example of a covered change in paragraph (i). We concluded that including this example would provide additional clarity. To the extent that the extension of an elected official's term is a discretionary change that affects the next regularly scheduled election for that office, there is no question that it constitutes a "change affecting voting" covered by section 5. Additionally, extending the term of a particular office affects the ability of voters to elect candidates of choice at regularly scheduled intervals.

The commenter also suggested that paragraph (k), which provides that changes affecting the right or ability of persons to participate in "political campaigns" are covered under section 5, be expanded to include "campaigns or other pre-election activity." We agreed that the phrase "political campaigns," without any elaboration, may carry partisan connotations not envisioned by the statute. Additionally, "political campaigns" may not include all pre-election activity related to voting, and a somewhat broader construction is consistent with the broad scope given to "changes affecting voting" covered under section 5. Such changes include any "voting qualification or prerequisite to voting or standard, practice, or procedure" related to the right to vote, 42 U.S.C. 1973(a), and the Supreme Court has recognized that voting includes "all action necessary to make a vote effective." *Allen* v. *State Board of Elections,* 393 U.S. 544, 566 (1969) (quoting 42 U.S.C. 1973l). As a result, section 5 coverage extends to "subtle, as well as the obvious," changes affecting voting. *Allen,* 393 U.S. at 565.

Using the phrase "pre-election activity," by itself, however, is too general and nebulous. As a result, we have revised the paragraph to reflect that any change affecting the right or ability of persons to participate in pre-election activity, such as political campaigns, is subject to review under section 5.

Another commenter objected to the inclusion of paragraph (l) as an example of changes affecting voting, stating that this change did not fall within the scope of section 5 coverage. A change in the voting-related authority of an official or governmental entity does alter election law and change rules governing voting. Thus, such changes meet the test of voting relatedness that is at the core of the Court's decision in *Presley* v. *Etowah County Commission,* 502 U.S. 491 (1992). In addition, a conclusion that such changes are not covered arguably would be inconsistent with the well-established rule that section 5 covers state enabling legislation that transfers authority to adopt a voting change from the state to its subjurisdictions. See *Allen* v. *State Board of Elections,* 393 U.S. 544 (1969) (holding that section 5 covered a Mississippi statute that granted county boards of supervisors the authority to change board elections from single-member districts to at-large voting).

Section 51.18 Federal Court-Ordered Changes

The purpose of the revisions to this section is to clarify the principle that section 5 review ordinarily should precede other forms of court review, that a court-ordered change that initially is not subject to section 5 may become covered through subsequent actions taken by the affected jurisdiction, and that the interim use of an covered change before it is established that such change complies with section 5 should be ordered by a court only in emergency circumstances.

One commenter opposed the changes contained in the section stating that the revisions appear to grant federal courts greater authority than the case law recognizes to implement voting changes that are subject to, but not yet reviewed under, section 5 on an emergency basis. Although that was not the intent of the revisions, we have modified § 51.18(a) to clarify that it reflects existing judicial precedent. After further consideration, we believe that, other than renumbering the paragraph as § 51.18(d), it is appropriate not to make any change to § 51.18(c) as it currently exists in the Procedures.

Section 51.28 Supplemental Contents

The proposed revision to paragraph (a) was omitted from the June 11, 2010, Notice of Proposed Rulemaking in error. The purpose of the revision is to make purely technical changes to the format in which information may be submitted to the Attorney General electronically. In addition, since the publication of the Notice, the Census Bureau has renamed the 15-character geographic identifier specified in paragraph (b); the final Procedures reflect this change in nomenclature.

Section 51.29 Communications Concerning Voting Changes

The purpose of the revisions to this section is to clarify the addresses and methods by which persons may provide written comments on section 5 submissions and to clarify the circumstances in which the Department may withhold the identity of those providing comments on section 5 submissions.

One commenter objected to the nondisclosure of the identity of an individual or entity where an assurance of confidentiality may reasonably be implied from the circumstances of the communication. The Department believes, however, that communications

where confidentiality can reasonably be implied are within the scope of information that "could reasonably be expected to disclose the identity of a confidential source." 5 U.S.C. 552(b)(7). Accordingly, this determination about confidentiality is within the scope of Section 552(b) concerning exemptions under both the Freedom of Information and the Privacy Acts.

Section 51.37 Obtaining Information From the Submitting Authority

The purpose of the revisions to this section is to clarify the procedures for the Attorney General to make oral and written requests for additional information regarding a section 5 submission.

One commenter recommended that we revise the paragraph concerning oral requests to make clear that the Attorney General reserves the authority to restart the 60-day review period upon receipt of material provided in response to the Attorney General's first such request made with respect to a submission, and that responses to an oral request do not affect the running of the 60-day period once a written request for information is made.

We declined to amend the proposed language regarding responses to an oral request because as the Procedures currently exist the Attorney General may request further information within the new 60-day period following the receipt of a response from the submitting authority to an earlier written request, but such a request shall not suspend the running the 60-day period, nor shall the Attorney General's receipt of such further information begin a new 60-day period. Moreover, § 51.39 provides that we may determine that information supplied in response to an oral request in the initial review period materially supplements the pending request such that it does extend the 60-day period.

We did conclude, however, on the basis of the comment that we received, that a reordering of the paragraphs would add clarity to the section and make it more useful.

Section 51.40 Failure To Complete Submissions

As described above, the paragraphs of § 51.37 are being reordered. To ensure consistency, the reference to § 51.37(a) in previous versions of the Procedures is amended to § 51.37(b).

Section 51.48 Decision After Reconsideration

The purpose of the revisions to this section is to clarify the manner in which the 60-day requirement applies to reconsideration requests and revise language to conform to the substantive section 5 standard in the 2006 amendments to the Act.

One commenter objected to the revisions in paragraph (a), expressing a concern that the revisions permit the Attorney General to exceed 60 days for the reconsideration of an objection. Section 51.48 provides that the 60-day reconsideration period may be extended to allow a 15-day decision period following a conference held pursuant to § 51.47. Moreover, the courts have held that when a submitting jurisdiction deems its initial submission on a reconsideration request to be inadequate and decides to supplement it, the 60-day period is commenced anew. The purpose of this interpretation is to provide the Attorney General time to give adequate consideration to materials submitted in piecemeal fashion. *City of Rome* v. *United States,* 446 U.S. 156, 171 (1980).

Section 51.50 Records Concerning Submissions

The purpose of the revision to this section is to clarify the procedures regarding access to section 5 records. One commenter opposed the changes to paragraph (b) and conveyed concerns that these changes will result in the removal of record keeping with regard to objection files.

Under paragraph (a), the Voting Section continues to maintain a section 5 file for each submission, including objection files. Accordingly, all appropriate records continue to be maintained with regard to all section 5 submissions.

Section 51.52 Basic Standard

The purpose of the revision to this section is to clarify the substantive standard so as to reflect the 2006 amendments to the Act and the manner in which the Attorney General will evaluate submissions under section 5.

One commenter suggested that paragraph (a) be amended further to reflect the fact that the Attorney General "shall apply the same standard of review," instead of "shall make the same determination," that would be made by a court in an action for a declaratory judgment under section 5. The section refers to making a "determination" as the activity that both the Attorney General and the district court undertake, *i.e.,* deciding whether the change complies with section 5, as opposed to the resulting substantive decision. Therefore, we concluded that no further revision to the paragraph is warranted.

Another commentator suggested we replace "purpose and effect" with "purpose or effect" in paragraph (c). Although we decided not to incorporate the commentator's exact change, we did decide that further refinement of the paragraph would provide more clarity. Therefore, the paragraph will reflect that in those situations where the evidence as to the purpose or effect of the change is conflicting and the Attorney General is unable to determine that the change is free of both the prohibited discriminatory purpose and effect, the Attorney General will interpose an objection. *Evers* v. *State Board of Election Commissioners,* 327 F. Supp. 640 (S.D. Miss 1971).

Section 51.54 Discriminatory Purpose and Effect

One commenter suggested various minor edits to the proposed language. We declined to make these changes. The proposed language reflects our extensive experience gained over the years in our administrative review of section 5 changes, while avoiding redundancy.

We did edit the language of paragraph (c) to reflect that the statutory language refers to a change in a standard, practice, or procedure affecting voting, not only a practice or procedure.

Section 51.57(e) Relevant Factors

One commenter suggested that we include "contemporaneous statements and viewpoints held by decision-makers" in the list of relevant factors. Such statements are an evidentiary source cited by the Court in its opinion in *Village of Arlington Heights* v. *Metropolitan Housing Development Corp.,* 429 U.S. 252, 268 (1977), and therefore we have revised the section to reflect the Court's holding more completely.

Section 51.58(b)(2) Background Factors

One commenter suggested that this paragraph be revised to state that whether "election-related activities," instead of "political activities," are racially segregated or exclusionary constitutes important background information when making section 5 determinations. The proposed paragraph provided that the Attorney General will consider the "extent to which voting in the jurisdiction is racially polarized and political activities are racially segregated." Courts in cases assessing whether the constitutional guarantees afforded to persons to exercise the franchise without discrimination have been infringed have often used the words "electoral" and "political" as synonyms for each other. See, *e.g., Harper* v. *Virginia State Board of Elections,* 383 U.S. 663, 667–68

(1966); *see also Johnson* v. *Miller,* 864 F. Supp. 1354, 1386–87 (S.D. Ga. 1994) (considering a claim under section 2 of the Voting Rights Act). These terms are similarly synonymous with respect to section 5, which also concerns the ability of voters to participate in the electoral process. After careful consideration of the comment, we determined that "election-related activities" provides greater clarity than "political activities" and revised the section accordingly.

Section 51.59 Redistricting Plans

Two commenters recommended various additions or deletions to paragraph 51.59(a). Because these factors are not intended to be exhaustive, not all factors are listed. Rather, the factors that are listed are illustrative, intended to provide guidance to jurisdictions regarding redistricting plans.

Other commenters suggested we delete or revise certain previously existing factors described in the paragraph. The Attorney General has, however, repeatedly cited factors identified in the section in past objection letters. Additionally, courts have cited "traditional redistricting principles," such as preserving recognized communities of interest and maintaining political and geographical boundaries, as relevant factors in a section 5 analysis. *Colleton County Council* v. *McConnell,* 201 F. Supp. 2d 618, 647 (D.S.C. 2002) (citing *S.C. State Conference of Branches of the NAACP* v. *Riley,* 533 F. Supp. 1178, 1180 (D.S.C.), *aff'd,* 459 U.S. 1025 (1982)). *See generally Guidance Concerning Redistricting Under Section 5 of the Voting Rights Act,* 76 FR 7470, 7472 (2011).

One commenter suggested we amend paragraph 51.59(a)(7) to focus on whether a proposed plan is inconsistent with the jurisdiction's "long-held" redistricting standards, instead of the jurisdiction's "stated standards." The commenter believes that by adding the term "long-held," jurisdictions will be discouraged from adopting ad hoc redistricting principles to insulate a redistricting plan during section 5 review. The current factors, particularly with regards to discriminatory purpose, encapsulate scenarios where a jurisdiction adopts pretextual or unusual redistricting criteria. The Procedures should not be interpreted to discourage jurisdictions from considering traditional redistricting principles such as one-person, one-vote, or maintaining natural political or geographic boundaries, even if they have not done so in the past. *Bush* v. *Vera,* 517 U.S. 952, 980–81 (1996). Therefore, we decline to revise these factors further.

Section 51.59(b) Discriminatory Purpose

Several commenters suggested this paragraph be revised in the interest of clarity. After reviewing the language, we agreed that it did not clearly reflect the relevant case law on this point and that some clarification would be helpful. We revised the paragraph accordingly.

Additional Provisions

One commenter suggested the addition of several provisions related to the substantive standards to be employed during the review of redistricting plans. The proposed revisions go beyond the scope of these Procedures.

Administrative Procedure Act

This rule amends interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice and therefore the notice requirement of 5 U.S.C. 553(b) is not mandatory. Although notice and comment was not required, we nonetheless chose to offer the proposed rule for notice and comment.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities because it applies only to governmental entities and jurisdictions that are already required by section 5 of the Voting Rights Act of 1965 to submit voting changes to the Department of Justice, and this rule does not change this requirement. It provides guidance to such entities to assist them in making the required submissions under section 5. Further, a Regulatory Flexibility Analysis was not required to be prepared for this rule because the Department of Justice was not required to publish a general notice of proposed rulemaking for this matter.

Executive Order 12866

This rule has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review," section 1(b), Principles of Regulation. The Department of Justice has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget. The amendments made by this rule clarify the scope of section 5 review based on recent amendments to section 5, make certain technical clarifications and updates, and provide better guidance to covered jurisdictions and citizens. In many instances, the amendments describe longstanding practices of the Attorney General in his review of section 5 submissions.

Executive Order 13132—Federalism

This rule does not have federalism implications warranting the preparation of a Federalism Assessment under section 6 of Executive Order 13132 because the rule does not alter or modify the existing statutory requirements of section 5 of the Voting Rights Act imposed on the States, including units of local government or political subdivisions of the States.

Executive Order 12988—Civil Justice Reform

This document meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 28 CFR Parts 0 and 51

Administrative practice and procedure, Archives and records, Authority delegations (government agencies), Civil rights, Elections, Political committees and parties, Voting rights.

Accordingly, by virtue of the authority vested in me as Attorney General, including 5 U.S.C. 301, 28 U.S.C. 509, 510, and 42 U.S.C. 1973b, 1973c, the following amendments are made to Chapter I of Title 28 of the Code of Federal Regulations:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for Part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510.

Subpart J—Civil Rights Division

■ 2. In § 0.50, revise paragraph (h) to read as follows:

§ 0.50 General functions.

* * * * *

(h) Administration of sections 3(c) and 5 of the Voting Rights Act of 1965, as amended (42 U.S.C. 1973a(c), 1973c).

* * * * *

PART 51—PROCEDURES FOR THE ADMINISTRATION OF SECTION 5 OF THE VOTING RIGHTS ACT OF 1965.

■ 3. The authority citation for Part 51 is revised to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, and 42 U.S.C. 1973b, 1973c.

■ 4. In § 51.1, revise paragraph (a)(1) to read as follows:

§ 51.1 Purpose.

(a) * * *

(1) A declaratory judgment is obtained from the U.S. District Court for the District of Columbia that such qualification, prerequisite, standard, practice, or procedure neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group, or

* * * * *

■ 5. In § 51.2, revise the definition for "Act"; remove the definition of "Change affecting voting"; and add a new definition of "Change affecting voting or change" in alphabetical order to read as follows:

§ 51.2 Definitions.

* * * * *

Act means the Voting Rights Act of 1965, 79 Stat. 437, as amended by the Civil Rights Act of 1968, 82 Stat. 73, the Voting Rights Act Amendments of 1970, 84 Stat. 314, the District of Columbia Delegate Act, 84 Stat. 853, the Voting Rights Act Amendments of 1975, 89 Stat. 400, the Voting Rights Act Amendments of 1982, 96 Stat. 131, the Voting Rights Language Assistance Act of 1992, 106 Stat. 921, the Fannie Lou Hamer, Rosa Parks, and Coretta Scott King Voting Rights Act Reauthorization and Amendments Act of 2006, 120 Stat. 577, and the Act to Revise the Short Title of the Fannie Lou Hamer, Rosa Parks, and Coretta Scott King Voting Rights Act Reauthorization and Amendments Act of 2006, 122 Stat. 2428, 42 U.S.C. 1973 *et seq.* Section numbers, such as "section 14(c)(3)," refer to sections of the Act.

* * * * *

Change affecting voting or *change* means any voting qualification, prerequisite to voting, or standard, practice, or procedure with respect to voting different from that in force or effect on the date used to determine coverage under section 4(b) or from the existing standard, practice, or procedure if it was subsequently altered and precleared under section 5. In assessing whether a change has a discriminatory purpose or effect, the comparison shall be with the standard, practice, or procedure in effect on the date used to determine coverage under section 4(b) or the most recent precleared standard, practice, or procedure. Some examples of changes affecting voting are given in § 51.13.

* * * * *

■ 6. Revise § 51.3 to read as follows:

§ 51.3 Delegation of authority.

The responsibility and authority for determinations under section 5 and section 3(c) have been delegated by the Attorney General to the Assistant Attorney General, Civil Rights Division. With the exception of objections and decisions following the reconsideration of objections, the Chief of the Voting Section is authorized to perform the functions of the Assistant Attorney General. With the concurrence of the Assistant Attorney General, the Chief of the Voting Section may designate supervisory attorneys in the Voting Section to perform the functions of the Chief.

■ 7. Revise § 51.5 to read as follows:

§ 51.5 Termination of coverage.

(a) *Expiration.* The requirements of section 5 will expire at the end of the twenty-five-year period following the effective date of the amendments made by the Fannie Lou Hamer, Rosa Parks, Coretta Scott King, César E. Chávez, Barbara C. Jordan, William C. Velásquez, and Dr. Hector P. Garcia Voting Rights Act Reauthorization and Amendments Act of 2006 (VRARA), which amendments became effective on July 27, 2006. *See* section 4(a)(8) of the VRARA.

(b) *Bailout.* Any political subunit in a covered jurisdiction or a political subdivision of a covered State, a covered jurisdiction or a political subdivision of a covered State, or a covered State may terminate the application of section 5 ("bailout") by obtaining the declaratory judgment described in section 4(a) of the Act.

■ 8. Revise § 51.6 to read as follows:

§ 51.6 Political subunits.

All political subunits within a covered jurisdiction (*e.g.,* counties, cities, school districts) that have not terminated coverage by obtaining the declaratory judgment described in section 4(a) of the Act are subject to the requirements of section 5.

■ 9. Revise § 51.9 to read as follows:

§ 51.9 Computation of time.

(a) The Attorney General shall have 60 days in which to interpose an objection to a submitted change affecting voting for which a response on the merits is appropriate (*see* § 51.35, § 51.37).

(b) The 60-day period shall commence upon receipt of a submission by the Voting Section of the Department of Justice's Civil Rights Division or upon receipt of a submission by the Office of the Assistant Attorney General, Civil Rights Division, if the submission is properly marked as specified in § 51.24(f). The 60-day period shall recommence upon the receipt in like manner of a resubmission (*see* § 51.35), information provided in response to a written request for additional information (*see* § 51.37(b)), or material, supplemental information or a related submission (*see* § 51.39).

(c) The 60-day period shall mean 60 calendar days, with the day of receipt of the submission not counted, and with the 60th day ending at 11:59 p.m. Eastern Time of that day. If the final day of the period should fall on a Saturday, Sunday, or any day designated as a holiday by the President or Congress of the United States, or any other day that is not a day of regular business for the Department of Justice, the next full business day shall be counted as the final day of the 60-day period. The date of the Attorney General's response shall be the date on which it is transmitted to the submitting authority by any reasonable means, including placing it in a postbox of the U.S. Postal Service or a private mail carrier, sending it by telefacsimile, email, or other electronic means, or delivering it in person to a representative of the submitting authority.

■ 10. In § 51.10, revise paragraph (a) to read as follows:

§ 51.10 Requirement of action for declaratory judgment or submission to the Attorney General.

* * * * *

(a) Obtain a judicial determination from the U.S. District Court for the District of Columbia that the voting change neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group.

* * * * *

■ 11. Revise § 51.11 to read as follows:

§ 51.11 Right to bring suit.

Submission to the Attorney General does not affect the right of the

submitting authority to bring an action in the U.S. District Court for the District of Columbia for a declaratory judgment that the change affecting voting neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group.

■ 12. Revise § 51.12 to read as follows:

§ 51.12 Scope of requirement.

Except as provided in § 51.18 (Federal court-ordered changes), the section 5 requirement applies to any change affecting voting, even though it appears to be minor or indirect, returns to a prior practice or procedure, seemingly expands voting rights, or is designed to remove the elements that caused the Attorney General to object to a prior submitted change. The scope of section 5 coverage is based on whether the generic category of changes affecting voting to which the change belongs (for example, the generic categories of changes listed in § 51.13) has the potential for discrimination. *NAACP* v. *Hampton County Election Commission,* 470 U.S. 166 (1985). The method by which a jurisdiction enacts or administers a change does not affect the requirement to comply with section 5, which applies to changes enacted or administered through the executive, legislative, or judicial branches.

■ 13. In § 51.13, revise paragraphs (e), (i), and (k) and add paragraph (l) to read as follows:

§ 51.13 Examples of changes.

* * * * *

(e) Any change in the constituency of an official or the boundaries of a voting unit (*e.g.,* through redistricting, annexation, deannexation, incorporation, dissolution, merger, reapportionment, changing to at-large elections from district elections, or changing to district elections from at-large elections).

* * * * *

(i) Any change in the term of an elective office or an elected official, or any change in the offices that are elective (*e.g.,* by shortening or extending the term of an office; changing from election to appointment; transferring authority from an elected to an appointed official that, in law or in fact, eliminates the elected official's office; or staggering the terms of offices).

* * * * *

(k) Any change affecting the right or ability of persons to participate in pre-election activities, such as political campaigns.

(l) Any change that transfers or alters the authority of any official or governmental entity regarding who may enact or seek to implement a voting qualification, prerequisite to voting, or standard, practice, or procedure with respect to voting.

■ 14. Revise § 51.18 to read as follows:

§ 51.18 Federal court-ordered changes.

(a) *In general.* Changes affecting voting for which approval by a Federal court is required, or that are ordered by a Federal court, are exempt from section 5 review only where the Federal court prepared the change and the change has not been subsequently adopted or modified by the relevant governmental body. *McDaniel* v. *Sanchez,* 452 U.S. 130 (1981). (*See also* § 51.22.)

(b) *Subsequent changes.* Where a Federal court-ordered change is not itself subject to the preclearance requirement, subsequent changes necessitated by the court order but decided upon by the jurisdiction remain subject to preclearance. For example, voting precinct and polling changes made necessary by a court-ordered redistricting plan are subject to section 5 review.

(c) *Alteration in section 5 status.* Where a Federal court-ordered change at its inception is not subject to review under section 5, a subsequent action by the submitting authority demonstrating that the change reflects its policy choices (*e.g.,* adoption or ratification of the change, or implementation in a manner not explicitly authorized by the court) will render the change subject to review under section 5 with regard to any future implementation.

(d) *In emergencies.* A Federal court's authorization of the emergency interim use without preclearance of a voting change does not exempt from section 5 review any use of that practice not explicitly authorized by the court.

■ 15. Revise § 51.19 to read as follows:

§ 51.19 Request for notification concerning voting litigation.

A jurisdiction subject to the preclearance requirements of section 5 that becomes involved in any litigation concerning voting is requested to notify the Chief, Voting Section, Civil Rights Division, at the addresses, telefacsimile number, or email address specified in § 51.24. Such notification will not be considered a submission under section 5.

■ 16. In § 51.20, revise paragraphs (b) through (e) and add a new paragraph (f) to read as follows:

§ 51.20 Form of submissions.

* * * * *

(b) The Attorney General will accept certain machine readable data in the following electronic media: 3.5 inch 1.4 megabyte disk, compact disc read-only memory (CD–ROM) formatted to the ISO–9660/Joliet standard, or digital versatile disc read-only memory (DVD–ROM). Unless requested by the Attorney General, data provided on electronic media need not be provided in hard copy.

(c) All electronic media shall be clearly labeled with the following information:

(1) Submitting authority.

(2) Name, address, title, and telephone number of contact person.

(3) Date of submission cover letter.

(4) Statement identifying the voting change(s) involved in the submission.

(d) Each magnetic medium (floppy disk or tape) provided must be accompanied by a printed description of its contents, including an identification by name or location of each data file contained on the medium, a detailed record layout for each such file, a record count for each such file, and a full description of the magnetic medium format.

(e) Text documents should be provided in a standard American Standard Code for Information Interchange (ASCII) character code; documents with graphics and complex formatting should be provided in standard Portable Document Format (PDF). The label shall be affixed to each electronic medium, and the information included on the label shall also be contained in a documentation file on the electronic medium.

(f) All data files shall be provided in a delimited text file and must include a header row as the first row with a name for each field in the data set. A separate data dictionary file documenting the fields in the data set, the field separators or delimiters, and a description of each field, including whether the field is text, date, or numeric, enumerating all possible values is required; separators and delimiters should not also be used as data in the data set. Proprietary or commercial software system data files (*e.g.,* SAS, SPSS, dBase, Lotus 1–2–3) and data files containing compressed data or binary data fields will not be accepted.

■ 17. Revise § 51.21 to read as follows:

§ 51.21 Time of submissions.

Changes affecting voting should be submitted as soon as possible after they become final, except as provided in § 51.22.

■ 18. Revise § 51.22 to read as follows:

§ 51.22 Submitted changes that will not be reviewed.

(a) The Attorney General will not consider on the merits:

(1) Any proposal for a change submitted prior to final enactment or administrative decision except as provided in paragraph (b) of this section.

(2) Any submitted change directly related to another change that has not received section 5 preclearance if the Attorney General determines that the two changes cannot be substantively considered independently of one another.

(3) Any submitted change whose enforcement has ceased and been superseded by a standard, practice, or procedure that has received section 5 preclearance or that is otherwise legally enforceable under section 5.

(b) For any change requiring approval by referendum, by a State or Federal court, or by a Federal agency, the Attorney General may make a determination concerning the change prior to such approval if the change is not subject to alteration in the final approving action and if all other action necessary for approval has been taken. (*See also* § 51.18.)

■ 19. Revise § 51.23 to read as follows:

§ 51.23 Party and jurisdiction responsible for making submissions.

(a) Changes affecting voting shall be submitted by the chief legal officer or other appropriate official of the submitting authority or by any other authorized person on behalf of the submitting authority. A State, whether partially or fully covered, has authority to submit any voting change on behalf of its covered jurisdictions and political subunits. Where a State is covered as a whole, State legislation or other changes undertaken or required by the State shall be submitted by the State (except that legislation of local applicability may be submitted by political subunits). Where a State is partially covered, changes of statewide application may be submitted by the State. Submissions from the State, rather than from the individual covered jurisdictions, would serve the State's interest in at least two important respects: first, the State is better able to explain to the Attorney General the purpose and effect of voting changes it enacts than are the individual covered jurisdictions; second, a single submission of the voting change on behalf of all of the covered jurisdictions would reduce the possibility that some State acts will be legally enforceable in some parts of the State but not in others.

(b) A change effected by a political party (*see* § 51.7) may be submitted by an appropriate official of the political party.

(c) A change affecting voting that results from a State court order should be submitted by the jurisdiction or entity that is to implement or administer the change (in the manner specified by paragraphs (a) and (b) of this section).

■ 20. Revise § 51.24 to read as follows:

§ 51.24 Delivery of submissions.

(a) *Delivery by U.S. Postal Service.* Submissions sent to the Attorney General by the U.S. Postal Service, including certified mail or express mail, shall be addressed to the Chief, Voting Section, Civil Rights Division, United States Department of Justice, Room 7254–NWB, 950 Pennsylvania Avenue, NW, Washington, DC 20530.

(b) *Delivery by other carriers.* Submissions sent to the Attorney General by carriers other than the U.S. Postal Service, including by hand delivery, should be addressed or may be delivered to the Chief, Voting Section, Civil Rights Division, United States Department of Justice, Room 7254–NWB, 1800 G Street, NW, Washington, DC 20006.

(c) *Electronic submissions.* Submissions may be delivered to the Attorney General through an electronic form available on the website of the Voting Section of the Civil Rights Division at www.justice.gov/crt/voting/. Detailed instructions appear on the website. Jurisdictions should answer the questions appearing on the electronic form, and should attach documents as specified in the instructions accompanying the application.

(d) *Telefacsimile submissions.* In urgent circumstances, submissions may be delivered to the Attorney General by telefacsimile to (202) 616–9514. Submissions should not be sent to any other telefacsimile number at the Department of Justice. Submissions that are voluminous should not be sent by telefacsimile.

(e) *Email.* Submissions may not be delivered to the Attorney General by email in the first instance. However, after a submission is received by the Attorney General, a jurisdiction may supply additional information on that submission by email to vot1973c@usdoj.gov. The subject line of the email shall be identified with the Attorney General's file number for the submission (YYYY–NNNN), marked as "Additional Information," and include the name of the jurisdiction.

(f) *Special marking.* The first page of the submission, and the envelope (if any), shall be clearly marked: "Submission under Section 5 of the Voting Rights Act."

(g) The most current information on addresses for, and methods of making, section 5 submissions is available on the Voting Section website at *www.justice.gov/crt/voting/.*

■ 21. In § 51.25, revise paragraph (a) to read as follows:

§ 51.25 Withdrawal of submissions.

(a) A jurisdiction may withdraw a submission at any time prior to a final decision by the Attorney General. Notice of the withdrawal of a submission must be made in writing addressed to the Chief, Voting Section, Civil Rights Division, to be delivered at the addresses, telefacsimile number, or email address specified in § 51.24. The submission shall be deemed withdrawn upon the Attorney General's receipt of the notice.

* * * * *

■ 22. In § 51.27, revise paragraphs (a) through (d) to read as follows:

§ 51.27 Required contents.

* * * * *

(a) A copy of any ordinance, enactment, order, or regulation embodying the change affecting voting for which section 5 preclearance is being requested.

(b) A copy of any ordinance, enactment, order, or regulation embodying the voting standard, practice, or procedure that is proposed to be repealed, amended, or otherwise changed.

(c) A statement that identifies with specificity each change affecting voting for which section 5 preclearance is being requested and that explains the difference between the submitted change and the prior law or practice. If the submitted change is a special referendum election and the subject of the referendum is a proposed change affecting voting, the submission should specify whether preclearance is being requested solely for the special election or for both the special election and the proposed change to be voted on in the referendum (*see* §§ 51.16, 51.22).

(d) The name, title, mailing address, and telephone number of the person making the submission. Where available, a telefacsimile number and an email address for the person making the submission also should be provided.

* * * * *

■ 23. In § 51.28, revise paragraph (a)(5), add (a)(6), and revise paragraph (c) to read as follows:

§ 51.28 Supplemental contents.

* * * * *

(a) * * *

(5) Demographic data on electronic media that are provided in conjunction

with a redistricting plan shall be contained in an ASCII, comma delimited block equivalency import file with two fields as detailed in the following table. A separate import file shall accompany each redistricting plan:

Field No.	Description	Total length	Comments
1	PL94–171 reference number: GEOID10	15	
2	District Number	3	No leading zeroes.

(i) *Field 1:* The PL 94–171/GEOID10 reference number is the state, county, tract, and block reference numbers concatenated together and padded with leading zeroes so as to create a 15-digit character field; and

(ii) *Field 2:* The district number is a 3 digit character field with no padded leading zeroes.

Example: 482979501002099,1 482979501002100,3 482979501004301,10 482975010004305,23 482975010004302,101

(6) Demographic data on magnetic media that are provided in conjunction with a redistricting can be provided in shapefile (.shp) spatial data format.

(i) The shapefile shall include at a minimum the main file, index file, and dBASE table.

(ii) The dBASE table shall contain a row for each census block. Each census block will be identified by the state, county, tract and block identifier [GEOID10] as specified by the Bureau of Census. Each row shall identify the district assignment and relevant population for that specific row.

(iii) The shapefile should include a projection file (.prj).

(iv) The shapefile should be sent in NAD 83 geographic projection. If another projection is used, it should be described fully.

* * * * *

(c) *Annexations.* For annexations, in addition to that information specified elsewhere, the following information:

(1) The present and expected future use of the annexed land (*e.g.,* garden apartments, industrial park).

(2) An estimate of the expected population, by race and language group, when anticipated development, if any, is completed.

(3) A statement that all prior annexations (and deannexations) subject to the preclearance requirement have been submitted for review, or a statement that identifies all annexations (and deannexations) subject to the preclearance requirement that have not been submitted for review. *See* § 51.61(b).

(4) To the extent that the jurisdiction elects some or all members of its governing body from single-member districts, it should inform the Attorney General how the newly annexed territory will be incorporated into the existing election districts.

* * * * *

■ 24. In § 51.29, revise paragraphs (b) and (d) to read as follows:

§ 51.29 Communications concerning voting changes.

* * * * *

(b) Comments should be sent to the Chief, Voting Section, Civil Rights Division, at the addresses, telefacsimile number, or email address specified in § 51.24. The first page and the envelope (if any) should be marked: "Comment under section 5 of the Voting Rights Act." Comments should include, where available, the name of the jurisdiction and the Attorney General's file number (YYYY–NNNN) in the subject line.

* * * * *

(d) To the extent permitted by the Freedom of Information Act, 5 U.S.C. 552, the Attorney General shall not disclose to any person outside the Department of Justice the identity of any individual or entity providing information on a submission or the administration of section 5 where the individual or entity has requested confidentiality; an assurance of confidentiality may reasonably be implied from the circumstances of the communication; disclosure could reasonably be expected to constitute an unwarranted invasion of personal privacy under 5 U.S.C. 552; or disclosure is prohibited by any applicable provisions of federal law.

* * * * *

■ 25. Revise § 51.35 to read as follows:

§ 51.35 Disposition of inappropriate submissions and resubmissions.

(a) When the Attorney General determines that a response on the merits of a submitted change is inappropriate, the Attorney General shall notify the submitting official in writing within the 60-day period that would have commenced for a determination on the merits and shall include an explanation of the reason why a response is not appropriate.

(b) Matters that are not appropriate for a merits response include:

(1) Changes that do not affect voting (*see* § 51.13);

(2) Standards, practices, or procedures that have not been changed (*see* §§ 51.4, 51.14);

(3) Changes that previously have received preclearance;

(4) Changes that affect voting but are not subject to the requirement of section 5 (*see* § 51.18);

(5) Changes that have been superseded or for which a determination is premature (*see* §§ 51.22, 51.61(b));

(6) Submissions by jurisdictions not subject to the preclearance requirement (*see* §§ 51.4, 51.5);

(7) Submissions by an inappropriate or unauthorized party or jurisdiction (*see* § 51.23); and

(8) Deficient submissions (*see* § 51.26(d)).

(c) Following such a notification by the Attorney General, a change shall be deemed resubmitted for section 5 review upon the Attorney General's receipt of a submission or other written information that renders the change appropriate for review on the merits (such as a notification from the submitting authority that a change previously determined to be premature has been formally adopted). Notice of the resubmission of a change affecting voting will be given to interested parties registered under § 51.32.

■ 26. Revise § 51.37 to read as follows:

§ 51.37 Obtaining information from the submitting authority.

(a) *Oral requests for information.* (1) If a submission does not satisfy the requirements of § 51.27, the Attorney General may request orally any omitted information necessary for the evaluation of the submission. An oral request may be made at any time within the 60-day period, and the submitting authority should provide the requested information as promptly as possible. The oral request for information shall not suspend the running of the 60-day period, and the Attorney General will proceed to make a determination within the initial 60-day period. The Attorney General reserves the right as set forth in § 51.39, however, to commence a new 60-day period in which to make the requisite determination if the written information provided in response to such request materially supplements the submission.

(2) An oral request for information shall not limit the authority of the Attorney General to make a written request for information.

(3) The Attorney General will notify the submitting authority in writing when the 60-day period for a submission is recalculated from the Attorney General's receipt of written information provided in response to an oral request as described in § 51.37(a)(1), above.

(4) Notice of the Attorney General's receipt of written information pursuant to an oral request will be given to interested parties registered under § 51.32.

(b) *Written requests for information.* (1) If the Attorney General determines that a submission does not satisfy the requirements of § 51.27, the Attorney General may request in writing from the submitting authority any omitted information necessary for evaluation of the submission. *Branch* v. *Smith,* 538 U.S. 254 (2003); *Georgia* v. *United States,* 411 U.S. 526 (1973). This written request shall be made as promptly as possible within the original 60-day period or the new 60-day period described in § 51.39(a). The written request shall advise the jurisdiction that the submitted change remains unenforceable unless and until preclearance is obtained.

(2) A copy of the request shall be sent to any party who has commented on the submission or has requested notice of the Attorney General's action thereon.

(3) The Attorney General shall notify the submitting authority that a new 60-day period in which the Attorney General may interpose an objection shall commence upon the Attorney General's receipt of a response from the submitting authority that provides the information requested or states that the information is unavailable. The Attorney General can request further information in writing within the new 60-day period, but such a further request shall not suspend the running of the 60-day period, nor shall the Attorney General's receipt of such further information begin a new 60-day period.

(4) Where the response from the submitting authority neither provides the information requested nor states that such information is unavailable, the response shall not commence a new 60-day period. It is the practice of the Attorney General to notify the submitting authority that its response is incomplete and to provide such notification as soon as possible within the 60-day period that would have commenced had the response been complete. Where the response includes a portion of the available information that was requested, the Attorney General will reevaluate the submission to ascertain whether a determination on the merits may be made based upon the information provided. If a merits determination is appropriate, it is the practice of the Attorney General to make that determination within the new 60-day period that would have commenced had the response been complete. *See* § 51.40.

(5) If, after a request for further information is made pursuant to this section, the information requested by the Attorney General becomes available to the Attorney General from a source other than the submitting authority, the Attorney General shall promptly notify the submitting authority in writing, and the new 60-day period will commence the day after the information is received by the Attorney General.

(6) Notice of the written request for further information and the receipt of a response by the Attorney General will be given to interested parties registered under § 51.32.

■ 27. Revise § 51.39 to read as follows:

§ 51.39 Supplemental information and related submissions.

(a)(1) *Supplemental information.* When a submitting authority, at its own instance, provides information during the 60-day period that the Attorney General determines materially supplements a pending submission, the 60-day period for the pending submission will be recalculated from the Attorney General's receipt of the supplemental information.

(2) *Related submissions.* When the Attorney General receives related submissions during the 60-day period for a submission that cannot be independently considered, the 60-day period for the first submission shall be recalculated from the Attorney General's receipt of the last related submission.

(b) The Attorney General will notify the submitting authority in writing when the 60-day period for a submission is recalculated due to the Attorney General's receipt of supplemental information or a related submission.

(c) Notice of the Attorney General's receipt of supplemental information or a related submission will be given to interested parties registered under § 51.32.

■ 28. Revise § 51.40 to read as follows:

§ 51.40 Failure to complete submissions.

If after 60 days the submitting authority has not provided further information in response to a request made pursuant to § 51.37(b), the Attorney General, absent extenuating circumstances and consistent with the burden of proof under section 5 described in § 51.52(a) and (c), may object to the change, giving notice as specified in § 51.44.

■ 29. Revise § 51.42 to read as follows:

§ 51.42 Failure of the Attorney General to respond.

It is the practice and intention of the Attorney General to respond in writing to each submission within the 60-day period. However, the failure of the Attorney General to make a written response within the 60-day period constitutes preclearance of the submitted change, provided that a 60-day review period had commenced after receipt by the Attorney General of a complete submission that is appropriate for a response on the merits. (*See* § 51.22, § 51.27, § 51.35.)

■ 30. Revise § 51.43 to read as follows:

§ 51.43 Reexamination of decision not to object.

(a) After notification to the submitting authority of a decision not to interpose an objection to a submitted change affecting voting has been given, the Attorney General may reexamine the submission if, prior to the expiration of the 60-day period, information comes to the attention of the Attorney General that would otherwise require objection in accordance with section 5.

(b) In such circumstances, the Attorney General may by letter withdraw his decision not to interpose an objection and may by letter interpose an objection provisionally, in accordance with § 51.44, and advise the submitting authority that examination of the change in light of the newly raised issues will continue and that a final decision will be rendered as soon as possible.

■ 31. In § 51.44, revise paragraph (c) to read as follows:

§ 51.44 Notification of decision to object.

* * * * *

(c) The submitting authority shall be advised further that notwithstanding the objection it may institute an action in the U.S. District Court for the District of Columbia for a declaratory judgment that the change objected to by the Attorney General neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group.

* * * * *

■ 32. In § 51.46, revise paragraph (a) to read as follows:

§ 51.46 Reconsideration of objection at the instance of the Attorney General.

(a) Where there appears to have been a substantial change in operative fact or relevant law, or where it appears there may have been a misinterpretation of fact or mistake in the law, an objection may be reconsidered, if it is deemed appropriate, at the instance of the Attorney General.

* * * * *

■ 33. In § 51.48, revise paragraphs (a) through (d) to read as follows:

§ 51.48 Decision after reconsideration.

(a) It is the practice of the Attorney General to notify the submitting authority of the decision to continue or withdraw an objection within a 60-day period following receipt of a reconsideration request or following notice given under § 51.46(b), except that this 60-day period shall be recommenced upon receipt of any documents or written information from the submitting authority that materially supplements the reconsideration review, irrespective of whether the submitting authority provides the documents or information at its own instance or pursuant to a request (written or oral) by the Attorney General. The 60-day reconsideration period may be extended to allow a 15-day decision period following a conference held pursuant to § 51.47. The 60-day reconsideration period shall be computed in the manner specified in § 51.9. Where the reconsideration is at the instance of the Attorney General, the first day of the period shall be the day after the notice required by § 51.46(b) is transmitted to the submitting authority. The reasons for the reconsideration decision shall be stated.

(b) The objection shall be withdrawn if the Attorney General is satisfied that the change neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group.

(c) If the objection is not withdrawn, the submitting authority shall be advised that notwithstanding the objection it may institute an action in the U.S. District Court for the District of Columbia for a declaratory judgment that the change objected to by the Attorney General neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group.

(d) An objection remains in effect until either it is specifically withdrawn by the Attorney General or a declaratory judgment with respect to the change in question is entered by the U.S. District Court for the District of Columbia.

* * * * *

■ 34. Revise § 51.50 to read as follows:

§ 51.50 Records concerning submissions.

(a) *Section 5 files.* The Attorney General shall maintain a section 5 file for each submission, containing the submission, related written materials, correspondence, memoranda, investigative reports, data provided on electronic media, notations concerning conferences with the submitting authority or any interested individual or group, and copies of letters from the Attorney General concerning the submission.

(b) *Objection letters.* The Attorney General shall maintain section 5 notification letters regarding decisions to interpose, continue, or withdraw an objection.

(c) *Computer file.* Records of all submissions and their dispositions by the Attorney General shall be electronically stored.

(d) *Copies.* The contents of the section 5 submission files in paper, microfiche, electronic, or other form shall be available for obtaining copies by the public, pursuant to written request directed to the Chief, Voting Section, Civil Rights Division, United States Department of Justice, Washington, DC. Such written request may be delivered to the addresses or telefacsimile number specified in § 51.24 or by electronic mail to *Voting.Section@usdoj.gov.* It is the Attorney General's intent and practice to expedite, to the extent possible, requests pertaining to pending submissions. Those who desire copies of information that has been provided on electronic media will be provided a copy of that information in the same form as it was received. Materials that are exempt from inspection under the Freedom of Information Act, 5 U.S.C. 552(b), may be withheld at the discretion of the Attorney General. The identity of any individual or entity that provided information to the Attorney General regarding the administration of section 5 shall be available only as provided by § 51.29(d). Applicable fees, if any, for the copying of the contents of these files are contained in the Department of Justice regulations implementing the Freedom of Information Act, 28 CFR 16.10.

■ 35. Revise § 51.52 to read as follows:

§ 51.52 Basic standard.

(a) *Surrogate for the court.* Section 5 provides for submission of a voting change to the Attorney General as an alternative to the seeking of a declaratory judgment from the U.S. District Court for the District of Columbia. Therefore, the Attorney General shall make the same determination that would be made by the court in an action for a declaratory judgment under section 5: whether the submitted change neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group. The burden of proof is on a submitting authority when it submits a change to the Attorney General for preclearance, as it would be if the proposed change were the subject of a declaratory judgment action in the U.S. District Court for the District of Columbia. *South Carolina* v. *Katzenbach,* 383 U.S. 301, 328, 335 (1966).

(b) *No objection.* If the Attorney General determines that the submitted change neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group, no objection shall be interposed to the change.

(c) *Objection.* An objection shall be interposed to a submitted change if the Attorney General is unable to determine that the change neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group. This includes those situations where the evidence as to the purpose or effect of the change is conflicting and the Attorney General is unable to determine that the change is free of both the prohibited discriminatory purpose and effect.

■ 36. Revise § 51.54 to read as follows:

§ 51.54 Discriminatory purpose and effect.

(a) *Discriminatory purpose.* A change affecting voting is considered to have a discriminatory purpose under section 5 if it is enacted or sought to be administered with any purpose of denying or abridging the right to vote on account of race, color, or membership in a language minority group. The term "purpose" in section 5 includes any discriminatory purpose. 42 U.S.C. 1973c. The Attorney General's evaluation of discriminatory purpose under section 5 is guided by the analysis in *Village of Arlington Heights* v. *Metropolitan Housing Development Corp.,* 429 U.S. 252 (1977).

(b) *Discriminatory effect.* A change affecting voting is considered to have a discriminatory effect under section 5 if it will lead to a retrogression in the position of members of a racial or language minority group (*i.e.,* will make members of such a group worse off than

they had been before the change) with respect to their effective exercise of the electoral franchise. *Beer* v. *United States,* 425 U.S. 130, 140–42 (1976).

(c) *Benchmark.* (1) In determining whether a submitted change is retrogressive the Attorney General will normally compare the submitted change to the voting standard, practice, or procedure in force or effect at the time of the submission. If the existing standard, practice, or procedure upon submission was not in effect on the jurisdiction's applicable date for coverage (specified in the Appendix) and is not otherwise legally enforceable under section 5, it cannot serve as a benchmark, and, except as provided in paragraph (c)(4) of this section, the comparison shall be with the last legally enforceable standard, practice, or procedure used by the jurisdiction.

(2) The Attorney General will make the comparison based on the conditions existing at the time of the submission.

(3) The implementation and use of an unprecleared voting change subject to section 5 review does not operate to make that unprecleared change a benchmark for any subsequent change submitted by the jurisdiction.

(4) Where at the time of submission of a change for section 5 review there exists no other lawful standard, practice, or procedure for use as a benchmark (*e.g.,* where a newly incorporated college district selects a method of election) the Attorney General's determination will necessarily center on whether the submitted change was designed or adopted for the purpose of discriminating against members of racial or language minority groups.

(d) *Protection of the ability to elect.* Any change affecting voting that has the purpose of or will have the effect of diminishing the ability of any citizens of the United States on account of race, color, or membership in a language minority group to elect their preferred candidates of choice denies or abridges the right to vote within the meaning of section 5. 42 U.S.C. 1973c.

■ 37. In § 51.55, revise paragraph (a) to read as follows:

§ 51.55 Consistency with constitutional and statutory requirements.

(a) *Consideration in general.* In making a determination under section 5, the Attorney General will consider whether the change neither has the purpose nor will have the effect of denying or abridging the right to vote on account of race, color, or membership in a language minority group in light of, and with particular attention being given to, the requirements of the 14th, 15th, and 24th Amendments to the Constitution, 42 U.S.C. 1971(a) and (b), sections 2, 4(a), 4(f)(2), 4(f)(4), 201, 203(c), and 208 of the Act, and other constitutional and statutory provisions designed to safeguard the right to vote from denial or abridgment on account of race, color, or membership in a language minority group.

* * * * *

■ 38. Revise § 51.57 to read as follows:

§ 51.57 Relevant factors.

Among the factors the Attorney General will consider in making determinations with respect to the submitted changes affecting voting are the following:

(a) The extent to which a reasonable and legitimate justification for the change exists;

(b) The extent to which the jurisdiction followed objective guidelines and fair and conventional procedures in adopting the change;

(c) The extent to which the jurisdiction afforded members of racial and language minority groups an opportunity to participate in the decision to make the change;

(d) The extent to which the jurisdiction took the concerns of members of racial and language minority groups into account in making the change; and

(e) The factors set forth in *Village of Arlington Heights* v. *Metropolitan Housing Development Corp.,* 429 U.S. 252 (1977):

(1) Whether the impact of the official action bears more heavily on one race than another;

(2) The historical background of the decision;

(3) The specific sequence of events leading up to the decision;

(4) Whether there are departures from the normal procedural sequence;

(5) Whether there are substantive departures from the normal factors considered; and

(6) The legislative or administrative history, including contemporaneous statements made by the decision makers.

■ 39. In § 51.58, revise paragraph (b) to read as follows:

§ 51.58 Representation.

* * * * *

(b) *Background factors.* In making determinations with respect to these changes involving voting practices and procedures, the Attorney General will consider as important background information the following factors:

(1) The extent to which minorities have been denied an equal opportunity to participate meaningfully in the political process in the jurisdiction.

(2) The extent to which voting in the jurisdiction is racially polarized and election-related activities are racially segregated.

(3) The extent to which the voter registration and election participation of minority voters have been adversely affected by present or past discrimination.

■ 40. Revise § 51.59 to read as follows:

§ 51.59 Redistricting plans.

(a) *Relevant factors.* In determining whether a submitted redistricting plan has a prohibited purpose or effect the Attorney General, in addition to the factors described above, will consider the following factors (among others):

(1) The extent to which malapportioned districts deny or abridge the right to vote of minority citizens;

(2) The extent to which minority voting strength is reduced by the proposed redistricting;

(3) The extent to which minority concentrations are fragmented among different districts;

(4) The extent to which minorities are over concentrated in one or more districts;

(5) The extent to which available alternative plans satisfying the jurisdiction's legitimate governmental interests were considered;

(6) The extent to which the plan departs from objective redistricting criteria set by the submitting jurisdiction, ignores other relevant factors such as compactness and contiguity, or displays a configuration that inexplicably disregards available natural or artificial boundaries; and

(7) The extent to which the plan is inconsistent with the jurisdiction's stated redistricting standards.

(b) *Discriminatory purpose.* A jurisdiction's failure to adopt the maximum possible number of majority-minority districts may not be the sole basis for determining that a jurisdiction was motivated by a discriminatory purpose.

■ 41. In § 51.61, revise paragraphs (a) and (b) to read as follows:

§ 51.61 Annexations and deannexations.

(a) *Coverage.* Annexations and deannexations, even of uninhabited land, are subject to section 5 preclearance to the extent that they alter or are calculated to alter the composition of a jurisdiction's electorate. *See, e.g., City of Pleasant Grove* v. *United States,* 479 U.S. 462 (1987). In analyzing annexations and deannexations under section 5, the Attorney General considers the purpose and effect of the annexations and

deannexations only as they pertain to voting.

(b) *Section 5 review.* It is the practice of the Attorney General to review all of a jurisdiction's unprecleared annexations and deannexations together. *See City of Pleasant Grove* v. *United States,* C.A. No. 80–2589 (D.D.C. Oct. 7, 1981).

* * * * *

■ 42. Revise the Appendix to Part 51 to read as follows:

Appendix to Part 51—Jurisdictions Covered Under Section 4(b) of the Voting Rights Act, as Amended

The requirements of section 5 of the Voting Rights Act, as amended, apply in the following jurisdictions. The applicable date is the date that was used to determine coverage and the date after which changes affecting voting are subject to the preclearance requirement. Some jurisdictions, for example, Yuba County, California, are included more than once because they have been determined on more than one occasion to be covered under section 4(b).

Jurisdiction	Applicable date	**Federal Register** citation	
		Volume and page	Date
Alabama	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Alaska	Nov. 1, 1972	40 FR 49422	Oct. 22, 1975.
Arizona	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
California:			
Kings County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Merced County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Monterey County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Yuba County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Yuba County	Nov. 1, 1972	41 FR 784	Jan. 5, 1976.
Florida:			
Collier County	Nov. 1, 1972	41 FR 34329	Aug. 13, 1976.
Hardee County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Hendry County	Nov. 1, 1972	41 FR 34329	Aug. 13, 1976.
Hillsborough County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Monroe County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Georgia	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Louisiana	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Michigan:			
Allegan County:			
Clyde Township	Nov. 1, 1972	41 FR 34329	Aug. 13, 1976.
Saginaw County:			
Buena Vista Township	Nov. 1, 1972	41 FR 34329	Aug. 13, 1976.
Mississippi	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
New Hampshire:			
Cheshire County:			
Rindge Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Coos County:			
Millsfield Township	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Pinkhams Grant	Nov. 1, 1968	39 FR 16912	May 10, 1974
Stewartstown Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Stratford Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Grafton County:			
Benton Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Hillsborough County:			
Antrim Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Merrimack County:			
Boscawen Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Rockingham County:			
Newington Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
Sullivan County:			
Unity Town	Nov. 1, 1968	39 FR 16912	May 10, 1974.
New York:			
Bronx County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Bronx County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Kings County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Kings County	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
New York County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
North Carolina:			
Anson County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Beaufort County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Bertie County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Bladen County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Camden County	Nov. 1, 1964	31 FR 3317	Mar. 2, 1966.
Caswell County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Chowan County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Cleveland County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Craven County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Cumberland County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Edgecombe County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Franklin County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.

Jurisdiction	Applicable date	Federal Register citation	
		Volume and page	Date
Gaston County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Gates County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Granville County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Greene County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Guilford County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Halifax County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Harnett County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Hertford County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Hoke County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Jackson County	Nov. 1, 1972	40 FR 49422	Oct. 22, 1975.
Lee County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Lenoir County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Martin County	Nov. 1, 1964	31 FR 19	Jan. 4, 1966.
Nash County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Northampton County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Onslow County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Pasquotank County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Perquimans County	Nov. 1, 1964	31 FR 3317	Mar. 2, 1966.
Person County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Pitt County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Robeson County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Rockingham County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Scotland County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Union County	Nov. 1, 1964	31 FR 5081	Mar. 29, 1966.
Vance County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Washington County	Nov. 1, 1964	31 FR 19	Jan. 4, 1966.
Wayne County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
Wilson County	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
South Carolina	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.
South Dakota:			
Shannon County	Nov. 1, 1972	41 FR 784	Jan. 5, 1976.
Todd County	Nov. 1, 1972	41 FR 784	Jan. 5, 1976.
Texas	Nov. 1, 1972	40 FR 43746	Sept. 23, 1975.
Virginia	Nov. 1, 1964	30 FR 9897	Aug. 7, 1965.

The following political subdivisions in States subject to statewide coverage are also covered individually:

Jurisdiction	Applicable date	Federal Register citation	
		Volume and page	Date
Arizona:			
Apache County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Apache County	Nov. 1, 1972	40 FR 49422	Oct. 22, 1975.
Cochise County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971
Coconino County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Coconino County	Nov. 1, 1972	40 FR 49422	Oct. 22, 1975.
Mohave County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Navajo County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Navajo County	Nov. 1, 1972	40 FR 49422	Oct. 22, 1975.
Pima County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Pinal County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Pinal County	Nov. 1, 1972	40 FR 49422	Oct. 22, 1975.
Santa Cruz County	Nov. 1, 1968	36 FR 5809	Mar. 27, 1971.
Yuma County	Nov. 1, 1964.	31 FR 982	Jan. 25, 1966.

The Voting Section maintains a current list of those jurisdictions that have maintained successful declaratory judgments from the United States District Court for the District of Columbia pursuant to section 4 of the Act on its Web site at *http://www.justice.gov/crt/voting.*

Dated: April 8, 2011.

Eric H. Holder, Jr.,

Attorney General.

[FR Doc. 2011–9083 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–13–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in May 2011. PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

DATES: Effective May 1, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: Interest assumptions are also published on PBGC's Web site (*http://www.pbgc.gov*). PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR Part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974.

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for May 2011.[1]

The May 2011 interest assumptions under the benefit payments regulation will be 2.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for April 2011, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during May 2011, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 211, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
211	5–1–11	6–1–11	2.50	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 211, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
211	5–1–11	6–1–11	2.50	4.00	4.00	4.00	7	8

Issued in Washington, DC, on this 7th day of April 2011.

Vincent K. Snowbarger,

Deputy Director for Operations, Pension Benefit Guaranty Corporation.

[FR Doc. 2011–8926 Filed 4–14–11; 8:45 am]

BILLING CODE 7709–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0252]

Drawbridge Operation Regulation; Company Canal, Lockport, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the LA 1 vertical lift span bridge across Company Canal, mile 0.4, at Lockport, Lafourche Parish, Louisiana. The deviation is necessary to perform electrical rehabilitation work on the bridge. This deviation allows the bridge to remain closed to navigation for twelve consecutive hours each day from Monday through Thursday for three weeks.

DATES: This deviation is effective from 6 a.m. on Monday, June 27, 2011 through 6 p.m. on Thursday, July 14, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0252 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0252 in the "Keyword" box and then clicking "Search". They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail David Frank, Bridge Administration Branch, Coast Guard; telephone 504–671–2128, e-mail *David.M.Frank@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Louisiana Department of Transportation and Development has requested a temporary deviation from the operating schedule of the vertical lift span bridge across Company Canal at mile 0.4 in Lockport, Lafourche Parish, Louisiana. The vertical clearance of the bridge is 5 feet above Mean High Water in the closed-to-navigation position and 50 feet above Mean High Water in the open-to-navigation position.

In accordance with 33 CFR 117.438(a), the vertical lift span of the bridge currently opens on signal except that, from 6 p.m. to 10 a.m. the draw opens on signal if at least 4 hours notice is given. This deviation allows the vertical lift span of the bridge to remain closed to navigation from 6 a.m. until 6 p.m. Monday through Thursday from Monday, June 27, 2011 through Thursday July 14, 2011.

The closure is necessary in order to replace electrical conductors and conduit throughout the bridge structure, including the removal and replacement of all navigation lights on the span and fender system. This maintenance is essential for the continued operation of the bridge. Temporary navigational lighting will be provided during the closure and power outage period. Notices will be published in the Eighth Coast Guard District Local Notice to Mariners and will be broadcast via the Coast Guard Broadcast Notice to Mariners System.

Navigation on the waterway consists of commercial and recreational fishing vessels, small to medium crew boats, and small tugs with and without tows. The bridge opens for the passage of navigation an average of 16 times per month. There are two alternate waterway routes available via the Gulf Intracoastal Waterway east to Bayou Lafourche and west to Navigation Canal. Small vessels may pass under the bridge while in the closed-to-navigation position provided caution is exercised.

Due to prior experience and coordination with waterway users, it has been determined that this closure will not have a significant effect on vessels that use the waterway.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 5, 2011.

David M. Frank,

Bridge Administrator.

[FR Doc. 2011–9147 Filed 4–14–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0939]

RIN 1625–AA00

Safety Zone; M/V DAVY CROCKETT, Columbia River

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The U.S. Coast Guard is extending and expanding the emergency safety zone established on the waters of the Columbia River surrounding the M/V DAVY CROCKETT at approximately river mile 117 on January 28, 2011. The safety zone is necessary to help ensure the safety of the response workers and maritime public from the hazards associated with deleterious state of and ongoing response operations involving the M/V DAVY CROCKETT. All persons and vessels are prohibited from entering or remaining in the safety zone unless authorized by the Captain of the Port, Columbia River or his designated representative.

DATES: This rule is effective from April 15, 2011 through May 17, 2011. This rule is effective with actual notice for purposes of enforcement on March 28, 2011. This rule will remain in effect through May 17, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the

docket are part of docket USCG–2010–0939 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0939 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail MST1 Jaime Sayers, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503–240–9319, e-mail *Jaime.A.Sayers@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because to do so would be contrary to public interest since the safety zones are immediately necessary to help ensure the safety of the response workers and maritime public due to deleterious state of and ongoing response operations involving the M/V DAVY CROCKETT.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** because the safety zones are immediately necessary to help ensure the safety of the response workers and maritime public due to deleterious state of and ongoing response operations involving the M/V DAVY CROCKETT.

Background and Purpose

The M/V DAVY CROCKETT, a 431 ft barge, is anchored on the Washington State side of the Columbia River at approximately river mile 117. The vessel is in a severe state of disrepair. The Coast Guard, other State and Federal agencies, and Federal contractors are working to remove the vessel. The response operations require a minimal wake in the vicinity of the vessel to minimize the spread of contaminants and help ensure the safety of response workers on or near the vessel and in the water. In addition, due to the deleterious state of the vessel only authorized persons and/or vessels can be safely allowed on or near it.

A 300 ft safety zone is necessary to keep vessels clear of the ongoing response operations surrounding the M/V DAVY CROCKETT. The previous 200 ft zone was an inadequate distance to mitigate the wake of transiting and nearby vessels.

Discussion of Rule

The Coast Guard is extending and expanding the stationary safety zone created by this rule 100 ft past the previous 200 ft safety zone. The amended safety zone will cover all waters of the Columbia River encompassed within the following four points: point one at 45°34′59.74″ N/122°28′35.00″ W on the Washington bank of the Columbia River then proceeding into the river to point two at 45°34′51.42″ N/122°28′35.47″ W, then proceeding upriver to the third point at 45°34′51.02″ N/122°28′07.32″ W, then proceeding to the shoreline to the fourth point on the Washington Bank at 45°34′56.06″ N/122°28′07.36″ W, then back along the shoreline to point one. Geographically this encompasses all the waters within an area starting at approximately 300 ft upriver from the M/V DAVY CROCKETT extending to 300 ft abreast of the M/V DAVY CROCKETT and then ending 300 ft down river of the M/V DAVY CROCKETT.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The Coast Guard has made this determination based on the fact that the safety zones created by this rule will not significantly affect the maritime public because the areas covered are limited in size and/or have little commercial or recreational activity. In addition, vessels may enter the safety zones with the permission of the Captain of the Port, Columbia River or his designated representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities some of which may be small entities: the owners and operators of vessels intending to operate in the areas covered by the safety zones created in this rule. The safety zones will not have a significant economic impact on a substantial number of small entities because the areas covered are limited in size. In addition, vessels may enter the safety zones with the permission of the Captain of the Port, Columbia River or his designated representative.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminates ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the creation of safety zones. An environmental analysis checklist and a categorical exclusion determination will be available in the docket where

List of Subjects in 33 CFR Part 165

Harbors, Marine safety Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–175 to read as follows:

§ 165.T13–175 Safety Zone; M/V DAVY CROCKETT, Columbia River.

(a) *Location:* The following area is a safety zone:

(1) All waters of the Columbia River encompassed within the following four points: point one at 45°34′ 59.74″ N/122°28′35.00″ W on the Washington bank of the Columbia River then proceeding into the river to point two at 45°34′51.42″ N/122°28′35.47″ W, then proceeding upriver to the third point at 45°34′51.02″ N/122°28′07.32″ W, then proceeding to the shoreline to the fourth point on the Washington Bank at 45°34′56.06″ N/122°28′07.36″ W, then back along the shoreline to point one. Geographically this encompasses all the waters within an area starting at approximately 300 ft upriver from the M/V DAVY CROCKETT extending to 300 ft abreast of the M/V DAVY CROCKETT and then ending 300 ft down river of the M/V DAVY CROCKETT.

(b) *Regulations.* In accordance with the general regulations in 33 CFR Part 165, Subpart C, no person may enter or remain in the safety zone created in this section or bring, cause to be brought, or allow to remain in the safety zone created in this section any vehicle, vessel, or object unless authorized by the Captain of the Port, Columbia River or his designated representative.

(c) *Enforcement Period.* The safety zone created in this section will be in effect from March 28, 2011 through May 17, 2011 unless cancelled sooner by the Captain of the Port, Columbia River.

Dated: March 28, 2011.

D.E. Kaup,

Captain, U.S. Coast Guard, Captain of the Port, Columbia River.

[FR Doc. 2011–9144 Filed 4–14–11; 8:45 am]

BILLING CODE 9110–04–P

Proposed Rules

Federal Register
Vol. 76, No. 73
Friday, April 15, 2011

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 327

Proposed Assessment Rate Adjustment Guidelines for Large and Highly Complex Institutions

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Request for comment.

SUMMARY: The FDIC seeks comment on proposed guidelines that would be used to determine how adjustments could be made to the total scores that are used in calculating the deposit insurance assessment rates of large and highly complex insured institutions. Total scores are determined according to the Assessments and Large Bank Pricing approved by the FDIC Board on February 7, 2011.

DATES: Comments must be received on or before May 31, 2011.

ADDRESSES: You may submit comments, identified by "Adjustment Guidelines," by any of the following methods:

- Agency Web site: *http://www.fdic.gov/regulations/laws/federal/propose.html.* Follow instructions for submitting comments on the Agency Web site.
- E-mail: *Comments@FDIC.gov.* Include "Adjustment Guidelines" in the subject line of the message.
- Mail: Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- Hand Delivery/Courier: Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

Instructions: All submissions received must include the agency name and "Adjustment Guidelines" in the heading. All comments received will be posted to the extent practicable and, in some instances, the FDIC may post summaries of categories of comments, with the comments themselves available in the FDIC's reading room. Comments will be posted at *http://www.fdic.gov/regulations/laws/federal/propose.html,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Lisa Ryu, Chief, Large Bank Pricing Section, Division of Insurance and Research, (202) 898–3538; Andrew Felton, Acting Chief, Large Bank Pricing Section, Division of Insurance and Research, (202) 898–3823; Mike Anas, Senior Financial Analyst, Division of Insurance and Research, (630) 241–0359 x 8252; and Christopher Bellotto, Counsel, Legal Division, (202) 898–3801, 550 17th Street, NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

I. Background

On February 7, 2011 (76 FR 10672 (Feb. 25, 2011)), the FDIC Board amended its assessment regulations (the Amended Assessment Regulations), by, among other things, adopting a new methodology for determining assessment rates for large institutions.[1] [2] The Amended Assessment Regulations eliminate risk categories for large institutions and combine CAMELS ratings and forward-looking financial measures into one of two scorecards, one for highly-complex institutions and another for all other large institutions.[3] Each of the two scorecards produces two scores—a performance score and a loss severity score—that are combined into a total score, which cannot be greater than 90 or less than 30. The FDIC can adjust a bank's total score up or down by no more than 15 points, but the resulting score cannot be greater than 90 or less than 30. The score is then converted to an initial base assessment rate, which, after application of other possible adjustments, results in a total assessment rate.[4] The total assessment rate is multiplied by the bank's assessment base to calculate the amount of its assessment obligation.

Tables 1 and 2 show the scorecards for large and highly complex institutions, respectively.

TABLE 1—SCORECARD FOR LARGE INSTITUTIONS

Scorecard measures and components	Measure weights (percent)	Component weights (percent)
P Performance Score		
P.1 *Weighted Average CAMELS Rating*	100	*30*
P.2 *Ability to Withstand Asset-Related Stress:*		*50*
Tier 1 Leverage Ratio	10	
Concentration Measure	35	
Core Earnings/Average Quarter-End Total Assets *	20	

[1] Assessments, Large Bank Pricing, 76 FR 10672 (February 25, 2011) (to be codified at 12 CFR 327.9).

[2] A large institution is defined as an insured depository institution: (1) That had assets of $10 billion or more as of December 31, 2006 (unless, by reporting assets of less than $10 billion for four consecutive quarters since then, it has become a small institution); or (2) that had assets of less than $10 billion as of December 31, 2006, but has since had $10 billion or more in total assets for at least four consecutive quarters, whether or not the institution is new.

[3] A "highly complex institution" is defined as: (1) An insured depository institution (excluding a credit card bank) that has had $50 billion or more in total assets for at least four consecutive quarters and that either is controlled by a U.S. parent holding company that has had $500 billion or more in total assets for four consecutive quarters, or is controlled by one or more intermediate U.S. parent holding companies that are controlled by a U.S. holding company that has had $500 billion or more in assets for four consecutive quarters, and (2) a processing bank or trust company. A processing bank or trust company is an insured depository institution whose last three years' non-lending interest income, fiduciary revenues, and investment banking fees, combined, exceed 50 percent of total revenues (and its last three years' fiduciary revenues are non-zero), whose total fiduciary assets total $500 billion or more and whose total assets for at least four consecutive quarters have been $10 billion or more.

[4] These adjustments are the unsecured debt adjustment, the depository institution debt adjustment, and the brokered deposit adjustment.

TABLE 1—SCORECARD FOR LARGE INSTITUTIONS—Continued

Scorecard measures and components	Measure weights (percent)	Component weights (percent)
Credit Quality Measure	35	
P.3 *Ability to Withstand Funding-Related Stress:*		*20*
Core Deposits/Total Liabilities	60	
Balance Sheet Liquidity Ratio	40	
L Loss Severity Score		
L.1 *Loss Severity Measure*		*100*

* Average of five quarter-end total assets (most recent and four prior quarters).

TABLE 2—SCORECARD FOR HIGHLY COMPLEX INSTITUTIONS

Measures and components	Measure weights (percent)	Component weights (percent)
P Performance Score		
P.1 *Weighted Average CAMELS Rating*	100	*30*
P.2 *Ability to Withstand Asset-Related Stress:*		*50*
Tier 1 Leverage Ratio	10	
Concentration Measure	35	
Core Earnings/Average Quarter-End Total Assets	20	
Credit Quality Measure and Market Risk Measure	35	
P.3 *Ability to Withstand Funding-Related Stress:*		*20*
Core Deposits/Total Liabilities	50	
Balance Sheet Liquidity Ratio	30	
Average Short-Term Funding/Average Total Assets	20	
L Loss Severity Score		
L.1 *Loss Severity*		*100*

* Average of five quarter-end total assets (most recent and four prior quarters).

Scorecard measures (other than the weighted average CAMELS rating) are converted to scores between 0 and 100 based on minimum and maximum cutoff values for each measure. A score of 100 reflects the highest risk and a score of 0 reflects the lowest risk. A value reflecting lower risk than the cutoff value receives a score of 0 and a value reflecting higher risk than the cutoff value receives a score of 100. A risk measure value between the minimum and maximum cutoff values converts linearly to a score between 0 and 100, which is rounded to 3 decimal points. The weighted average CAMELS rating is converted to a score between 25 and 100, where 100 reflects the highest risk and 25 reflects the lowest risk.

In most cases, the total score produced by the applicable scorecard will correctly reflect an institution's overall risk relative to other large institutions; however, the scorecard includes assumptions that may not be appropriate for all institutions. Therefore, the FDIC believes that it is important that it have the ability to consider idiosyncratic or other relevant risk factors that are not adequately captured in the scorecards and make appropriate adjustments to an institution's total score. The Amended Assessment Regulations state that, after consultation with an institution's primary Federal regulator, the FDIC may make a limited adjustment to an institution's total score based upon risks that are not adequately captured in the scorecard. The Amended Assessment Regulations provide that no new adjustments will be made until new guidelines have been published for comment and approved by the FDIC's Board of Directors.[5]

The proposed guidelines describe the process the FDIC would follow to determine whether to make an adjustment and to determine the size of any adjustment. This request for comments also outlines the process the FDIC would use when notifying an institution regarding an adjustment.

These proposed guidelines would supersede the large bank pricing adjustment guidelines published by the FDIC on May 14, 2007 (the 2007 Guidelines).[6] The 2007 Guidelines outline the adjustment process for the large bank assessment system then in effect. The Amended Assessment Regulations include scorecards that explicitly incorporate some of the risks that were previously captured primarily through large bank adjustments. The proposed guidelines take these changes into account; however, the processes for communicating with affected institutions and implementing adjustments once determined remain largely unchanged from the 2007 Guidelines, except that the FDIC is now explicitly allowing institutions to request a large bank adjustment.

The FDIC seeks comments on the proposed guidelines and the procedures for making an adjustment to an institution's score. Although the FDIC has in this instance chosen to publish the proposed guidelines and solicit comment from the industry, notice and comment are not required and need not be employed to make future changes to the guidelines.

[5] The Amended Assessment Regulations also require that the FDIC publish aggregate statistics on adjustments each quarter once the guidelines are adopted. 76 FR 10699.

[6] Assessment Rate Adjustment Guidelines for Large Institutions and Insured Foreign Branches in Risk Category I, 72 FR 27122 (May 14, 2007).

II. Overview of Proposed Guidelines on Large Bank Adjustment

The proposed large bank adjustment process would be based on a set of guidelines designed to ensure that the adjustment process is fair and transparent and that any decision to adjust a score is well supported. The following general guidelines would govern the adjustment process, which is described in greater detail below.

Analytical Guidelines

- The FDIC would focus on identifying institutions for which a combination of risk measures and other information suggests either materially higher or lower risk than their total scores indicate. The FDIC would consider all available material information relating to the likelihood of failure or loss severity in the event of failure.
- The FDIC would primarily consider two types of information in determining whether to make a large bank adjustment: A scorecard ratio or measure that exceeds the maximum cutoff value for a ratio or measure or is less than the minimum cutoff value for a ratio or measure along with the degree to which the ratio or measure differs from the cutoff value (scorecard measure outliers); or information not directly captured in the scorecard, including complementary quantitative risk measures and qualitative risk considerations.
- If an institution has one or more scorecard measure outliers, the FDIC would conduct further analysis to determine whether underlying scorecard ratios are materially higher or lower than the established cutoffs for a given scorecard measure and whether other mitigating or supporting information exists.
- The FDIC would use complementary quantitative risk measures to determine whether a given scorecard measure is an appropriate measure for a particular institution.
- When qualitative risk considerations materially affect the FDIC's view of an institution's probability of failure or loss given failure, these considerations could be the primary factor supporting the adjustment. Qualitative risk considerations include, but are not limited to, underwriting practices related to material concentrations, risk management practices, strategic risk, the use and management of government support programs, and factors affecting loss severity.
- Specific risk measures would vary in importance for different types of institutions. In some cases, a single risk factor or indicator may support an adjustment if the factor suggests a significantly higher or lower likelihood of failure, or loss given failure, than the total score reflects.
- To the extent possible in comparing risk measures, the FDIC would consider the performance of similar institutions, taking into account that variations in risk measures exist among institutions with substantially different business models.
- Adjustments would be made only if the comprehensive analysis of an institution's risk, generally based on the two types of information listed above, and the institution's relative risk ranking warrant a meaningful adjustment of the institution's total score (generally, an adjustment of five points or more).

Procedural Guidelines

The processes for communicating with affected institutions and implementing adjustments once determined would remain largely unchanged by this proposal, except that the FDIC would now explicitly allow institutions to request an adjustment.

- The FDIC would consult with an institution's primary Federal regulator and appropriate state banking supervisor before making any decision to adjust an institution's total score (and before removing a previously implemented adjustment).
- The FDIC would give institutions advance notice of any decision to make an upward adjustment to a total score, or to remove a previously implemented downward adjustment. The notice would include the reasons for the proposed adjustment or removal, the size of the proposed adjustment or removal, specify when the adjustment or removal would take effect, and provide institutions with up to 60 days to respond.
- The FDIC would re-evaluate the need for total score adjustments on a quarterly basis.
- Institutions could make written request to the FDIC for an adjustment, but must support the request with evidence of a material risk or risk-mitigating factor that is not adequately accounted for in the scorecard.
- An institution could request review of or appeal an upward adjustment, the magnitude of an upward adjustment, removal of a previously implemented downward adjustment or an increase in a previously implemented upward adjustment pursuant to 12 CFR 327.4(c). An institution could similarly request review of or appeal a decision not to apply an adjustment following a request by the institution for an adjustment.

III. The Assessment Rate Adjustment Process

A. Identifying the Need for an Adjustment

The FDIC believes that any adjustment should improve the rank ordering of institutions according to risk. Institutions with similar risk profiles should have similar total scores and corresponding initial assessment rates, and institutions with higher or lower risk profiles should have higher or lower total scores and initial assessment rates, respectively. The FDIC would evaluate scorecard results each quarter to identify institutions with a score that is clearly too high or too low when considered in light of risks or risk-mitigating factors that are inadequately accounted for by the scorecard. Some examples of these types of risks and risk-mitigating factors include considerations for purchased credit impaired (PCI) loans, accounting rule changes such as FAS 166/167, credit underwriting and credit administration practices, collateral and other risk mitigants, including the materiality of guarantees and franchise value. Commenters on the proposed large bank pricing rule published on November 9, 2010 (the Large Bank NPR) [7] suggested that these factors be considered in determining an institution's assessment rate. As discussed in the preamble to the Final Rule on Assessments and Large Bank Pricing approved by the FDIC Board in February 2011, the FDIC stated that it would consider these factors in the large bank assessment rate adjustments.[8]

In addition to considering an institution's relative risk ranking among all large institutions, the FDIC would consider how an institution compares to similar institutions. The comparison would allow the FDIC to account for variations in risk measures that may exist among institutions with differing business models. For purposes of the comparison, the FDIC would, where appropriate, assign an institution to a peer group. The proposed peer groups are:

Processing Banks and Trust Companies: Large institutions whose last three years' non-lending interest income, fiduciary revenues, and investment banking fees, combined, exceed 50 percent of total revenues (and its last three years' fiduciary revenues

[7] 75 FR 72612 (Nov. 24, 2010).

[8] 76 FR 10672 (Feb. 25, 2011).

are non-zero), and whose total fiduciary assets total $500 billion or more.

Residential Mortgage Lenders: Large institutions not described in the peer group above whose mortgage loans plus mortgage-backed securities exceed 50 percent of total assets.

Non-diversified Regional Institutions: Large institutions not described in a peer group above if: credit card plus securitized receivables exceed 50 percent of assets plus securitized receivables; or the sum of residential mortgage loans, credit card loans, and other loans to individuals exceeds 50 percent of assets.

Large Diversified Institutions: Large institutions not described in a peer group above with over $150 billion in assets.

Diversified Regional Institutions: Large institutions not described in a peer group above with less than $150 billion in assets.

An institution can also request that the FDIC make an adjustment to its score by submitting a written request to the FDIC's Director of the Division of Insurance and Research in Washington, DC. Similar to FDIC-initiated adjustments, an institution's request for an adjustment would be considered only if it is supported by evidence of a material risk or risk-mitigating factor that is not adequately accounted for in the scorecard. The FDIC would consider these requests as part of its ongoing effort to identify and adjust scores that require adjustment. An institution-initiated request would not preclude a subsequent request for review (12 CFR 327.4(c)) or appeal pursuant to the assessment appeals process.[9]

B. Determining the Adjustment Amount

Once it determines that an adjustment may be warranted, the FDIC would determine the adjustment amount necessary to bring an institution's total score into better alignment with those of other institutions that pose similar levels of risk. The FDIC would initiate adjustments only when a combination of risk measures and other information suggests either materially higher or lower risk than their total scores indicate, generally resulting in an adjustment of an institution's total score by five points or more. The FDIC believes that the adjustment process should be used to address material idiosyncratic issues in a small number of institutions rather than as a fine-tuning mechanism for a large number of institutions. If the size of the adjustment required to align an institution's total score with institutions of similar risk is not material, no adjustment would be made.

B. Further Analysis and Consultation With Primary Federal Regulator

As under the 2007 Guidelines, before making an adjustment, the FDIC would consult with an institution's primary Federal regulator and state banking supervisor to obtain further information and comment.

C. Advance Notice

Decisions to lower an institution's total score would not be communicated to institutions in advance. Rather, as under the 2007 Guidelines, they would be reflected in the invoices for a given assessment period along with the reasons for the adjustment.

To give an institution an opportunity to respond, the FDIC would give advance notice to an institution when proposing to make an upward adjustment to the institution's total score.[10] Consistent with the 2007 Guidelines, the timing of the notice would correspond approximately to the invoice date for an assessment period. For example, an institution would be notified of a proposed upward adjustment to its assessment rates covering the period April 1 through June 30 by approximately June 15, which is the invoice date for the January 1 through March 31 assessment period.[11]

D. Institution's Opportunity To Respond

Before implementing an upward adjustment to a total score, the FDIC would review the institution's response to the advance notice, along with any subsequent changes to supervisory ratings, scorecard measures, or other relevant risk factors. Similar to the 2007 Guidelines, if the FDIC decided to implement the upward adjustment, it would notify an institution of its decision along with the invoice for the quarter in which the adjustment would become effective.

Extending the example above, if the FDIC notified an institution of a proposed upward adjustment on June 15, the institution would have 60 days from this date to respond to the notification. If, after evaluating the institution's response and updated information for the quarterly assessment period ending June 30, the FDIC decided to proceed with the adjustment, it would communicate this decision to the institution by approximately September 15, which is the invoice date for the April 1 through June 30 assessment period. In this case, the adjusted rate would be reflected in the September 15 invoice.

The time frames and example above also apply to a decision by the FDIC to remove a previously implemented downward adjustment as well as a decision to increase a previously implemented upward adjustment.

E. Duration of the Adjustment

Consistent with the 2007 Guidelines, the adjustment would remain in effect for subsequent assessment periods until the FDIC determined either that the adjustment was no longer warranted or that the magnitude of the adjustment needed to be reduced or increased (subject to the 15-point limitation and the requirement for further advance notification).[12]

F. Requests for Review and Appeals

An institution could request review of or appeal an upward adjustment, the magnitude of an upward adjustment, removal of a previously implemented downward adjustment or an increase in a previously implemented upward adjustment pursuant to 12 CFR 327.4(c). An institution could similarly request review of or appeal a decision not to apply an adjustment following a request by the institution for an adjustment.

IV. Additional Information on the Adjustment Process, Including Examples

As discussed above, the FDIC would primarily consider two types of information in determining whether to make a large bank adjustment: Scorecard measure outliers or information not directly captured in the scorecard, including complementary quantitative risk measures and qualitative risk considerations.

A. Scorecard Measure Outliers

In order to convert each scorecard ratio into a score that ranges between 0 and 100, the Amended Assessment Regulations use minimum and maximum cutoff values that generally correspond to the 10th and 90th percentile values for each ratio based on data for the 2000 to 2009 period. All values less than the 10th percentile or all values greater than the 90th

[9] See Guidelines for Appeals of Deposit Insurance Assessment Determinations, 75 FR 20362 (April 19, 2010).

[10] The institution would also be given advance notice when the FDIC determines to eliminate any downward adjustment to an institution's total score.

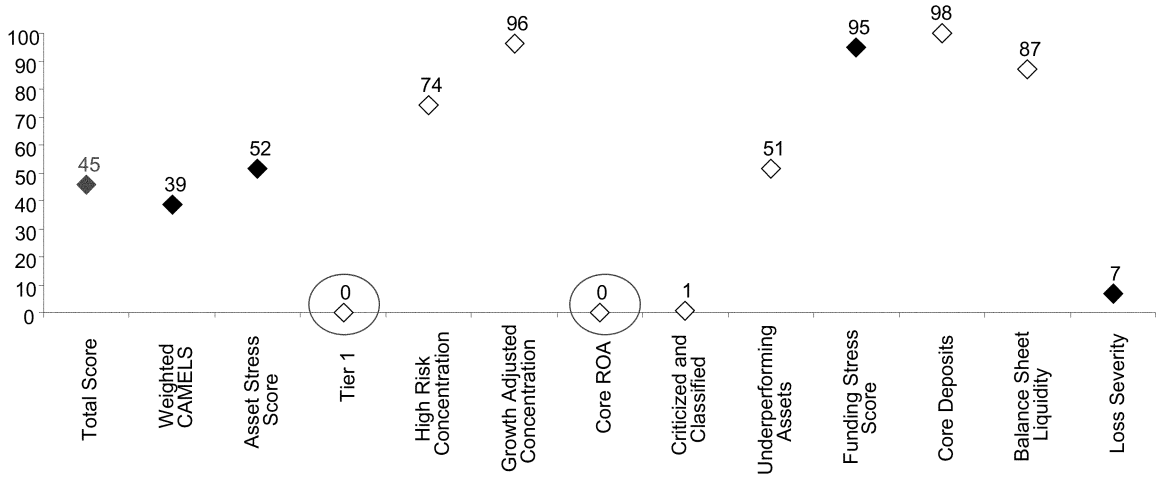
[11] The invoice covering the assessment period January 1 through March 31 in this example would not reflect the upward adjustment.

[12] As noted in the Amended Assessments Regulation, an institution's assessment rate can increase without notice if the institution's supervisory, agency ratings, or financial ratios deteriorate.

percentile are assigned the same score. This process enables the FDIC to compare different ratios in a standardized way and assign statistically-based weights; however, it may mask significant differences in risk among institutions with the minimum or maximum score. The FDIC believes that an institution with one or more scorecard ratios well in excess of the maximum cutoffs or well below the minimum cutoffs may pose significantly greater or lower risk to the deposit insurance fund than its score suggests.

The example below illustrates the analytical process the FDIC would follow in determining to propose a downward adjustment based on scorecard measure outliers. The example is merely illustrative. As shown in Chart 1, Bank A has a total score of 45 and two scorecard measures with a score of 0 (indicating lower risk).

Chart 1
Total and Component Scores for Bank A



Note: Solid diamonds denote either the total score or scorecard component scores; clear diamonds denote scores for the scorecard measures that make up the components.

Since at least one of the scorecard measures has a score of 0, the FDIC would further review whether the ratios underlying these measures materially differ from the cutoff value associated with a score of 0. Materiality would generally be determined by the amount that the underlying ratio differed from the relevant cutoff as a percentage of the overall scoring range (the maximum cutoff minus the minimum cutoff). Table 3 shows that Bank A's Tier 1 Leverage ratio (17 percent) far exceeds the cutoff value associated with a score of 0 (13 percent), with the difference representing 57 percent of the associated scoring range. Based on this additional information and assuming no other mitigating factors, the FDIC could determine that the Bank A's loss absorbing capacity is not fully recognized, particularly when compared with other institutions receiving the same overall score. By contrast, Bank A's Core ROA ratio is much closer to its cutoff values, suggesting that an adjustment based on consideration of those factors may not be justified.

TABLE 3—OUTLIER ANALYSIS FOR BANK A

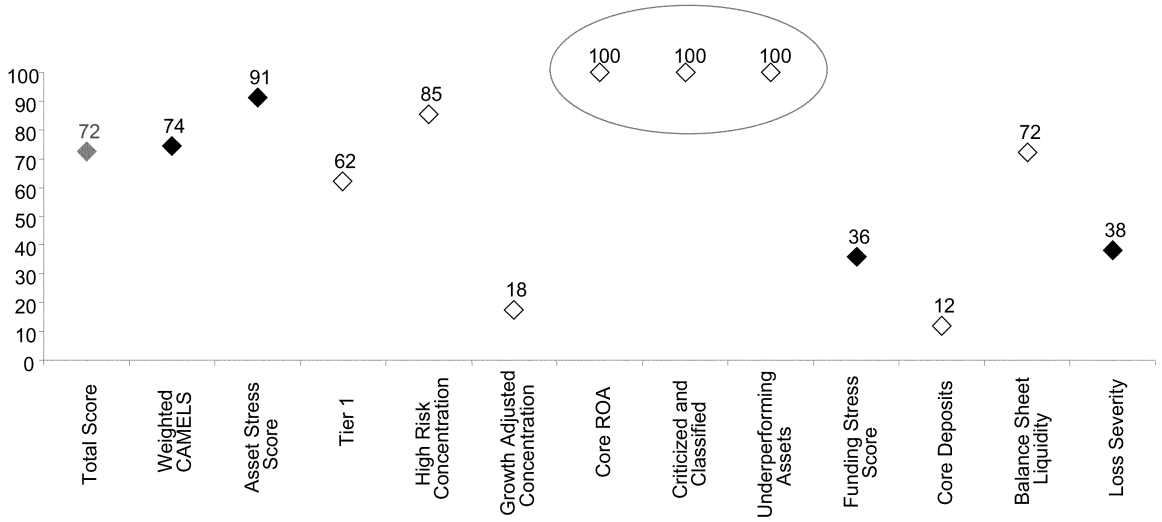
Scorecard measure	Score	Cutoffs		Value (percent)	Outlier amount (value minus cutoff) as percentage of the scoring range (percent)
		Minimum (percent)	Maximum (percent)		
Core ROA	0	0	2	2.08	4
Tier 1 Capital Ratio	0	6	13	17	57

Before initiating an adjustment, however, the FDIC would consider whether Bank A had significant risks that were not captured in the scorecard. If no information on such risks existed, the FDIC would initiate a downward adjustment to Bank A's total score.

The amount of the adjustment would be the amount needed to make the total score consistent with those of banks of comparable overall risk, with particular emphasis on institutions of the same institution type (*e.g.,* diversified regional institutions), as described above. Typically, however, adjustments supported by only one extreme outlier value would be less than the FDIC's potential adjustment authority of 15 points. In the case of multiple outlier values, inconsistent outlier values, or outlier values that are exceptionally beyond the scoring range, an overall analysis of each measure's relative importance may call for higher or lower adjustment amounts. For Bank A, a 5-point adjustment may be most appropriate.

The next example illustrates the analytical process the FDIC would follow in determining to propose an upward adjustment based on scorecard measure outliers. As in the example above, the example is merely illustrative; an institution with less extreme values could also receive an upward adjustment. As shown in Chart 2, Bank B has a total score of 72 and three scorecard measures with a score of 100 (indicating higher risk).

Chart 2
Total and Component Scores for Bank B



Note: Solid diamonds denote either the total score or scorecard component scores; clear diamonds denote scores for the scorecard measures that make up the components.

Since at least one of the scorecard measures has a score of 100, the FDIC would further review whether the ratios underlying these measures materially exceed the cutoff value associated with a score of 100. Table 4 shows that Bank B's Criticized and Classified Items to Tier 1 Capital and Reserves ratio (198 percent) far exceeds the cutoff value associated with a score of 100 (100 percent), with the difference representing 105 percent of the associated scoring range. Based on this additional information and assuming no other mitigating factors, the FDIC could determine that the risk associated with Bank B's ability to withstand asset-related stress and, therefore, its overall risk, may be materially greater than its score suggests, particularly when compared with other institutions receiving the same overall score. By contrast, the Core ROA and Underperforming Assets to Tier 1 Capital and Reserves values are much closer to their respective cutoff values, suggesting that an adjustment based on these factors may not be justified.

TABLE 4—OUTLIER ANALYSIS FOR BANK B

Scorecard measure	Score	Cutoffs		Value (percent)	Outlier amount (value minus cutoff) as percentage of the scoring range (percent)
		Minimum (percent)	Maximum (percent)		
Core ROA	100	0	2	−0.05	−3
Criticized and Classified to Tier 1 Capital & Reserves	100	7	100	198	105
Underperforming Assets to Tier 1 Capital & Reserves	100	2	35	36	3

After considering any risk-mitigating factors, the FDIC would determine the amount of adjustment needed to make the total score consistent with those of banks of comparable overall risk. For Bank B, a 5-point adjustment may be most appropriate.

B. Information Not Directly Captured by the Scorecard

1. Complementary Risk Measures

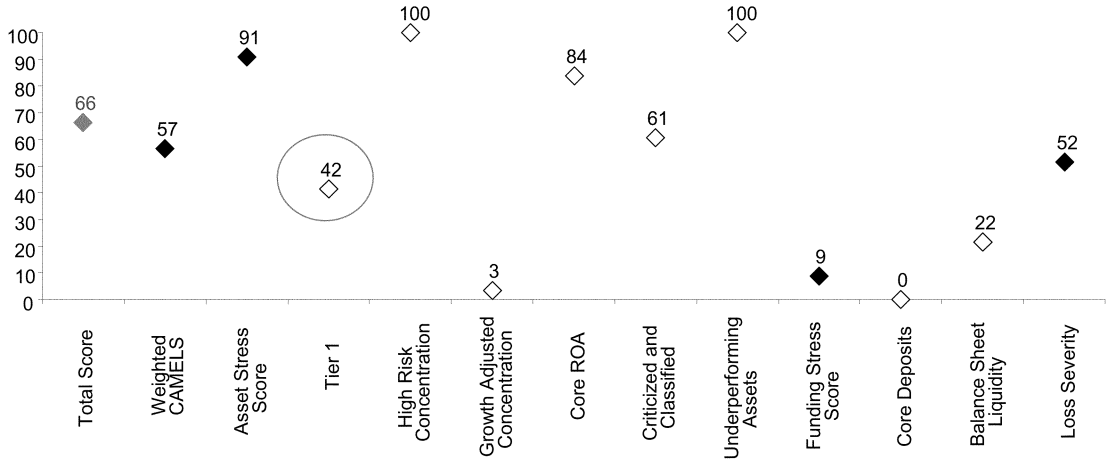
Complementary risk measures are measures that are not included in the scorecard, but that can inform the appropriateness of a given scorecard measure for a particular institution. These measures are readily available for all institutions and include quantitative metrics and market indicators that provide further insights into an institution's ability to withstand financial adversity, and the severity of losses in the event of failure.[13]

Analyzing complementary risk measures would help the FDIC determine whether the assumptions applied to a scorecard measure are appropriate for a particular institution. For example, as detailed in the Amended Assessments Regulation, the scorecard includes a loss severity measure based on the FDIC's loss severity model that applies a standard set of assumptions to all large banks to estimate potential losses to the insurance fund. These assumptions, including liability runoffs and asset recovery rates, are derived from actual bank failures; however, the FDIC recognizes that a large bank may have unique attributes that could have a bearing on the appropriateness of those assumptions. When data or quantitative metrics exist that support materially different runoff assumptions or asset recovery rates for a particular institution, the FDIC may consider an adjustment to the total score, particularly if such information is further supported by qualitative loss severity considerations as discussed below.

The example below illustrates the analytical process the FDIC would follow in determining to propose an upward adjustment based on complementary risk measures. Again, the example is merely illustrative. Chart 3 shows that Bank C has a total score of 66. Some of Bank C's risk measure scores are significantly higher than the total score, while others, including the Tier 1 leverage ratio score (42), are significantly lower.

Chart 3

Total Score and Component Scores for Bank C



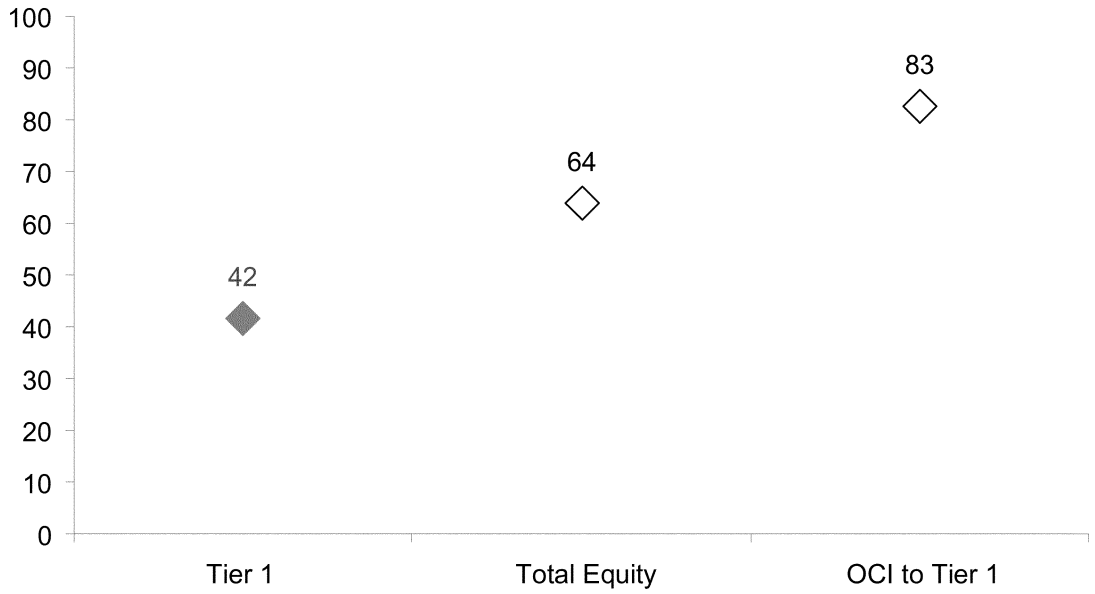
Note: Solid diamonds denote either the total score or scorecard component scores; clear diamonds denote scores for the scorecard measures that make up the components.

After reviewing complementary measures for all financial ratios contained in the scorecard, in the hypothetical example, the complementary measures for Tier 1 leverage ratio showed that the level and quality of capital protection may not be correctly reflected in the Tier 1 leverage ratio score. Chart 4 shows that two other complementary capital measures for Bank C—the total equity ratio and the ratio of other comprehensive income (OCI) to Tier 1 capital—suggest higher risk than the Tier 1 leverage ratio score suggests. Additional review reveals that sizeable unrealized losses in the securities portfolio account for these differences and that Bank C's loss absorbing capacity is potentially overstated by the Tier 1 leverage ratio.

[13] In the context of large institution insurance pricing, loss severity refers to the relative loss, scaled to its current domestic deposits, that an institution poses to the Deposit Insurance Fund in the event of a failure.

Chart 4

Complementary Risk Measures for Capital for Bank C



Note: The solid diamond denotes a scorecard measure; the clear diamonds denote complementary risk measures.

An upward adjustment to Bank C's total score may be appropriate, again assuming that no significant risk mitigants are evident. An adjustment of 5 points would be likely since the underlying level of unrealized losses is extremely high (greater than 25% of Tier 1 capital). While the adjustment in this case would likely be limited to 5 points because the bank's concentration measure and credit quality measure already receive the maximum possible score, in other cases modest unrealized losses could lead to a higher overall adjustment amount, if the concentration and credit quality measures are understated as well.[14]

2. Qualitative Risk Considerations

The FDIC believes that it is important to consider all relevant qualitative risk considerations in determining whether to apply a large bank adjustment. Qualitative information often provides significant insights into institution-specific or idiosyncratic risk factors that cannot be captured in the scorecard. Similar to scorecard outliers and complementary risk measures, the FDIC would use the qualitative information to consider whether potential discrepancies exist between the risk ranking of institutions based on their total score and the relative risk ranking suggested by a combination of risk measures and qualitative risk considerations. Such information includes, but is not limited to, analysis based on information obtained through the supervisory process, such as underwriting practices, interest rate risk exposure and other information obtained through public filings.

Another example of qualitative information that the FDIC would consider is available information pertaining to an institution's ability to withstand adverse events. Sources of this information are varied but may include analyses produced by the institution or supervisory authorities, such as stress test results, capital adequacy assessments, or information detailing the risk characteristics of the institution's lending portfolios and other businesses. Information pertaining to internal stress test results and internal capital adequacy assessment would be used qualitatively to help inform the relative importance of other risk measures, especially concentrations of credit exposures and other material non-lending business activities. As an example, in cases where an institution has a significant concentration of credit risk, results of internal stress tests and internal capital adequacy assessments could obviate FDIC concerns about this risk and therefore provide support for a downward adjustment, or alternatively, provide additional mitigating information to forestall a pending upward adjustment. In some cases, stress testing results may suggest greater risk than would normally be evident through the scorecard methodology alone.

Qualitative risk considerations would also include information that could have a bearing on potential loss severity, and could include, for example, the ease with which the FDIC could make quick deposit insurance determinations and depositor payments, or the availability of sufficient information on qualified financial contracts to allow the FDIC to make timely and correct determinations on these contracts in the event of failure.

In general, qualitative factors would become more important in determining whether to apply an adjustment when an institution has high performance risk

[14] The concentration measure and the credit quality measure are expressed as a percent of Tier 1 capital plus the allowance for loan loss reserves.

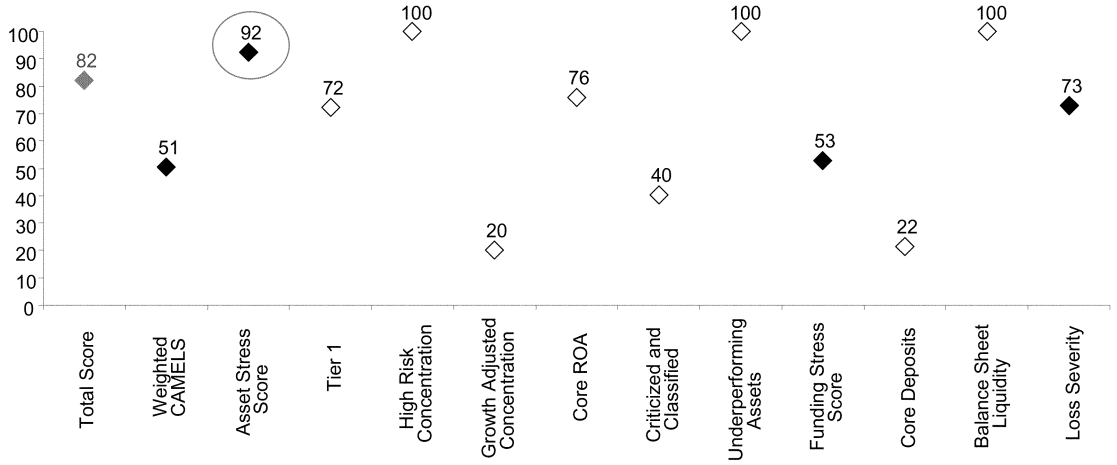
or if the institution has high asset, earnings, or funding concentrations. For example, if a bank is near failure, qualitative loss severity information becomes more important in the adjustment process. Further, if a bank has material concentrations in some asset classes, the quality of underwriting becomes more important in the adjustment process.

Additionally, engaging in certain business lines may warrant further consideration of qualitative factors. For instance, supervisory assessments of operational risk and controls at processing banks are likely to be important regardless of the institution's performance.

The specific example below illustrates the analytical process the FDIC would follow to determine whether to make an adjustment based on qualitative information. Chart 5 shows that Bank D has a high score of 82 that is largely driven by a high score for the ability to withstand asset-related stress component, which is, in turn, largely driven by the higher-risk asset concentration score and the underperforming asset score. The ability to withstand asset-related stress component is heavily weighted in the scorecard (50 percent weight), and, as a result, significant qualitative information that is not considered in the scorecard could lead to an adjustment to the institution's total score.

Chart 5

Total Score and Component Scores for Bank D



Note: Solid diamonds denote either the total score or scorecard component scores; clear diamonds denote scores for the scorecard measures that make up the components.

The FDIC would review qualitative information pertaining to the higher-risk asset concentration measure and the underperforming asset measure for Bank D to determine whether there are one or more important risk mitigants that are not factored into the scorecard. We assume that the further review revealed that, while Bank D has concentrations in non-traditional mortgages, its mortgage portfolio has the following characteristics that suggest lower risk:

a. Most of the loan portfolio is composed of bank-originated residential real estate loans on owner-occupied properties;

b. The portfolio has strong collateral protection (*e.g.,* few or no loans with a high loan-to-value ratio) compared to the rest of the industry;

c. Debt service coverage ratios are favorable (*e.g.,* few or no loans with a high debt-to-income ratio) compared to the institution's peers;

d. The primary Federal regulator notes in its examination report that the institution has strong collection practices and reports no identified risk management deficiencies.

Additionally, these qualitative factors surrounding the bank's real estate portfolio suggest loss rate assumptions applied to Bank D's residential mortgage portfolio may be too severe, resulting in a loss severity score that is too high relative to its risk.

Based on the information above, the bank would be a strong candidate for a 10- to 15-point reduction in total score, primarily since the ability to withstand asset-related stress score and loss severity score do not reflect a number of significant qualitative risk mitigants that suggest lower risk.

V. Request for Comment

The FDIC seeks comment on all aspects of the proposed guidelines for determining how to make potential adjustments to the initial total score of large institutions. In particular, the FDIC seeks comment on:

1. Whether the proposed guidelines governing the adjustment process are appropriate and sufficient to ensure fairness and consistency in deposit insurance pricing determinations. More specifically the FDIC seeks comment on the appropriateness of the following:

a. Reviewing outlier values on scorecard risk measures;

b. Augmenting the analysis of scorecard risk measures with a review of additional complementary and qualitative risk measures;

c. Basing adjustment decisions on considerations of multiple risk indicators;

d. Assessing financial performance risk measures relative to other institutions engaged in similar business activities; and

e. Using additional risk information, including qualitative information, to determine the magnitude of adjustment to an institution's total score that would be necessary to bring its total score into better alignment with institutions with similar risk profiles.

2. Are there additional guidelines that should govern the analytical process to ensure fairness and consistency in deposit insurance pricing determinations?

3. What qualitative information should the FDIC use to best evaluate loss severity?

4. Are the proposed guidelines for controlling the assessment rate adjustment process sufficient to ensure that adjustment decisions are justified, fully supported, and take into account the views of the primary Federal regulator and the institution?

VI. Paperwork Reduction Act

A. Request for Comment on Proposed Information Collection

In accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) the FDIC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The collection of information contained in this proposed rule is being submitted to OMB for review.

Interested parties may submit written comments to the FDIC concerning the Paperwork Reduction Act (PRA) implications of this proposal. Commenters should refer to "PRA Comments—Adjustment Guidelines" in the subject line. Comments may be submitted by any of the following methods:

- Agency Web site: *http://www.fdic.gov/regulations/laws/federal/propose.html.* Follow instructions for submitting comments on the Agency Web site.
- E-mail: *Comments@FDIC.gov.* Include "PRA Comments—Adjustment Guidelines, 3064–ADXX" in the subject line of the message.
- Mail: Gary A. Kuiper, Counsel, F–1086, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- Hand Delivery/Courier: Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.

A copy of the comments may also be submitted to the OMB desk officer for the FDIC, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

Comment is solicited on:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) The quality, utility, and clarity of the information to be collected;

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses; and

(5) Estimates of capital or start-up costs and costs of operation, maintenance, and purchases of services to provide information.

B. Proposed Information Collection

An information collection would occur when a large or highly complex insured depository institution makes a written request that the FDIC make an adjustment to its total score. An institution's request for adjustment would be considered only if it is supported by evidence of a material risk or risk-mitigating factor that is not adequately accounted for in the scorecard.

Respondents: Large and Highly Complex insured depository institutions.

Number of responses: 0–11 per year.

Frequency of response: Occasional.

Average number of hours to prepare a response: 8 hours.

Total annual burden: 0–88 hours.

Dated at Washington, DC, this 12th day of April 2011.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2011–9209 Filed 4–14–11; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 329 and 330

RIN 3064–AD78

Interest on Deposits; Deposit Insurance Coverage

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking (NPR) and request for comment.

SUMMARY: Effective July 21, 2011, the statutory prohibition against the payment of interest on demand deposits will be repealed pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (the DFA).[1] In light of this, the FDIC proposes to rescind regulations that have implemented this prohibition with respect to state-chartered nonmember (SNM) banks. Because the regulations include a definition of "interest" that may assist the FDIC in interpreting a recent statutory amendment that provides temporary, unlimited deposit insurance coverage for noninterest-bearing transaction accounts, the FDIC also proposes to retain and move the definition of "interest" into the deposit insurance regulations.

DATES: Comments must be received on or before May 16, 2011.

ADDRESSES: You may submit comments on the notice of proposed rulemaking, identified by RIN number and the words "Interest on Deposits; Deposit Insurance Coverage NPRM," by any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal/propose.html.* Follow the instructions for submitting comments on the Agency Web site.
- *E-mail: Comments@fdic.gov.* Include the RIN number in the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, *Attention:* Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.
- *Instructions:* All submissions received must include the agency name and RIN for this rulemaking.
- *Public Inspection:* All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/propose.html* including any personal information provided. Paper copies of public comments may be ordered from the Public Information Center by telephone at 1–877–275–3342 or 703–562–2200.

FOR FURTHER INFORMATION CONTACT: Martin Becker, Senior Consumer Affairs Specialist, Division of Consumer and Depositor Protection (703) 254–2233, Mark Mellon, Counsel, Legal Division, (202) 898–3884, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

[1] Public Law 111–203, 124 Stat. 1376.

SUPPLEMENTARY INFORMATION:

I. Background

Section 343 of the DFA amended section 11(a)(1) of the Federal Deposit Insurance Act, 12 U.S.C. 1821(a)(1), to provide full insurance coverage for depository institution noninterest-bearing transaction accounts from December 31, 2010, through December 31, 2012. Section 627 of the DFA repealed the statutory prohibition against the payment of interest on demand deposits, effective one year from the date of the DFA's enactment, July 21, 2011.

In light of the prospective repeal of the demand deposit interest prohibition, the FDIC proposes to rescind 12 CFR Part 329, the regulation which implements that prohibition with respect to SNM banks, to be effective on the same date as the statutory repeal, July 21, 2011. At the same time, however, a regulatory definition of the term "interest" will still be useful in interpreting the requirements of section 343 of the DFA providing temporary, unlimited deposit insurance coverage for noninterest-bearing transaction accounts. For this reason, the FDIC proposes, as part of this same rulemaking, to transfer the definition of "interest" currently found at 12 CFR 329.1(c) to Part 330, specifically the definitions section at 12 CFR 330.1. The FDIC also specifically solicits comment on whether other parts of Part 329 could also prove useful and therefore should be moved into Part 330 as well. For example, section 329.103 provides an interpretive rule that defines what constitutes a "premium" which may prove useful in determining whether an account qualifies as a noninterest-bearing transaction account. The FDIC seeks comment on every aspect of this proposed rule.

II. Regulatory Analysis and Procedure

A. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, 1471 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. We invite your comments on how to make this proposal easier to understand. For example:

- Have we organized the material to suit your needs? If not, how could this material be better organized?
- Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be more clearly stated?
- Does the proposed regulation contain language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes to the format would make the regulation easier to understand?
- What else could we do to make the regulation easier to understand?

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that each federal agency either certify that a proposed rule would not, if adopted in final form, have a significant economic impact on a substantial number of small entities or prepare an initial regulatory flexibility analysis of the rule and publish the analysis for comment. For purposes of the RFA analysis or certification, financial institutions with total assets of $175 million or less are considered to be "small entities." The FDIC hereby certifies pursuant to 5 U.S.C. 605(b) that the NPR, if adopted, will not have a significant economic impact on a substantial number of small entities. This is because the FDIC already applies the Part 329 definition of "interest" for purposes of determining whether an account qualifies for full deposit insurance coverage as a noninterest-bearing transaction account. The FDIC is only proposing to transfer the definition from Part 329 to Part 330 because the former regulation will become moot on July 21, 2011, pursuant to section 627 of the DFA and its repeal of the statutory ban on the payment of interest on demand deposits. There will therefore be no significant economic impact on a substantial number of small entities as a result of this change.

C. Paperwork Reduction Act

No collections of information pursuant to the Paperwork Reduction Act (44 U.S.C. Ch. 3501 *et seq.*) are contained in the proposed rule.

D. The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The FDIC has determined that the proposed rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 ().

List of Subjects

12 CFR Part 329

Banks, banking, interest rates.

12 CFR Part 330

Bank deposit insurance, Banks, Banking, Reporting and recordkeeping requirements, Savings and loan associations, Trusts and trustees.

For the reasons set forth in the preamble, and under the authority of 12 U.S.C. 1813, the FDIC proposes to amend chapter III of title 12 of the Code of Federal Regulations as follows:

PART 329—[REMOVED]

1. Part 329 is removed and reserved.

PART 330—DEPOSIT INSURANCE COVERAGE

2. The authority for part 330 continues to read as follows: 12 U.S.C. 1813(*l*), 1813(m), 1817(i), 1818(q), 1819(Tenth), 1820(f), 1821(a), 1822(c).

3. In § 330.1, paragraphs (k) through (r) are redesignated as paragraphs (l) through (s), respectively, and new paragraph (k) is added to read as follows:

§ 330.1 Definitions.

* * * * *

(k) *Interest,* with respect to a deposit, means any payment to or for the account of any depositor as compensation for the use of funds constituting a deposit. A bank's absorption of expenses incident to providing a normal banking function or its forbearance from charging a fee in connection with such a service is not considered a payment of interest.

* * * * *

By order of the Board of Directors.

Dated at Washington, DC, this 12th day of April 2011.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2011–9210 Filed 4–14–11; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0070; Airspace Docket No. 10–ASO–43]

Proposed Amendment of Class E Airspace; Cocoa, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E Airspace at Cocoa, FL, as

the Merritt Island Non-Directional Beacon (NDB) has been decommissioned and new Standard Instrument Approach Procedures have been developed at Merritt Island Airport. This action would enhance the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before May 31, 2011.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Ave., SE., Washington, DC 20590–0001; *Telephone:* 1–800–647–5527; *Fax:* 202–493–2251. You must identify the Docket Number FAA–2011–0070; Airspace Docket No. 10–ASO–43, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on this rule by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2011–0070; Airspace Docket No. 10–ASO–43) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Annotators wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2011–0070; Airspace Docket No. 10–ASO–43." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (*see* the **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, Georgia 30337.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet above the surface to support new standard instrument approach procedures developed at Merritt Island Airport, Cocoa, FL. Airspace reconfiguration is necessary due to the decommissioning of the Merritt Island NDB and cancellation of the NDB approach, and for continued safety and management of IFR operations at the airport.

Class E airspace designations are published in Paragraph 6005 of FAA order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This proposed rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This proposed regulation is within the scope of that authority as it would amend Class E airspace at Merritt Island Airport, Cocoa, FL.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASO FL E5 Cocoa, FL [Amended]

Merritt Island Airport, FL
(Lat. 28°20′30″ N., long. 80°41′08″ W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Merritt Island Airport and within 2.5 miles each side of the 303° bearing from the Merritt Island Airport, extending from the 6.3-mile radius to 7 miles northwest of the airport; excluding that airspace within the Titusville, FL, and Melbourne, FL, Class E airspace areas.

Issued in College Park, Georgia, on April 6, 2011.

Mark D. Ward,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2011–9223 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

Docket No. FAA–2010–0987; Airspace Docket No. 10–ANM–14

Proposed Establishment of Class E Airspace; Lincoln, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Lincoln, OR. Controlled airspace is necessary to accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Samaritan North Lincoln Hospital Heliport, Lincoln, OR. The FAA is proposing this action to enhance the safety and management of aircraft operations at the heliport.

DATES: Comments must be received on or before May 31, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2010–0987; Airspace Docket No. 10–ANM–14, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2010–0987 and Airspace Docket No. 10–ANM–14) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2010–0987 and Airspace Docket No. 10–ANM–14". The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (*see* the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 to establish Class E airspace extending upward from 700 feet or more above the surface at Samaritan North Lincoln Hospital Heliport, Lincoln, OR. Controlled airspace is necessary to accommodate aircraft using the new RNAV (GPS) standard instrument approach procedures at Samaritan North Lincoln Hospital Heliport. This action would enhance the safety and management of aircraft operations at Samaritan North Lincoln Hospital Heliport, Lincoln, OR.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR Part 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1,

Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes additional controlled airspace at Samaritan North Lincoln Hospital Heliport, Lincoln, OR.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Lincoln, OR [New]

Samaritan North Lincoln Hospital Heliport, OR

(Lat. 44°59′11″ N., long. 123°59′39″ W.)

That airspace extending upward from 700 feet above the surface within 3-mile radius of Samaritan North Lincoln Hospital Heliport.

Issued in Seattle, Washington, on April 7, 2011.

Christine Mellon,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–9225 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–0986; Airspace Docket No. 10–ANM–13]

Proposed Establishment of Class E Airspace; Florence, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Florence Municipal Airport, Florence, OR. Controlled airspace is necessary to accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Florence Municipal Airport, Florence, OR. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport.

DATES: Comments must be received on or before May 31, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2010–0986; Airspace Docket No. 10–ANM–13, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2010–0986 and Airspace Docket No. 10–ANM–13) and be submitted in triplicate to the Docket Management System (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2010–0986 and Airspace Docket No. 10–ANM–13". The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov/airports_airtraffic/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace extending upward from 700 feet or more above the surface at

Florence Municipal Airport, Florence, OR. Controlled airspace is necessary to accommodate aircraft using the new RNAV (GPS) standard instrument approach procedures at Florence Municipal Airport, Florence, OR. This action would enhance the safety and management of aircraft operations at Florence Municipal Airport, Florence, OR.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes controlled airspace at Florence Municipal Airport, Florence, OR.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Florence, OR [New]

Florence Municipal Airport, OR
(Lat. 43°58′58″ N., long. 124°06′41″ W.)

That airspace extending upward from 700 feet above the surface within 3-mile radius of Florence Municipal Airport.

Issued in Seattle, Washington, on April 7, 2011.

Christine Mellon,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011–9233 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA–2011–0367]

Interpretation of Duty and Rest Provisions for Maintenance Personnel

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed interpretation.

SUMMARY: This draft letter of interpretation addresses a request by the Aeronautical Repair Station Association (ARSA) to rescind a letter of interpretation issued May 18, 2010 which clarified what activities may constitute duty for maintenance personnel and the application of the rest provisions under 14 CFR 121.377. The FAA requests comment on the May 18, 2010 proposed response to United Technologies Corporation.

DATES: Send your comments on or before June 14, 2011.

ADDRESSES: You may send comments identified by Docket Number FAA–2011–0367 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://DocketsInfo.dot.gov.*

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time and follow the online instructions for accessing the docket or Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Anne Bechdolt, Attorney, Regulations Division, Office of Chief Counsel (AGC–220), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, 20591; e-mail: *Anne.Bechdolt@faa.gov;* telephone 202–267–3073.

SUPPLEMENTARY INFORMATION: On December 13, 2010, ARSA requested the FAA withdraw a legal interpretation issued on May 18, 2010 to United

Technologies Corporation (May 18, 2010 interpretation). The legal interpretation addressed what types of activities may be considered part of the duty period for maintenance personnel under § 121.377. In addition, the legal interpretation provided that the FAA would not consider compliant a work schedule in which maintenance personnel were required to work several consecutive weeks without an uninterrupted, consecutive 24-hour rest period during any seven consecutive days. This interpretation clarifies the limitations of the equivalency standard in § 121.377 resulting from two conflicting legal interpretations. *Compare* Legal Interpretation 1987–15 (June 14, 1987) (noting that the flexibility in § 121.377 was intended to apply only in cases of national emergency or unusual occurrence in the air carrier industry) *with* Legal Interpretation to Ron Webb from Donald P. Byrne, Assistant Chief Counsel, Regulations (June 21, 1991) (noting that "the term "or equivalent thereof" allows for time off (in 24 consecutive hour increments) to be deferred or accumulated, making it possible to take four 24 hour periods off toward the end of a calendar month"). ARSA asserts that the May 18, 2010 interpretation changes the plain language of the regulation and requests that it be withdrawn. The FAA has decided against withdrawing the May 18, 2010 interpretation at this time. However, based on ARSA's request, the agency has decided to seek comment on the impact of the interpretation. Based on a review of the comments, the FAA may decide to modify or rescind the May 18, 2010 interpretation.

The FAA believes that this type of schedule (*i.e.,* working 26 days followed by 4 days off) is contrary to the intent of the regulation, which was designed to mitigate the effects of fatigue for maintenance personnel. Fatigue degrades a person's ability to work effectively. Some causes of fatigue are sleep deprivation and time spent on duty. *See* Advisory Circular AC 120–72, *Maintenance Resource Management Training,* (Sept. 28, 2000). Given that § 121.377 places no limit on the amount of time maintenance personnel may work, it may be possible for these personnel to work consecutive 8, 12, or 16-hour shifts. This type of schedule, combined with delaying rest periods until the end of the month, may result in reduced reaction time, impaired short-term memory, decreased vigilance, reduced motivation, increased irritability, and an increase in the number of errors made for maintenance personnel. In light of these factors, the allowance for some flexibility in scheduling the 24-hour consecutive rest period required by § 121.377 is not without limitation. Thus, a schedule that delays providing the requisite rest under § 121.377 until the end of the calendar month, such that the exception in § 121.377 becomes the normal practice, would not be considered compliant with the rest requirements of 14 CFR 121.377. The text of the May 18, 2010 interpretation is as follows:

Alexandra M. McHugh,

Assistant Counsel.

United Technologies Corporation, Pratt & Whitney Legal Services, 400 Main Street, M/S 132–12, East Hartford, CT 06108

Dear Ms. McHugh: This is in response to Pratt & Whitney's letter of May 19, 2008, concerning the application of § 121.377 to maintenance personnel at Pratt's repair facility certified under Part 145 of the Federal Aviation Regulations. Based on the several factual scenarios contained in the letter and subsequent conversations between Pratt and my office, I have organized this response into three general issues. The first deals with whether Pratt can view as non-duty time the time an employee spends completing non-maintenance work or tasks while being compensated by Pratt, even while away from Pratt's facility. The second explores the extent to which Pratt may view as non-duty time the time an employee spends at other employment while off duty from Pratt, even if it is aviation related work. The last issue concerns the limit of scheduling flexibility provided by the regulation. I believe you will be able to apply the answers to these three questions to all of the specific scenarios you posited in your letter.

For repair stations certificated under Part 145 that perform maintenance work for air carriers operating under Part 121, § 121.377 establishes a maximum duty period for maintenance personnel working for that repair station. That section reads:

Within the United States, each certificate holder (or person performing maintenance or preventive maintenance functions for it) shall relieve each person performing maintenance or preventive maintenance from duty for a period of at least 24 consecutive hours during any seven consecutive days, or the equivalent thereof within any one calendar month.

14 CFR § 121.377. Thus, generally, maintenance personnel must be allowed 24 consecutive hours of rest during any seven consecutive days. In the context of discussing Maintenance Resource Management concepts, the FAA has stated in Advisory Circular (AC) 120–72 (September 28, 2000) that addressing fatigue-related errors ensures the safety of flight in passenger carrying operations. Fatigue often leads to decreased vigilance and impaired short term memory, resulting in a likely increase in human error. A common known cause of fatigue is "time on duty." AC 120–72, para. 9(h)(2)(f). Therefore, the general rule in § 121.377 is intended to reduce the likelihood of fatigue-related maintenance errors in air carrier operations.

Section 121.377 requires that a person performing maintenance or preventative maintenance be relieved from "duty" for, generally, one day out of every seven. One question, then, is what is considered "duty." In other contexts, the FAA has defined duty as "actual work for the [employer] or the present responsibility for such should the occasion arise." *See* Legal Interpretation 1993–31 (Dec. 13, 1993). Prior interpretations have concluded that performing a mix of tasks, some of which do not involve work for a Part 121 air carrier or even non-aviation related tasks, but are tasks assigned to the employee by the employer, still fall within the category of "duty" for purposes of applying § 121.377. Legal Interpretation to Ron Webb from Donald P. Byrne, Assistant Chief Counsel, Regulations (June 21, 1991); *cf.* Legal Interpretation to Jim Mayors from Rebecca B. MacPherson, Assistant Chief Counsel for Regulations (Mar. 2, 2009) (noting that the time a pilot participated in a 2-hour company meeting that was not related to a company assignment of flight time, must still be calculated as part of his duty day because he was not free from all work obligations during that time); Legal Interpretation to Jay Wells from Rebecca MacPherson, Assistant Chief Counsel, Regulations Division (October 29, 2007); Legal Interpretation to James W. Johnson from Donald P. Byrne, Assistant Chief Counsel for Regulations (May 9, 2003).

Therefore, for purposes of applying § 121.377, any time for which an employee "has actual work for the employer, or the present responsibility for such work, should it arise," constitutes "duty" time. Accordingly, the time an employee is engaged in maintenance tasks, attending a bargaining unit meeting, attending a training session, doing work related to Pratt's educational benefit, traveling from the point on Pratt's campus where the employee "clocked in" to the employee's work area, or working for another unit within Pratt's corporate

umbrella, constitutes time that must be included in the calculation of duty time to determine the rest required under § 121.377, whether or not that unit itself must adhere to the requirements of § 121.377. An employee using accrued vacation or credit time is not "on duty" even though the employee may receive compensation for that time. Nevertheless, the regulation aims to require repair stations to give its maintenance personnel at least one day off every week without requiring that employee to use accrued vacation time to be free from any responsibility for work.

Once Pratt relieves the employee from duty, the regulation does not require Pratt to monitor the employee's activities. The scenario where an employee uses the time off from Pratt to work at another maintenance facility does not implicate Pratt's compliance with § 121.377. Unlike the regulations governing crewmember duty time, § 121.377 does not contain a limit on an employee's total accumulated working hours within a specified period of time. The FAA does not recommend this practice, however, for the reasons discussed in AC 120–72 related to fatigue. Thus, an employee relieved from duty by Pratt may perform other aviation related maintenance, even for other facilities which themselves are bound by § 121.377, provided the employee is provided the requisite time off by each facility for which the employee works. Pratt must use caution, however, not to create the appearance of requiring an employee to work during off hours for another facility that is just a corporate sister to the Pratt facility.

You also raise the question of whether a facility can schedule employees to work more than six consecutive days, thereby grouping required days off, and still remain in compliance with § 121.377. The regulatory standard requires 24 consecutive hours off duty during any seven consecutive days but also contains some flexibility in the phrase "or the equivalent thereof within any one calendar month." The FAA intended that the regulation allow employees to work in excess of six consecutive days in the event of a national emergency or unusual occurrence in the air carrier industry. *See* Legal Interpretation 1987–15 (June 14, 1987). The regulatory flexibility found in § 121.377 allows maintenance personnel to work a schedule that maintains the "equivalent" to one day off every week even though that schedule might provide for more than six consecutive days of work.

The equivalent standard, however, does have limits. The tenants of statutory and regulatory interpretation suggest that the specific standard of one day off every week cannot be rendered completely inoperative by the more general equivalent standard. A previous interpretation allowed that a work schedule that provides for personnel to have a group of 4 days off followed by up to 24 days of work, or vice versa, would still meet the standard of being "equivalent" to one day off in every seven within a month. Legal Interpretation to Ron Webb from Donald P. Byrne, Assistant Chief Counsel, Regulations (June 21, 1991). That interpretation, however, was issued prior to the findings relating fatigue to maintenance related errors in the air carrier industry discussed in AC 120–72. Webster's dictionary defines "equivalent" as having logical equivalence, or corresponding or virtually identical in effect or function. Today, we would not view as compliant a schedule that provides over the course of eight weeks for four days off followed by 48 straight days of duty followed by four more days off. Such a work schedule that generally provides for an average of one day off over several weeks cannot be said to be "equivalent" to the more specific standard requiring one day off out of every seven days.

Lastly, you correctly note that the regulation does not address the length of the work day, only the length of the required time off work. The legal interpretation from Mr. Byrne to Mr. Webb also makes clear that the general equivalency provision in § 121.377 does not apply to the specific requirement to give 24 consecutive hours of time off. Time off may not be provided in smaller increments over several days even though the total time off over any seven day period may equal or exceed 24 hours.

We appreciate your patience and trust that the above responds to your concerns. If you need further assistance, please contact my staff at (202) 267–3073. This response was prepared by Anne Bechdolt, Attorney in the Operations Law Branch of the Regulations Division of the Office of the Chief Counsel, and coordinated with the Aircraft Maintenance and Air Transportation divisions of Flight Standards Service.

Rebecca B. MacPherson,
Assistant Chief Counsel, Regulations Division

[FR Doc. 2011–9236 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 294

RIN 0596–AC74

Special Areas; Roadless Area Conservation; Applicability to the National Forests in Colorado

AGENCY: Forest Service, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Forest Service, U.S. Department of Agriculture (USDA), is proposing to establish a State-specific rule to provide management direction for conserving and managing inventoried roadless areas on National Forest System (NFS) lands in Colorado. A proposed rule was published in the July 25, 2008, **Federal Register**. In response to public comment on the 2008 Proposed Rule and a revised petition submitted by the State of Colorado on April 6, 2010, the Forest Service is publishing a new proposed rule.

The Agency is inviting public comment on this new proposed rule and accompanying revised draft environmental impact statement (RDEIS). The Agency is interested in public comments on the changes to exceptions and prohibitions on activities in roadless areas that have been developed in response to public comments on the 2008 Proposed Rule. The Agency is particularly interested in receiving public comments on the concept, management, and rationale for designation of specific areas within Colorado Roadless Areas identified as "upper tier." In this proposed rule, these areas are provided a higher level of protection than the 2001 Roadless Rule,

DATES: Comments must be received in writing by July 14, 2011.

ADDRESSES: Comments may be sent via e-mail to *COComments@fsroadless.org.* Comments may also be submitted via the Internet at *http://www.regulations.gov.* Written comments concerning this notice should be addressed to: Colorado Roadless Rule/EIS, P.O. Box 1919, Sacramento, CA 95812.

All comments, including names and addresses, are placed in the record and are available for public inspection and copying. The public may inspect comments received at *http://roadless.fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Colorado Roadless Rule Team Leader Ken Tu at (303) 275–5156. Individuals using telecommunication devices for the deaf (TDD) may call the Federal

Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

As a leader in natural resource conservation, the Forest Service provides direction for the management and use of the Nation's forests, rangeland, and aquatic ecosystems under its jurisdiction. Similarly, the State of Colorado is committed to sustained natural resource use and conservation of State and Federal land within its borders. Furthermore, the Forest Service is charged to collaborate cooperatively with States and other interested parties regarding the use and management of the National Forest System (NFS).

Colorado's Roadless Areas are of great importance to the people of Colorado and the Nation. These magnificent landscapes provide a variety of resources and open space opportunities for all Americans. They provide the setting and backdrop for recreational experiences of all kinds, including non-motorized and/or motorized recreational trail use. They are sources of clean and safe public drinking water. They contain intact habitat for species dependent on large, undisturbed areas of land. The scenic quality of these naturally appearing landscapes is among the highest in the Nation. These areas serve as bulwarks against the spread of non-native invasive plant species and provide reference areas for study and research. The USDA, Forest Service, and State consider these areas an important component of the NFS and are committed to the conservation and protection of Colorado Roadless Areas (CRAs).

The unique perspectives and knowledge provided by the State and the public was of great assistance throughout the development of this proposed rule. Many of the CRAs form the setting and backdrop for Colorado communities and have become part of their identity. These areas help provide a high quality of life for local residents. They are also the backdrop for world-class skiing, hunting and fishing, and backcountry experiences for non-residents. Local communities are sensitive to the economic consequences of Federal land management, whether for tourism or other purposes.

The new proposed rule addresses both local and national interests in the management of Colorado Roadless Areas. Recommendations from the USDA Secretary's Roadless Area Conservation National Advisory Committee (RACNAC) and public comment on the 2008 Proposed Rule both provided a national perspective. The RACNAC was specifically designed as an advisory committee composed of national interests to provide a national perspective, and it no longer exists. The vast majority of respondents to the 2008 Proposed Rule expressed a desire for a rule that protects roadless area characteristics now and for future generations. However, some respondents suggested alternative, less restrictive roadless regulations. This proposed rule includes prohibitions on tree-cutting, sale, or removal; road construction/reconstruction; and linear construction zones, all with limited exceptions tailored to address specific issues. This proposed rule requires, in many cases, the Regional Forester to make specific determinations prior to authorizing exceptions.

In this proposed rule, substantially altered acres have been removed from the roadless inventory and new acres with high level of roadless characteristics have been added. In the standard tier, 20,000 acres are in the North Fork coal mining area, where there is an exception for temporary roads for underground coal activities such as methane drainage wells. Existing ski areas (8,300 acres) have been removed from the roadless inventory, although only 1,700 acres would be currently restricted by the 2001 Rule due to the fact that there are existing permits on the other 6,600 ski area acres.

Linear construction zones are prohibited with some exceptions. There is no prohibition of linear construction zones in the 2001 Rule.

In the proposed rule, there are exceptions for temporary roads for fuels treatment and for ecosystem maintenance and restoration, but these are restricted to locations within one half mile of communities. Road construction for these purposes is not allowed in the 2001 Rule. There is an exception for roads for authorized water conveyance structures operated according to a State water court decree in existence at the time of the promulgation of the final rule. There is no exception for roads for water conveyance structures in the 2001 Rule.

In the proposed rule, the tree cutting exceptions for fuel treatment and ecosystem maintenance and restoration are restricted spatially in this proposed rule to a maximum of one and a half miles from communities. The only condition in which tree cutting could occur outside the community protection zone (CPZ) requires a Regional Forester determination that there is a significant risk from wildfire to a municipal water supply system. The 2001 Rule exception for ecosystem maintenance and restoration allows tree cutting anywhere within roadless areas.

In the proposed rule, an upper tier of protection has been designated with fewer exceptions than the 2001 Rule for road construction and reconstruction and tree cutting. Exceptions are not allowed for road reconstruction and realignment, and temporary roads for public health and safety. The 2001 Rule tree-cutting exceptions for maintenance and restoration of ecosystem characteristics, and for habitat improvement for endangered, threatened or sensitive species are not allowed in the upper tier of the proposed rule.

State of Colorado Petitions

On July 14, 2005, the State of Colorado announced it would submit a petition requesting specific regulatory protections for the inventoried roadless areas within the State. The State's commitment to participate was evidenced by Colorado Senate Bill 05–243, the Roadless Areas Review Task Force legislation signed into Colorado law on June 8, 2005. The law identified membership and responsibilities of a 13-member bipartisan task force to make recommendations to the Governor regarding inventoried roadless areas in Colorado. The law also identified the Federal 2001 Roadless Area Conservation Rule (2001 Roadless Rule) as the starting point for the task force. The task force held nine public meetings throughout the State, reviewed and considered over 40,000 public comments, and conducted a comprehensive review of Colorado's 4.4 million acres of inventoried roadless areas included in the 2001 Roadless Rule.

Colorado's petition (2006 Petition) was submitted by then-Governor Owens on November 13, 2006, to the Secretary of Agriculture for consideration under section 553(e) of the Administrative Procedure Act and USDA regulations at 7 CFR 1.28. On April 11, 2007, Governor Ritter resubmitted the 2006 petition with additions (2007 Petition). After reviewing the recommendation from the RACNAC, the Secretary of Agriculture accepted the 2007 Petition on August 24, 2007, and directed the Forest Service to initiate rulemaking based on the petition. The State of Colorado was granted cooperating agency status for purposes of compliance with the National Environmental Policy Act (NEPA) pursuant to 40 CFR 1501.6 of the Council on Environmental Quality regulations in a memorandum of

understanding dated January 8, 2008. A notice of intent (NOI) to prepare an environmental impact statement (EIS) was published in the **Federal Register** on December 26, 2007 (72 FR 72982). The public comment period ended on February 25, 2008. The Forest Service received about 88,000 responses.

On July 25, 2008, the Forest Service published the 2008 Proposed Rule to establish State-specific management direction for conserving roadless areas on NFS land in Colorado in the **Federal Register** (73 FR 43544). A notice of availability for the draft EIS was published in the **Federal Register** on August 1, 2008 (73 FR 44991). The availability of the regulatory risk assessment for the 2008 Proposed Rule was published in the **Federal Register** on September 18, 2008 (73 FR 54125). The comment period for all three documents closed on October 23, 2008.

Information applying to the 2008 Proposed Rule was provided to the Ute Mountain Ute and Southern Ute Indian Tribes, located in Colorado, prior to the release of the NOI. An introductory letter, the NOI, background information on the 2008 Proposed Rule, and an offer for additional information or meetings were sent to the Tribes. The 2008 Proposed Rule and DEIS were sent to each Tribe and each was contacted by phone to determine interest in meeting or obtaining information. The Tribes did not request additional government to government involvement, and no formal comments from any of the Tribes were received. A letter was sent to the Tribes with a draft version of this revised proposed rule and the Forest Service met with those Tribes requesting further consultation. In accordance with Executive Order 13175, consultation efforts will continue throughout the process and preparation of a final Rule.

As a result of its July, August, and September 2008 notices, the Forest Service received approximately 106,000 responses of which 105,000 were form letters. Responses included advocacy for a particular outcome or for specific regulatory language, and calls for compliance with laws and regulations. Some responses contained suggestions on further analyses and changes to issues, alternatives, and CRA boundaries.

The RACNAC held public meetings in Washington, DC, and Salt Lake City, Utah, and submitted recommendations to the Secretary of Agriculture on December 5, 2008, to be considered in the development of the rule.

Throughout the public involvement process, the USDA, Forest Service, and State repeatedly heard comments requesting a reduction in the scope of the Colorado State Petition's proposed exceptions for tree-cutting, sale, or removal and road construction and reconstruction. Based on the comments, the State requested the USDA postpone further rulemaking efforts until the State considered revision of its 2007 Petition.

On August 3, 2009, the State of Colorado released a proposed revision of rule language to be used for its formulation of a revised petition to the public. The State received approximately 22,000 comments during the 60-day comment period, the majority of which were form letters. The State considered the public comments and submitted a revised petition to the Secretary on April 6, 2010 (2010 Petition).

Upon receipt of the revised petition and consideration of the public comments submitted on the petition, Secretary of Agriculture Thomas J. Vilsack instructed the Forest Service to "analyze the potential of adding substantially to the number of acres receiving a higher level of protection" (upper tier lands) than the 2001 Roadless Rule. The 2010 Petition contained 257,000 upper tier acres. Based on the Secretary's direction, acres were added such that there are now 562,200 upper tier acres in this proposed rule. These areas were selected to become upper tier based on their roadless characteristics, and that they were already designated for higher levels of protection in either draft or final forest plans.

The Forest Service analyzed four alternatives for managing roadless areas in this RDEIS. Alternative 1 uses provisions of the 2001 Roadless Rule and applies them to the 2001 roadless area inventory. Alternative 2 is the proposed rule, applies the rule to inventoried Colorado Roadless Areas, and includes 562,200 acres in the upper tier. Alternative 3 uses forest plan direction to manage roadless areas, and alternative 4 uses the proposed rule direction, applies the direction to Colorado Roadless Areas, and includes approximately 2.6 million acres of upper tier. The RDEIS may be found at *http://roadless.fs.fed.us.* Following Secretarial instructions, as well as reviewing public comments received to date, and the RACNAC recommendations, the Forest Service in consultation with the State, made additional adjustments and clarifications to this proposed rule.

Roadless Area Inventories in Colorado

Finally, the proposed rule includes an updated inventory of roadless areas. The 2007 State Petition proposed using the inventories used in the 2001 Roadless Rule. In some cases, these were based on inventories from the late 70s. Those inventories used mapping technologies that are now outdated, and also roads had been constructed between the time of the original inventories and their use in the 2001 Roadless Rule. The Forest Service has reviewed and updated the 2001 inventories for the purpose of this rulemaking; making technical corrections, removing private property and making other boundary adjustments, including additions and deletions due to land exchanges. Newly congressionally-designated areas have also been removed from the CRA inventory.

During the public comment period on the 2008 Proposed Rule, comments were received on many of the boundaries of individual CRAs. The Forest Service and Colorado Department of Wildlife field staff worked jointly to identify corrections to the inventories used for the 2008 Proposed Rule. Further information on the boundary changes and a description of the uniqueness of each CRA can be found at *http://roadless.fs.fed.us.*

CRA boundaries have been adjusted where they overlap with ski areas that have special use authorizations or land use management plan allocations for ski areas that allow road construction.

PROPOSED NET CHANGE IN ROADLESS ACRES DESIGNATIONS BY FOREST—INVENTORIED ROADLESS AREA ACRES TO COLORADO ROADLESS AREA ACRES

	2001 rule total IRA acres	Corrected Colorado IRA acres [1]	Corrected IRA acres not included within Colorado roadless areas	Roadless acres added to Colorado roadless areas	Total roadless acres to be managed under Colorado rule	Proposed net change
Region 2 Colorado						
Arapaho-Roosevelt	391,000	352,500	10,800	5,400	347,100	(5,400)
GMUG	1,127,000	1,058,300	280,800	124,200	901,900	(156,500)
Pike San Isabel	688,000	667,300	63,000	170,300	774,600	107,300
Rio Grande	530,000	529,000	14,300	3,800	518,500	(10,500)
Routt	442,000	442,300	10,300	1,700	433,700	(8,600)
San Juan	604,000	543,600	76,600	98,900	565,900	22,300
White River	640,000	639,500	7,500	4,700	636,700	(2,800)
Region 4 Colorado						
Manti La Sal	11,000	11,000	3,800	500	7,700	(3,300)
TOTAL STATE of COLORADO	4,433,000	4,243,600	467,100	409,500	4,186,000	(57,600)

Column 1 acres rounded to nearest 1,000 acres; others rounded to nearest 100 acres. Totals may not add due to rounding.
[1] Net acres after technical corrections to 2001 rule IRA map acres.

Land Management Planning Efforts

The Agency is continuing land management planning efforts at the national level as well on several forests in Colorado concurrent with this rulemaking. The Rocky Mountain Region is presently conducting a revision of the San Juan National Forest land management plan and the revision schedule may be found at *http://ocs.fortlewis.edu/forestplan.* A complete schedule of plan revisions is posted at *http://www.fs.fed.us/emc/nfma/includes/LRMPschedule.pdf.* At the national level, the Agency is engaging in a revision of its land management planning regulations. Information is posted at *http://www.fs.usda.gov/planningrule.* Some provisions of this proposed rule use terminology and concepts from existing plans and planning regulations (*e.g.* "sensitive species"). The use of such terminology is potentially subject to adjustment.

Specific Request for Public Comment

The Agency is particularly interested in receiving public input regarding specific areas within the CRAs that should or should not be included in the upper tier lands including the reason for the inclusion or exclusion (see RDEIS, Appendix B and map packet); and what exceptions to the prohibitions on tree-cutting, sale, or removal, and road construction/reconstruction should apply to upper tier lands. In addition, the Agency is interested in receiving comments on effective means of managing linear facilities, such as electric power lines and telecommunications lines, within roadless areas in context of this proposed rule.

Section by Section Highlights of Changes From the July 2008 Proposed Rule

This proposed rule replaces the proposed rule published in July 2008. The section numbers of this proposed rule do not correspond with the numbering used in the 2008 Proposed Rule. Minor changes, edits, or corrections are not discussed.

Section 294.40 Purpose

The purpose remains to provide State-specific direction for the protection of roadless areas on NFS land in Colorado that sustains roadless area characteristics now and for future generations.

Section 294.41 Definitions

Several terms have been added for clarification and some terms have been removed where no longer needed.

The term *at-risk community* as defined in section 101 of the Healthy Forest Restoration Act (HFRA) has been added.

The term *Colorado Roadless Area upper tier acres* has been added. These are specific portions of or entire CRAs identified in the set of CRA maps. The proposed rule prohibits all tree-cutting, sale, or removal on these acres, except where incidental to the implementation of a management activity not otherwise prohibited by the rule, or as needed and appropriate for personal or administrative use. The proposed rule would prohibit all road construction or reconstruction on these lands, except where needed pursuant to reserved or outstanding rights or as provided for by statute or treaty. All 562,200 acres analyzed in alternative 2 of the RDEIS are part of the preferred alternative (proposed rule).

The term *Wildland Urban Interface* (WUI) is removed and replaced by the term *Community Protection Zone* (CPZ). A CPZ is defined as either an area one-half mile from the boundary of an at-risk community or an area up to 1½ miles from the boundary of an at-risk community where: the land has a sustained steep slope that creates the potential for wildfire behavior endangering the at-risk community; or has a geographic feature that aids in creating an effective fire break, such as a river or a ridge top; or where the trees are in condition class 3 as defined by the HFRA. The CPZ is measured from the boundary of the at-risk community and not from the boundary of the CRA.

The term *hazardous fuels* has been added. Hazardous fuels are defined as excessive live or dead wildland fuel accumulations that increase the potential for intense wildland fire and decrease the capability to protect life, property and other resources.

The term *roadless area characteristics* has been retained, but modified from the definition offered in the 2008 Proposed Rule. The 2008 definition indicated that the enumeration of the various resources and features was not intended to constitute in any way the establishment of any legal standard, requirement, or cause for any administrative appeal or legal action related to any project or activity

otherwise authorized by this rule. The 2010 State Petition recommended removing that language from the definition and inserting interpretive language in the scope and applicability section of the regulation. The proposed rule states in § 294.40 that the intent of this regulation is to protect roadless areas. Activities must be designed to conserve the roadless area characteristics listed in § 294.41, although the proposed rule acknowledges that applying the exceptions in § 294.42, § 294.43, and § 294.44 may have effects to some roadless area characteristics.

The terms *catchment, native cutthroat trout,* and *water influence zone* have been added to describe requirements that provide additional protection for native cutthroat trout species when a road construction/reconstruction or linear construction zone exception is authorized.

The term *linear construction zone* has been added.

The term *utility* has been removed, and replaced by *linear facility* which includes pipelines, electrical power lines, and telecommunication lines.

The definition for *water conveyance structures* has been modified to include reservoirs to clarify that they are included under the exception for construction, reconstruction or maintenance of roads for authorized water conveyance structures. This exception in the proposed rule applies only to those water conveyance structures operated pursuant to a water court decree existing as of the date of the final rule.

The term *Pre-existing Water Court Decree* has been defined.

Section 294.42 Prohibition on Tree-Cutting, Sale, or Removal

On lands designated as upper tier, tree-cutting, sale, or removal would be prohibited except when the Responsible Official determines that the activity is consistent with the applicable land management plan (LMP), and incidental to the implementation of a management activity not otherwise prohibited, or as needed and appropriate for personal or administrative use. Upper tier areas provide for a higher level of protection than the 2001 Roadless Rule because the exceptions in the 2001 Roadless Rule to allow tree-cutting, sale or removal for species habitat and for maintenance and restoration of ecosystem composition and structure, including the reduction of risk of uncharacteristic wildfire effects, are not applied to upper tier in this proposed rule.

On the remaining CRA lands, the proposed rule would require the Responsible Official to determine whether any proposed tree-cutting, sale, or removal project would be consistent with the applicable LMP, would maintain or improve one or more roadless area characteristic over the long-term, and would qualify as a listed exception. Tree-cutting incidental to a management activity otherwise authorized by this proposed rule or for personal or administrative use would not be required to maintain or improve one or more of the roadless area characteristics over the long-term.

The exceptions concerning tree-cutting, sale, or removal allowed to reduce fuel loadings to moderate the potential effects of a catastrophic wildland fire have been refined. The proposed rule takes into account that homes that have been constructed adjacent to Colorado's national forests and the increasing threat of fire to these at-risk communities. Treating hazardous fuels, and creating safety zones for fire crews in areas around communities can make a difference in the ability of firefighters to control wildfire moving toward an at-risk community. Such conditions have been a major consideration in developing the proposed rule language.

In Colorado, about 340 of the HFRA at-risk communities listed in the **Federal Register** (66 FR 753, January 4, 2001) are within 1½ miles of a CRA. In the period between 1980 and 2008, over 1,700 ignitions affecting over 45,000 acres occurred within roadless areas in Colorado. Over 45 percent of these ignitions and 25 percent of the acres burned were within the 1½ mile CPZ. The proposed rule allows flexible treatment prior to imminent fire activity and provides a more restrictive approach than the 2001 Rule by limiting fuel treatments to the CPZ. In addition, the proposed rule, by requiring treatment areas beyond one-half mile from an at-risk community to be identified in a Community Wildfire Protection Plan (CWPP), ensures consideration of community and practitioner knowledge about conditions in a specific area.

Within the CPZ, tree-cutting, sale, or removal may occur within the first one-half mile of a CPZ only when the Regional Forester determines it is needed to reduce the wildfire hazard to either an at-risk community or a municipal water supply system, including reservoirs and dams, diversion structures, headgates, canals, ditches, tunnels, pipelines, and other surface facilities and systems.

Within the outer one mile of the CPZ, tree-cutting, sale, or removal, if determined to be needed by the Regional Forester, may only occur in an area identified in a CWPP. The CPZ would still be the maximum boundary for allowed treatments within CRAs. If the CPZ boundary exceeds the CWPP boundary, treatments would be limited to the CWPP area.

Projects within the CPZ are to be focused on small diameter trees to create fuel conditions to modify fire behavior while retaining large trees to the maximum extent practical, as appropriate to the forest type. In forest types such as lodgepole pine, trees may be dead or dying, regardless of size, and may need to be removed, both to prevent hazards to firefighters from falling and fallen trees, and for successful hazardous fuel reduction.

Tree-cutting, sale, or removal for the protection of municipal water supply systems outside of a CPZ is allowed only if the Regional Forester determines that a significant risk exists to the municipal water supply system or the maintenance of that system. This section states that a significant risk exists under conditions in which the history of fire occurrence and fire hazard and risk indicate a serious likelihood that a wildland fire disturbance event would present a high risk of threat to a municipal water supply system.

Projects outside of the CPZ are to be focused on small diameter trees to create fuel conditions to modify fire behavior, while retaining large trees to the maximum extent practical as appropriate to the forest type. It is expected such projects will be infrequent.

The requested exception that allows tree-cutting, sale, or removal to prevent or suppress an insect or disease epidemic has been replaced with an exception that allows tree-cutting, sale, or removal to restore the characteristics of ecosystem, composition, structure and processes. This exception is intended to be used infrequently.

Tree-cutting, sale or removal for the purposes of wildlife habitat improvement is limited to Federally threatened, endangered, and proposed species or those listed as a regionally designated sensitive species by the Forest Service, instead of all wildlife and plant species as was allowed in the previously proposed rule.

Tree-cutting that is incidental to a management activity that is otherwise not prohibited by the rule is allowed. Examples include, but are not limited to, trail construction or maintenance; removal of hazard trees adjacent to forest roads for public health and safety reasons; fire line construction for wildland fire suppression or control of

prescribed fire; survey and maintenance of property boundaries; or for road construction and linear construction zones where allowed by this rule.

Tree-cutting for personal or administrative use is allowed and includes, but is not limited to, activities such as Christmas tree and firewood cutting.

Section 294.43 Prohibition on Road Construction and Reconstruction

The proposed rule revises the exceptions to the prohibitions on road construction or reconstruction from the previous proposal. Upper tier land designations have been added that prohibit all road construction/reconstruction, except when pursuant to reserved or outstanding rights or as provided for by statute or treaty. Even in such a situation, the Responsible Official would be required to make a series of determinations to decide whether a proposal fits the exception within the upper tier lands. The determinations would include: consideration of technically feasible options without road construction; when proposing to construct a forest road, consideration of whether a temporary road would provide reasonable access; and within a native cutthroat trout catchment or identified recovery watershed, a determination whether road construction will diminish, over the long-term, conditions in the water influence zone and in the native cutthroat habitat.

The rule provisions concerning proposed road construction or reconstruction for authorized water conveyance structures have been modified. The definition of water conveyances has been expanded to include reservoirs, and the exception is limited only to those conveyances operated pursuant to a pre-existing water court decree as of the effective date of a final rule. Water court decrees dated after the final date of the rule would not be eligible for roaded access in CRAs. Finally, the Regional Forester would be required to determine the need for the road access.

The exception for temporary road construction associated with tree-cutting, sale, or removal to reduce the wildfire hazard to an at-risk community or municipal water supply system and tree-cutting associated with maintenance and restoration of characteristics of ecosystem composition, structure and processes, is limited to the first half mile of the CPZ and would require a determination by the Regional Forester.

The road construction exception for the management of livestock grazing has been eliminated. New grazing authorizations would be limited to use of existing roads.

Temporary road construction may be authorized when associated with exploration or development of an oil and gas lease that was issued prior to the effective date of the rule and when the lease and stipulations do not prohibit surface occupancy or roading.

Approximately 9,000 acres of the Currant Creek CRA, have been removed from the North Fork Coal Mining Area exception due to public comments regarding the wildlife values of this particular CRA and the lack of existing coal leases in this area. In the remaining proposed 20,000 acres, temporary road construction would be allowed for coal exploration and coal-related surface support activities, such as the drilling of vent holes to extract methane gas to facilitate miner safety. These same temporary roads could also be used for the purpose of collecting and transporting coal mine methane to avoid venting methane into the atmosphere. The authorized road right-of-way would serve as the site for buried infrastructure, such as pipelines. The proposed rule allows for the opportunity to develop this important low-sulfur, cleaner-burning coal resource in a limited portion of the CRA inventory, with areas being returned to long term management for roadless area protection following the decommissioning of the associated temporary roads.

Under all road exceptions, projects would have to be designed and completed to reduce unnecessary or unreasonable surface disturbance. All roads constructed would be decommissioned and the affected landscape restored when a road was no longer needed for the original purpose and/or when the authorization expired, whichever was sooner. These decommissioning requirements would be included in all related contracts or permits and could not be waived.

To prevent roads from affecting the landscape longer than intended, temporary roads authorized under this subpart would not be converted to a forest road (be designated as a permanent road), unless the specific exception under which the temporary road was constructed allows for forest road construction and reconstruction. All roads would also restrict use to the purpose for the road, limiting the traffic and overall impact to the area. Motorized use by the general public including use by off-highway vehicles would be prohibited. General use restrictions would not apply to administrative use by the Forest Service, motor vehicle use that is specifically under an authorization issued under Federal law or regulation, or use for public health and safety or law enforcement reasons. Maintenance of temporary or forest roads would be permitted.

Section 294.44 Prohibition on Linear Construction Zones

Prohibitions on linear construction zones (LCZs) have been added to the proposed rule. The 2001 Roadless Rule did not restrict the use of LCZs. LCZs would be prohibited in CRAs unless they meet one of three exceptions: water conveyance structures with a pre-existing water court decree; electrical power or telecommunication lines; and pipelines associated with oil and gas leases that allow surface use within CRAs or an oil and gas lease outside of CRA that connects to infrastructure inside of CRAs. For all three LCZ exceptions, the Regional Forester would be required to determine that motorized access is not possible without an LCZ that the LCZ is consistent with applicable LMP, and that in the long term the LCZ will not diminish conditions in native cutthroat trout habitat.

The Regional Forester may authorize a LCZ when needed for construction, reconstruction, or maintenance of an authorized water conveyance structure that was operated pursuant to a pre-existing water court decree, as of the effective date of this rule. This exception is similar to the road construction/reconstruction for water conveyance structures, but can be selected when a road is not necessary.

Colorado's petition and public comment identify that the current electrical power line system, some of which is already located in CRAs, will need to be maintained and upgraded. Additionally, demand for additional lines is expected. The rule recognizes these possibilities and would allow LCZs, when appropriate, as the method requiring the least disturbance. For the construction, reconstruction, or maintenance of existing or future electrical power lines or telecommunication lines within a CRA, the Regional Forester would determine if a LCZ is needed. The rule further clarifies that any future electrical power lines or telecommunication lines could only be authorized within a CRA if there is no opportunity for the project to be implemented outside the CRA without causing substantially greater environmental damage. The agency is inviting public comments on this exception.

The rule similarly recognizes that it may be appropriate to authorize a LCZ within CRAs to allow the movement of product to market from within a pre-existing oil and gas lease within the CRA. The proposed rule also allows an LCZ when a proponent requests to connect from outside the CRA to an existing infrastructure within a CRA in order to avoid creation of a duplicate pipeline system and unnecessary environmental harm. The Regional Forester would be required to determine that such a connection would cause substantially less environmental damage than alternative routes. An LCZ would not be allowed for new pipelines that would merely pass through a CRA.

All LCZs would be constructed in a manner that minimizes ground disturbance, and would include a reclamation plan. After installation of the linear facility, the LCZ and all areas of surface disturbance would be reclaimed according to the reclamation plan, and those requirements would not be waived.

Section 294.45 Environmental Documentation

The Forest Service will comply with NEPA for activities within CRAs. The Forest Service NEPA regulations at 36 CFR 220.5(a)(2) normally require preparation of an EIS for any proposal that would substantially alter the undeveloped character of an inventoried roadless area, including CRAs.

The Forest Service would be required to offer the State of Colorado cooperating agency status for all proposed projects and planning events within CRAs. When the Forest Service is not the lead agency and does not have the authority to offer formal cooperating agency status to the State of Colorado, the Forest Service would offer to coordinate with the State.

Section 294.46 Other Activities

The proposed rule would prohibit temporary and permanent road construction and reconstruction associated with new oil and gas leases issued within a Colorado Roadless Area. Some comments suggested that the Colorado Roadless Rule establish restrictions to be applied retroactively to oil and gas leases within CRAs. The proposed rule does not implement that suggestion. Consistent with other past Department rulemakings concerning roadless area management, this proposed rule is not designed or intended to alter previously approved decisions but instead establishes prospective management direction for the protection and management of CRAs. Nevertheless, the proposed rule would establish requirements to limit future discretionary decisions concerning oil and gas leasing within CRAs. Specifically, the proposed rule would require that only temporary roads could be developed in association with pre-existing leases. In addition, the proposed rule would prohibit the Agency from authorizing the Bureau of Land Management to grant any request for a waiver, exception, or modification to any oil or gas lease, if doing so would result in any road construction within a Colorado Roadless Area beyond that authorized at the time of issuance of the lease.

Comments were also received for and against establishment of a prohibition on new oil and gas leasing or surface occupancy within CRAs. Again, like prior rules, the proposed rule does not establish such prohibitions. Instead, the proposed rule would allow only such leasing that can be accomplished without road construction or reconstruction and would require mandatory and non-waiveable stipulations prohibiting road construction. The proposed rule identifies regulatory requirements in 36 CFR 294.44 that would be imposed for any linear construction zone associated with new leases.

The proposed rule also confirms that the forest travel management processes will continue to be used for all future decisions regarding motorized and non motorized use on trails within CRAs. Motorized access not involving the construction or reconstruction of roads would continue according to existing authorizations. CRA designation would not eliminate or preclude any lands from being available for livestock grazing.

Section 294.47 Modifications and Administrative Corrections

The Chief of the Forest Service would be able to modify CRA boundaries based on a changed circumstance such as, the inclusion or exclusion of lands due to land exchanges, and updated inventories. Such changes to the boundaries would require public notice and a minimum 90-day public comment period. Changes due to new congressional designations would not require a modification, and would be adjusted to conform to the applicable statute.

The Chief of the Forest Service would be able to make administrative corrections to CRA boundaries. Administrative corrections would require public notice and a 30-day comment period. Administrative corrections include adjustments such as to correct clerical errors or to reflect improved field data due to updated imagery, global positioning data, or other collected field data.

Rulemaking would be required for any modification to final rule language. The Secretary would provide for public notice and a minimum 90-day comment period, and the State would be consulted on any rulemaking proposals.

Section 294.48 Scope and Applicability

The proposed rule's applicability would be limited to authorizations for occupancy and use of NFS lands issued after the effective date of a final rule. The proposed rule's provisions would not affect project or activity decisions issued prior to the effective date of a final rule.

Components of a LMP can be more restrictive than the rule and will continue to provide guidance and direction for projects within CRAs. The proposed rule does not compel amendment or revision of a LMP. A project decision or LMP amendment or revision may not waive or supersede the provisions of this proposed rule.

The proposed rule does not waive any requirements during project analyses to consult with Tribes and other agencies, comply with applicable laws, and involve the public.

If any provision of the rule or its application were held to be invalid, the Department's intention is that the remainder of the regulation would remain in force.

After promulgation of a final rule, the rule promulgated on January 12, 2001, would have no effect within the State of Colorado.

Section 294.49 List of Designated Colorado Roadless Areas

There are 363 Colorado Roadless Areas in the proposed rule; an increase of 18 CRAs from the July 2008 Proposed Rule.

Regulatory Certifications

Regulatory Planning and Review

The proposed rule was reviewed under USDA procedures, Executive Order 12866 (E.O. 12866), and the major rule provisions of the Small Business Regulatory Enforcement and Fairness Act (5 U.S.C. 800). E.O. 12866 addresses regulatory planning and review and requires agencies conduct a regulatory impact assessment for economically significant regulatory actions. Economically significant regulatory actions are those that have an annual effect on the economy of $100 million or more, or adversely affect the economy or economic sectors. Total annual

output associated with oil, gas, and coal production in the affected areas is projected to be approximately $970 million under the proposed rule, compared to approximately $1,030 million under baseline conditions, implying the annual impact of the proposed rule is estimated to be a decrease of approximately $60 million for energy mineral sectors. Due to the potential magnitude of economic impacts and the level of interest in inventoried roadless area management, this proposed rule has been designated as significant and is subject to Office of Management and Budget (OMB) review under E.O. 12866.

A regulatory impact assessment has been prepared for this proposed rule. OMB Circular A–4 as well as guidance regarding E.O. 12866 indicate that regulatory impact analysis should include an assessment of distributional effects. The benefits, costs, and distributional effects of four alternatives are analyzed over a 15-year time period. These four alternatives referred to as follows: Alternative 1—the provisions of the 2001 Roadless Rule (2001 rule); alternative 2—the proposed Colorado Roadless Rule (proposed rule); alternative 3—Forest Plans (no action); and alternative 4 (the proposed rule with public identified upper tier acreage). The difference between alternative 2 and 4 is the number and location of upper tier acres identified within the CRAs. For the purpose of regulatory impact assessment, the forest plan alternative represents baseline conditions or goods and services provided by NFS lands in the near future in the absence of the proposed rule. In August 2008, the Wyoming District Court set aside and enjoined the 2001 Roadless Rule. Colorado is under the Wyoming Court's ruling. In the revised DEIS the baseline conditions are therefore assumed to mean that IRAs in Colorado will be managed according to direction set forth in the applicable forest plan (alternative 3).

The proposed rule is programmatic in nature and intended to guide future development of proposed actions in roadless areas. The proposed rule is intended to provide greater management flexibility under certain circumstances to address unique and local land management challenges, while continuing to conserve roadless values and characteristics. Increased management flexibility is primarily needed to reduce hazardous fuels around communities to allow access to coal reserves in the North Fork coal mining areas, and to allow access to future water conveyances.

The proposed rule does not authorize the implementation of any ground-disturbing activities, but rather it describes circumstances under which certain activities may be allowed or restricted in roadless areas. Before authorizing land use activities in roadless areas, the Forest Service must complete a more detailed and site-specific environmental analysis pursuant to the National Environmental Policy Act (NEPA) and its implementing regulations.

Because the proposed rule does not prescribe site-specific activities, it is difficult to predict changes in benefits and costs or other changes under the different alternatives. It should also be emphasized that the types of benefits derived from uses of roadless areas in Colorado are far ranging and include a number of non-market and non-use benefit categories that are difficult to measure in monetary terms. As a consequence, benefits are not monetized, nor are net present values or benefit cost ratios estimated. Instead, increases and/or losses in benefits are discussed separately for each resource area in a quantitative or qualitative manner. Benefits and costs are organized and discussed in the context of local land management challenges or concerns ('local challenges') and 'roadless area characteristics' in an effort to remain consistent with the overall purpose of the proposed rule, recognizing that benefits associated with local challenges may trigger or overlap with benefits associated with roadless area characteristics in some cases (*e.g.,* forest health). Access and designations for motorized versus non-motorized recreation is a topic raised in comments, however, the proposed rule does not provide direction on where and when off-highway vehicle (OHV) use would be permissible and makes clear that travel planning-related actions should be addressed through travel management planning and individual forest plans.

Distributional effects or economic impacts, in terms of jobs and labor income, are quantified for the oil and gas and the coal sectors for an economic area consisting of five Colorado counties (Delta, Garfield, Mesa, Montrose, and Rio Blanco) using a regional impact model. Fiscal impacts (*i.e.,* mineral lease payments) are estimated for counties where changes in mineral activity are expected to be physically located (Delta, Garfield, Gunnison, Mesa, Montrose, and Pitkin). The distributional effects associated with reducing wildfire hazard are characterized by estimating the extent to which CPZ areas (*i.e.,* 0.5 to 1.5 mile buffer areas surrounding communities at-risk from wildfire) overlap roadless areas where tree-cutting for fuel treatments has been identified as being likely to occur. Distributional effects or economic impacts are not evaluated for other economic sectors (*e.g.,* timber harvest, recreation) due to evidence presented in Table 2 suggesting that the extent or magnitude of changes in output or services are not sufficient to cause significant changes in jobs and income for those economic sectors.

Details about the environmental impacts associated with the proposed rule can be found in the RDEIS. Effects on opportunities for small entities under the proposed rule are discussed in the context of E. O. 13272 regarding proper consideration of small entities and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), which amended the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

The results of the regulatory impact assessment for the proposed rule are summarized in the following tables. Table 1 provides information related to roadless area acreage, road miles, and tree-cutting. Table 2 summarizes the potential benefits and costs of alternatives 1, 2, 3 and 4. Table 3 summarizes distributional effects and economic impacts of the proposed rule and alternatives.

TABLE 1—FRAMEWORK FOR ANALYSIS: COMPARISON OF ROADLESS AREA ACREAGE, ROAD MILES, AND TREE-CUTTING

	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres [1]
Roadless Areas	Inventoried Roadless Areas (IRAs) = 4,243,600 acres.	Colorado Roadless Areas (CRAs) = 4,186,000 acres.	4,243,600 acres	Colorado Roadless Areas (CRAs) = 4,186,000 acres.
Total Existing Authorized Road Miles in Roadless Areas [1].	1,260 miles in IRAs	8.5 miles in CRAs	1,260 miles in IRAs	8.5 miles in CRAs.

TABLE 1—FRAMEWORK FOR ANALYSIS: COMPARISON OF ROADLESS AREA ACREAGE, ROAD MILES, AND TREE-CUTTING—Continued

	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres [1]
Road Construction and Reconstruction Projected in the Analysis Area.	14 miles/year (11 miles in IRAs).	20 miles/year (16 in CRAs)	28 miles/year	18 miles/year (14 in CRAs).
Tree-cutting Projected in the Analysis Area.	2,300 acres/year (1,200 in IRAs).	7,000 acres/year (5,800 acres in CRAs).	16,900 acres/year	3,000 acres/year (1,800 acres in CRAs).

[1] Approximately 24 miles of roads are projected to be decommissioned in IRAs and 8 miles decommissioned in CRAs. Alternative 4 is the same as Alternative 2 with the exception that more roadless areas are assigned to the upper tier restrictions.

TABLE 2—COMPARISON OF ENVIRONMENTAL CONSEQUENCES BY ALTERNATIVE

Issue or affected resource	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 (No Action) Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres
Local Challenges and Resources: Roadless Area Management				
Fire and Fuels (Hazardous Fuel Reductions).	Tree-cutting projected for 1,800 acres per year in the analysis area to reduce hazardous fuels (900 of which are within IRAs); this amounts to 3% of average annual fuel treatments on all NFS lands in CO. Least flexibility to conduct hazardous fuel reduction and reduce fire risk to communities and municipal water supply systems.	Tree-cutting projected for 5,900 acres per year in the analysis area to reduce fuels (5,300 of which are within CRAs); this amounts to 9% of annual fuel treatments on all NFS lands in CO. More flexibility to conduct hazardous fuel reduction and reduce fire risk to communities and municipal water supply systems. Unable to conduct hazardous fuels reduction on 12% of 0.5 mile CPZ and 13% of 1.5 mile CPZ due to upper tier acre prohibitions.	Tree-cutting projected for 13,100 acres per year in the analysis area to reduce fuels; this amounts to 20% of annual fuel treatments on all NFS lands in CO. Greatest flexibility to conduct hazardous fuel reduction and reduce fire risk to communities and municipal water supply systems.	Tree-cutting projected for 2,200 acres per year in the analysis area to reduce fuels (1,600 of which are within CRAs); this amounts to 3% of annual fuel treatments on all NFS lands in CO. Within the CRAs that are not upper tier acres, the flexibility to conduct hazardous fuel reduction and reduce fire risk to communities and municipal water supply systems is identical to alternative 2, but there are more upper tier acres that cannot be treated. Unable to conduct hazardous fuels reduction on 48% of 0.5 mile CPZ and 52% of 1.5 mile CPZ due to upper tier acre prohibitions.
Ecosystem Maintenance and Restoration Treatments.	500 acres per year in the analysis area have projected tree-cutting activities (300 acres within IRAs). Fewest opportunities to maintain and restore ecosystem characteristics, including resilience to insect and disease outbreaks and climate-induced stressors.	1,000 acres per year in the analysis area have projected tree-cutting activities (400 acres within CRAs). More opportunities than alternatives 1 and 4, but fewer opportunities than alternative 4 to maintain and restore ecosystem characteristics, including resilience to insect and disease outbreaks and climate-induced stressors. Unable to treat upper tier acres.	3,500 acres per year within the analysis area have projected tree-cutting activities. Greatest opportunities to maintain and restore ecosystem characteristics, including resilience to insect and disease outbreaks and climate-induced stressors.	800 acres per year in the analysis area have projected tree-cutting activities (200 acres within CRAs). More opportunities to maintain and restore ecosystem characteristics, including resilience to insect and disease outbreaks and climate-induced stressors than alternative 1 but less than alternative 3 and alternative 2 due to upper tier acres.
Timber	Tree-cutting (sale or removal) in the roadless analysis area is projected to occur in association with treatments on 2,300, 3,000, 7,000, and 16,900 acres per year respectively under Alternatives 1, 2, 3, and 4. However, average annual treatment acreage on all NFS land is not expected to be affected substantially by the alternatives, with the only change being the extent to which treatments occur in roadless versus non-roadless areas on NFS lands. Minimal impacts to the wood products sector are therefore expected.			
Oil and Gas	Projections are for approximately 686 oil and gas wells in the analysis area with access to 1,046 bcfg over a 15-year period (same for Alternatives 1, 2, and 4). Projected annual road construction and reconstruction is about 10 miles in roadless areas.		Projections are for approximately 783 oil and gas wells in the analysis area with access to 1,154 bcfg over a 15-year period, providing slightly more opportunity compares to the other alternatives. Annual road construction/reconstruction is 11 miles.	Same as Alternative 1 and 2.

TABLE 2—COMPARISON OF ENVIRONMENTAL CONSEQUENCES BY ALTERNATIVE—Continued

Issue or affected resource	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 (No Action) Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres
Coal Analysis Area	Projections are for 16 miles of new roads in the analysis area, of which 7 are in IRAs. Restricts access to potential coal resources in IRAs more than other alternatives. 8,600 acres of road-accessible reserves (7,100 in current leases; 1,500 in unleased areas outside of IRAs) with access to 157 million tons.	Projections are for 52 miles of new roads in the analysis area, of which 50 are in CRAs. Reduces restrictions on access to potential coal resources in CRAs compared to the 2001 rule, but is more restrictive than Alternative 3 (limits new roads to the North Fork coal mining area). 27,500 acres of road-accessible reserves (7,100 in current leases; 18,900 in unleased areas outside of CRAs) with access to 514 million tons. Within North Fork coal mining area, 15,600 unleased within CRAs, 5300 in unleased areas outside of CRAs.	Projections are for 73 miles of new roads in the analysis area, of which 64 are in areas that overlap IRAs. Least restrictive on access to potential coal resources in IRAs compared to the other two alternatives. 39,600 acres of road-accessible reserves (7,100 in current leases; 32,500 in unleased areas) with access to 724 million tons.	Same as Alternative 2.
Geothermal	Opportunities for geothermal development in roadless areas would not occur under the 2001 rule, the proposed rule, and Alternative 4 due to new road prohibitions. Opportunities for geothermal development in roadless areas would occur under the forest plans alternative as most land management plans allow new roads in roadless areas for this purpose. There are no current leases on NFS lands in Colorado, though potential for geothermal resources is being studied.			
Public Safety	All of the alternatives provide flexibility to respond to emergency situations or major threats to public health and safety in roadless areas (refer to features common to all alternatives). In contrast, the potential for accidents and safety hazards increases as the amount of activity and traffic increases. The Forest Service will continue to respond to wildfires, chemical or oil spills, abandoned mine hazards, road-design hazards, hazard trees, and other similar situations. Roads for this purpose must be temporary under the proposed rule, and would be expected to be temporary under the 2001 rule and forest plans. Upper tier acres in Alternatives 2 and 4 do not have a specific public health and safety exception for road construction, as does alternative 1.			
Special Uses: Non-recreational (pipelines, electrical or telecommunication lines, water conveyances).	Special use authorizations issued prior to the effective date of rulemaking would be unaffected.			
	Future special use authorizations in IRAs would generally prohibit road construction, but there would be no prohibition on the use of LCZs. 3.2 miles per year of LCZs projected.	Future special use authorizations in CRAs would generally prohibit road construction. Limited exceptions for the construction of LCZ for future oil and gas pipelines, electrical power lines or telecommunication lines, and water conveyance structures in CRAs. 3.2 miles per year of LCZs projected.	Future special use authorizations would generally allow for road construction; except where prohibited under forest plans. There would be no prohibition on the construction of LCZs. 3.6 miles per year of LCZs projected.	Same as alternative 2.
Developed Ski Areas	Least opportunities for ski area development and expansion. Road construction and tree-cutting permitted on 6,600 acres within IRA boundaries and also under permit prior to the effective date of this rule. Roads and tree-cutting would be prohibited in 1,700 acres of ski areas allocated under forest plans but outside of existing permits.	Greater opportunity for ski area development and expansion. Road construction and tree-cutting permitted on 6,600 acres under permit as well as the additional 1,700 acres of ski areas allocated under forest plans and located outside existing permits.	Same as alternative 2 Forest plans can be amended or revised to expand ski area allocations beyond the current allocation.	Same as alternative 2.
Other Developed Recreation	Only one mile of new road is current projected for recreational purposes over the next 15 years under No Action; effects on developed recreation opportunities therefore do not differ substantially across alternatives.			
Livestock Management	None of the projected activities in roadless areas that vary by alternative would be likely to have any substantial beneficial or adverse impacts on livestock management operations in roadless area grazing allotments.			
Roadless Area Characteristics and Values				
Scenic Quality	Projected activity levels (*e.g.,* tree-cutting) occur on relatively small percentages of total roadless area under all alternatives.			
	Least risk to scenic resources.	More risk to scenic resources than alternatives 1 and 4. Upper tier acres same as alternative 1.	Greatest risk to scenic resources.	Same as alternative 2 within CRA boundaries that are not upper tier; upper tier areas same as alternative 1.

TABLE 2—COMPARISON OF ENVIRONMENTAL CONSEQUENCES BY ALTERNATIVE—Continued

Issue or affected resource	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 (No Action) Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres
Wilderness and Other Congressionally Designated Areas.	No major difference among the alternatives related to the risk of adverse effects on congressionally designated areas. There would be no potential direct effect on these areas as they are outside the roadless areas that are the subject of each alternative. Effects on areas in forest plans as recommended wilderness would not differ by alternative as land management plans generally prohibit road construction and tree-cutting and removal activities in those areas. However, restrictions on activities in IRAs under the 2001 rule provide a greater opportunity to maintain future options for recommending roadless acres as wilderness in the future, compared to the proposed rule and forest plans.			
	Indirect effects on wilderness area characteristics or experience from activities in adjacent roadless areas are expected to be low under Alternatives 1 and 2 because projected activities are not expected to occur adjacent to wilderness area boundaries.		Higher risk of indirect adverse effects on wilderness experience from activities in the analysis area due to higher likelihood that activities could occur adjacent to wilderness boundaries.	Similar to Alternatives 1 and 2. Greater opportunity to establish uniform management approaches for recommended wilderness through placement of roadless areas in upper tier.
Soil	No major difference among alternatives related to the risk of soil impacts. Alternative 1 and 4 would have the least risk of adverse effects, and alternative 2 would have a slightly higher risk, followed by alternative 3. However, these differences are expected to be small in magnitude and spread over a wide geographic area. Most of the potential effects would be mitigated by site-specific mitigation measures. The risk of post-fire soil erosion may be higher under Alternative 1 and lowest under Alternative 3 as a result of projected levels of fuel treatments.			
Water and Water Quality	Activities under all alternatives are unlikely to contribute to water quality impairment (*i.e.,* exceeding water quality standards) due to application of mitigation measures and BMPs as a result of NEPA process and site-specific analysis.			
	Lowest risk of direct adverse effects from tree-cutting and road construction. Higher risk from adverse impacts from floods and sedimentation resulting from wildfires.	Slightly greater risk of direct adverse effects from tree-cutting and road construction. Decreased risks from floods and sedimentation resulting from wildfire, relative to alternatives 1 and 4, due to increased fuel treatments to protect communities and/or water supplies.	Higher risk of direct adverse effects from tree-cutting and road construction. Greatest decrease in risk from floods and sedimentation resulting from wildfire due to increased fuel treatments to protect communities and/or water supplies.	Similar to Alternative 2 though slightly lower risk from tree-cutting and road construction activities.
Air Resources	Differences in effects on air quality do not substantially differ between the alternatives. Atmospheric emissions within the analysis area are not expected to increase to a level that would be likely to exceed State or Federal air quality standards.			
Threatened Endangered or Sensitive Plants.	No adverse impacts to threatened or endangered plants because no road construction or tree-cutting, sale, or removal is projected to occur where threatened or endangered plants exist. Site-specific design criteria and mitigation measures are expected to minimize risk. Individual sensitive plants may be affected by projected activities; however, none of the alternatives are expected to result in the loss of viability nor cause a trend toward Federal listing of sensitive species.			
	Least risk to adverse impacts to sensitive plants, including threats from invasives.	More risk of adverse impacts to sensitive plants, including threats from invasives, than alternatives 1 or 4; less than alternative 3.	Greatest risk of adverse impacts to sensitive plants, including threats from invasives.	More risk of adverse impacts to sensitive plants, including threats from invasives, than alternative 1; less than alternatives 2 or 3.
Aquatic Species and Habitat	No long-term adverse effects are expected on threatened and endangered (T&E) species, sensitive species, and MIS population trends; downstream T&E species; or wetlands and riparian areas under any alternative due to the assumption that mitigation measures and best management practices would help avoid or minimize impacts from the projected activities.			
	Least risk for adverse impacts on aquatic species.	Increase in risk of adverse impacts to aquatic species. Provides greater protection for cutthroat trout compared to alternatives 1 and 3.	Greatest potential for adverse impacts to aquatic species.	Lower risk of adverse impacts to aquatic species compared to alternative 2 and 3. A portion of upper tier acres are within watersheds occupied by TES fish, implying potential improvements in protection relative to Alternative 2.
Terrestrial Species and Habitat	For all alternatives, potential adverse effects are expected to be avoided or minimized through compliance with standards and guidelines in land management plans and other applicable laws and policies. For all alternatives, activities may affect individual animals but are not likely to adversely affect populations or critical habitat of T&E species, nor result in the loss of viability or cause a trend toward Federal listing for sensitive species.			
	Least risk to terrestrial species and habitat. Limitations of tree-cutting to small diameter trees helps maintain larger trees and variability in forest structure.	Increased risk to terrestrial species and habitat due to activity projections.	Greatest risk to terrestrial species and habitat due to activity projections.	Increased risk to terrestrial species and habitat, but less than Alternative 2 due to activity projections and acreage allocation to upper tier.

TABLE 2—COMPARISON OF ENVIRONMENTAL CONSEQUENCES BY ALTERNATIVE—Continued

Issue or affected resource	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 (No Action) Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres
		Tree-cutting to improve habitat for threatened, endangered, and protected species (TEPS) prohibited in upper tier acres but fewer upper tier acres compared to Alternative 4. Opportunities to improve early seral stage and lower elevation habitat is higher as a result of improved capacity to treat fuels. Restricting tree-cutting inside and outside of CPZs to small diameter trees helps maintain larger trees and forest structure (also applies to Alternative 4).	Opportunities to improve early seral stage and lower elevation habitat is highest as a result of increased flexibility to treat fuels.	Tree-cutting to improve habitat for TEPS species prohibited on a greater number of upper tier acres compared to Alternative 2. Opportunities to improve early seral stage and lower elevation habitat is lower than alternative 2 but higher than alternative 1 (due to treatment projections).
Biodiversity	The value of roadless areas in conserving biodiversity is likely to increase as habitat loss and habitat degradation increase in scope and magnitude in lands outside of roadless areas. Opportunities for protected large contiguous blocks of habitat, biological strongholds, and habitat connectivity would be greatest for the 2001 rule and lowest under the forest plans alternative. Increasing opportunities for treatments under Alternatives 4, 2, and 3 respectively to address hazardous fuels and maintenance and restoration of ecosystem characteristics may have off-setting beneficial effects on long-term biodiversity.			
Invasive Plants	Site-specific design criteria and mitigation measures are expected to minimize risk.			
	Lowest risk of spread due to low projections of road construction or tree-cutting.	Some higher risk of the spread due to greater projections of road construction or tree-cutting. Acres removed may experience increased rates of spread while acres added may have decreased rates (same applies for Alternative 4).	Greatest risk of the spread due to the greatest projections for road construction or tree-cutting compared to other alternatives.	Slightly higher risk of the spread compared to Alternative 1 but less than alternatives 2 and 3 due to projected levels of road construction and tree-cutting.
Recreation—Primitive and Semi-primitive Recreation Settings and Opportunities.	Tree-cutting activity is projected to occur on only a small percentage of roadless areas over 15 years across the alternatives. Dispersed recreation opportunities (including hunting and fishing) are therefore not expected to change under any alternative, but feelings of remoteness and solitude may change for periods of time in areas where activity occurs.			
	Likely to retain the greatest proportion of IRA acreage in a primitive or semi-primitive setting. The substantially altered areas and developed ski areas in IRAs may continue to appear inconsistent with semi-primitive characteristics expected in roadless areas. The newly identified roadless acres (409,500 acres) where road construction and tree-cutting, sale or removal is projected to occur that are not within the IRAs could shift to less primitive settings.	Likely to retain a high proportion of CRA acreage in a semi-primitive setting; although some CRA acres would shift toward roaded natural settings in areas where the most roads and energy operations are projected to occur in CRAs. By not including substantially altered areas and developed ski areas in CRAs and adding unroaded areas to CRAs, the CRAs would appear more consistent with semi-primitive characteristics expected in roadless areas.	Greatest risk of shifts from primitive/semi-primitive settings to roaded natural settings in areas where the most roads and energy operations are projected to occur.	Same as Alternative 2 but more likely to retain high proportion of primitive/semi-primitive acres given slight reductions in construction and tree-cutting activity.
Outfitters and Guides (recreation).	Out of 1,390 recreational special use permits authorized on NFS lands in Colorado, 1,066 are associated with outfitters and guides, some of which are likely to operate in roadless areas. The alternatives are expected to have negligible adverse effects on recreational special uses, including outfitter and guide opportunities, based on the magnitude and distribution of reasonably foreseeable activity projections; 7,000 acres of tree-cutting and 20 miles of road construction per year are projected over more than 4 million CRA acres under the proposed rule. Limitations on road construction and tree-cutting under any alternative would not be likely to affect ability to obtain or use a recreation use authorization.			
Cultural Resources	Least risk of damage to cultural resources because this alternative has the least projections for tree-cutting, sale, or removal. Site-specific design criteria and mitigation measures are expected to minimize risk.	Slightly higher risk of damage to cultural resources because this alternative has a high projection of tree-cutting, sale, or removal and road construction. Site-specific design criteria and mitigation measures are expected to minimize risk.	Highest risk of damage to cultural resources because this alternative has the highest projection of tree-cutting, sale, or removal and road construction. Site-specific design criteria and mitigation measures are expected to minimize risk.	Same or less than alternative 2 due to larger number of acres in the upper tier. Site-specific design criteria and mitigation measures are expected to minimize risk.

TABLE 2—COMPARISON OF ENVIRONMENTAL CONSEQUENCES BY ALTERNATIVE—Continued

Issue or affected resource	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 (No Action) Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres
Native Plants, Including Special Status Plants.	No major difference among alternatives related to the risk of adverse effects on native threatened, endangered, or sensitive plant species. There would be very little to no increases in roads, tree-cutting, or energy development activities in the roadless areas that support those plant species. The main difference is the higher risk under the proposed rule and the forest plans alternative that invasive plants would increase from the higher levels of ground-disturbance, thereby increasing this threat to native plant communities.			
Geological and Paleontological Resources.	None of the projected activities in roadless areas that vary by alternative would be likely to adversely affect geological or paleontological resources, which would either be avoided or otherwise protected from potential adverse impacts.			
Climate Change	None of the alternatives are expected to cause a measurable change in the amount of carbon dioxide or other greenhouse gas emissions. With regard to energy resources, it is assumed that if production is not allowed in roadless areas, the same greenhouse impacts will be moved to sites outside roadless areas and contribute the same amount to the atmosphere. In terms of fuels treatments, biomass removed can be burned, used in products, replace fossil fuels, or be left in piles elsewhere on the landscape. Except for prescribed burning, any of these disposal methods would slow release of carbon to the atmosphere.			
Agency Costs				
Vegetation and Fuel Treatments.	Treatments are likely to be less efficient and more costly in IRAs.	Increased flexibility to achieve management objectives in critical insect and disease areas; increase ability to strategically locate treatments and improve efficiency.	Capacity to shift even more treatment acres into IRAs; increased efficiency, effectiveness and timeliness of wildfire suppression response as well as fuel reductions in CPZs.	Management flexibility is similar to Alternative 2, but projected treatment amounts are lower due to constraints imposed by more upper tier acreage under Alternative 4.
Other Costs	Administrative costs are unlikely to change due to flat or static budgets and corresponding constraints on projects. Emphasis on road decommissioning and temporary roads is expected to ease demands on maintenance backlog. Overall need to address invasive plants is expected to remain relatively constant across alternatives; although new roads can contribute to the spread of invasive plants, roads can also be an asset in helping to effectively control invasive populations.			

TABLE 3—SUMMARY OF DISTRIBUTIONAL EFFECTS AND ECONOMIC IMPACTS OF THE PROPOSED RULE AND ALTERNATIVES

	Alternative 1 2001 Roadless Rule	Alternative 2 Proposed Rule	Alternative 3 (No Action) Forest Plans	Alternative 4 Proposed Rule with Public Identified Upper Tier Acres
Leaseable Minerals: Coal, Oil and Gas—Output Value, Jobs and Income (2006$) Contributed (1).	$636 million/yr Output. 1,557 Jobs supported. $101.4 million per year Labor Income.	$969 million/yr Output. 2,679 Jobs supported. $183.2 million per year Labor Income.	$1,026 million/yr Output. 2,796 Jobs supported. $190 million per year Labor Income.	$969 million/yr Output. 2,679 Jobs supported. $183.2 million per year Labor Income.
Revenue Sharing: Mineral Lease Payments and Tax Revenues (2007$) (2).	State Total: $28.4 million. Energy-Affected Counties: $7.3 million. All other CO Counties: $1.1 million.	State Total: $47.3 million. Energy-Affected Counties: $10.2 million. All other CO Counties: $1.9 million.	State Total: $49.7 million. Energy-Affected Counties: $11.1 million. All other CO Counties: $2.0 million.	State Total: $47.3 million. Energy-Affected Counties: $10.2 million. All other CO Counties: $1.9 million.
Values at risk: Number of Counties Where Potential for Fuel Treatments in CPZs May Increase or Decrease Compared to Baseline Conditions (3).	Decrease: 13 counties. Increase: 1 county.	Decrease: 2 county. Increase: 3 counties.	NA.	Decrease: 18 counties. Increase: 5 counties.

(1) Jobs and income contributed annually (2006 dollars) based on projected levels of coal, oil, and gas production and regional economic modeling multipliers derived from an IMPLAN model representing the five counties where employment effects are assumed to occur (Delta, Garfield, Mesa, Montrose, and Rio Blanco).
(2) Payments consist of property tax receipts from coal, oil, and gas production; State distribution of severance taxes and Federal royalties. Energy-affected counties are Delta, Garfield, Gunnison, Mesa, Montrose, and Pitkin counties. Changes in payments associated with the Secure Rural Schools and Self Determination Act and Payments in Lieu of Taxes (PILT) are not expected to change significantly.
(3) CPZs = community protection zones (0.5 to 1.5 mile buffer area surrounding communities that have been identified as being at-risk to wildfire. "Potential for fuel treatments" implies that at least one CPZ area in a county overlaps with an IRA or CRA where tree-cutting has at least a low likelihood of occurring, according to national forest unit field staff.

Proper Consideration of Small Entities

The proposed rule has also been considered in light of Executive Order 13272 (E. O. 13272) regarding proper consideration of small entities and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), which amended the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Forest Service with the assistance of the State of Colorado has determined that this action will not have a significant economic impact on a substantial number of small entities as defined by the E.O. 13272 and SBREFA, because the proposed rule does not directly impose small entities to regulatory requirements. The effects on small businesses will not be substantial. Therefore, an initial regulatory flexibility analysis is not required for this proposed rule.

For small businesses affiliated with most industry sectors involved with activities in roadless areas (*e.g.,* coal, oil and gas), there are minimal differences between the proposed rule and baseline or no-action conditions (*i.e.,* forest plans alternative). As a result, there is little or no potential for significant adverse economic impacts to small businesses under the proposed rule relative to forest plans.

There are about 1,390 recreation special use permits currently authorized within NFS lands in Colorado of which a large majority are small businesses, and 1,066 (77%) are associated with outfitter and guide permits, some of

which are likely to operate within roadless areas. However, there is little difference between alternatives with respect to recreation special use authorizations in roadless areas, because limitations on roading and tree-cutting under any alternative would not be likely to affect ability to obtain or use recreation use authorizations. Impacts under the proposed rule compared to forest plans are not expected to be significant due to the small percentage of acreage affected (7,000 acres of tree-cutting per year) and roads constructed (20 miles per year) spread across more than 4 million acres of Colorado Roadless Areas. It is also noted that a significant percentage of roads and tree-cutting activity will occur within or near the community protection zones where primitive or semi-primitive settings may already be affected. Flat budgets imply that the percentage of harvest from roadless areas may change under the alternatives, but aggregate volumes across all NFS land are expected to remain relatively unchanged, on average, implying little potential for adverse impacts to small entities.

For leasable minerals associated energy resources (coal, oil and gas), significant changes in output are projected across alternatives. More than 95 percent of the firms associated with these sectors can be classified as small as defined by Small Business Administration standards. Any changes in oil and gas, or coal development or production can therefore have an effect on small business opportunities in these sectors. A five county region has been defined to model the economic impacts associated with energy resources (Delta, Garfield, Mesa, Montrose, and Rio Blanco counties). A total of 355 firms associated with oil and gas, and coal development and extraction are estimated to be located within this region, of which 95% are likely to be small (337 firms). However, energy resource sector jobs, supported annually by projected activity within roadless areas, are estimated to increase from 1,557 under the 2001 rule alternative to 2,679 jobs under the proposed rule (as well as alternative 4), and 2,796 jobs under the no action (forest plans) alternative. Labor income increases by a similar degree from $101 million to $183.2 million and 190 million per year under all alternatives. There is slightly higher job numbers (2,796) under the forest plan alternative (alternative 3) relative to the proposed rule (2,679) alternatives (alternatives 2 and 4), but the magnitude of the difference between these alternatives does not suggest that adverse impacts will be significant if choosing between the proposed rule and forest plans. These results indicate minimal adverse impacts to small entities associated with energy resource development and extraction under the proposed rule relative to the forest plans alternative.

For all other economic sectors considered, changes in resource outputs are not projected to be significant to the extent that adverse impacts to small entities could occur in aggregate or within regions.

Among 64 counties in the State of Colorado, 36 counties (56%) are considered to be small governments (population less than 50,000). These 36 counties are considered to be small rural counties having NFS lands within IRAs/CRAs. Six counties are energy (coal, oil and gas) producing counties. These six counties (Delta, Garfield, Gunnison, Mesa, Montrose, and Pitkin) are expected to be the counties most likely to benefit from mineral lease payments and revenue sharing under the proposed rule (as well as alternative 4), and forest plans. All of these counties, with the exception of Mesa can be considered small governments (population less than 50,000), and all are forecast to receive significant increases in property tax receipts from coal, and oil and gas production, as well as State distributions of severance taxes and Federal royalties under the proposed rule and forest plans relative to the 2001 rule. There are slight increases in payments under forest plans, relative to the proposed rule (aggregate payments increase from $10.2 million to $11.1 million per year). Payments associated with the Secure Rural Schools and Self Determination Act (SRSA) and Payments in Lieu of Taxes (PILT) are not expected to change significantly, or any decreases would be largely offset by increases in Federal mineral lease payments.

Under the proposed rule, as compared to the no action alternative, the potential opportunities for fuel treatments near communities-at-risk (*i.e.,* within community protection zones (CPZs)) may increase for two 'small population' counties (*i.e.,* populations less than 50,000). In contrast, potential opportunities for fuel treatments near communities-at-risk may decrease for nine and eight 'small population' counties under Alternative 1 (2001 rule) and Alternative 4 (proposed rule with additional upper tier acreage) respectively, compared to the no action alternative. These results indicate that adverse impacts to small governments, in association with protection of values at risk from wildfire, are not likely, when comparing the proposed rule with no action.

Therefore, for small governments, including counties with small populations and at-risk-communities from wildfire within those counties, opportunities for revenue sharing, as well as protection of values-at-risk are not expected to significantly decrease under the proposed rule relative to forest plans. Mitigation measures associated with existing programs and laws regarding revenue sharing with counties and small business shares or set-asides will continue to apply.

Controlling Paperwork Burdens on the Public

This proposed rule does not call for any additional record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use and, therefore, imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Federalism

The Department has considered this proposed rule under the requirements of Executive Order 13132 issued August 4, 1999 (E.O. 13132), Federalism. The Department has made an assessment that the proposed rule conforms with the Federalism principles set out in E.O. 13132; would not impose any compliance costs on the States; and would not have substantial direct effects on the States, on the relationship between the national government and the States, nor on the distribution of power and responsibilities among the various levels of government. Therefore, the Department concludes that this proposed rule does not have Federalism implications. This proposed rule is based on a petition submitted by the State of Colorado under the Administrative Procedure Act at 5 U.S.C. 553(e) and pursuant to Department of Agriculture regulations at 7 CFR 1.28. The State's petition was developed through a task force with the involvement of local governments. The State is a cooperating agency pursuant to 40 CFR 1501.6 of the Council on Environmental Quality regulations for the development of the supporting environmental impact statement. State and local governments are encouraged to comment on this proposed rule, in the course of this rulemaking process.

Consultation With Indian Tribal Governments

The United States has a unique relationship with Indian Tribes as provided in the Constitution of the United States, treaties, and Federal statutes. The relationship extends to the Federal government's management of public lands and the Forest Service strives to assure that its consultation with Native American Tribes is meaningful, in good faith, and entered into on a government-to-government basis.

On November 5, 2009, President Obama signed a Memorandum emphasizing his commitment to "regular and meaningful consultation and collaboration with Tribal officials in policy decisions that have Tribal implications including, as an initial step, through complete and consistent implementation of Executive Order 13175." He charged agencies with engaging in consultation and collaboration with Indian Tribal governments; strengthening government-to-government relationship between the United States and Indian Tribes; and reducing the imposition of unfunded mandates upon Indian Tribes.

Management of roadless areas has been a topic of interest and importance to Tribal governments. During promulgation of the 2001 Roadless Rule, Forest Service line officers in the field were asked to make contact with Tribes to ensure awareness of the initiative and of the rulemaking process. Outreach to Tribes was conducted at the national forest and grassland level, which is how Forest Service government-to-government dialog with Tribes is typically conducted. Tribal representatives remained engaged concerning these issues during the subsequent litigation and rulemaking efforts.

The State's petition identifies that a vital part of its public process in developing its petition were the recommendations and comments received from Native American Tribes. The Governor's office was keenly aware of the spiritual and cultural significance some of these areas hold for the Tribes.

There are two resident Tribes in Colorado, both retaining some of their traditional land base as reservations via a series of treaties, agreements, and laws. The Ute Mountain Ute and Southern Ute Tribes (consisting originally of the Weeminuche, Capote, Tabeguache, and Mouaches Bands)—each a "domestic sovereign" nation—have reserved some specific off-reservation hunting rights in Colorado and retain inherent aboriginal rights throughout their traditional territory. Many other Tribes located outside Colorado maintain Tribal interests, including aboriginal and ceded territories, and retain inherent aboriginal rights within the State.

The Forest Service has been consulting with Colorado-affiliated Tribes regarding this proposed rulemaking action and analysis process. Tribal concerns surfaced during phone or e-mail consultations. Information applying to the proposed Colorado Roadless Rule was provided to the Ute Mountain Ute and Southern Ute Indian Tribes, located in Colorado prior to the release of the NOI. The San Juan National Forest staff held meetings with both Tribes to discuss the proposed rule as well as other Forest issues. At these meetings, the Tribes expressed concerns about hunting access, and unauthorized roads. Nothing in this rule changes access or existing rights. The management of unauthorized roads is addressed through travel management processes.

Additionally, an introductory letter and the NOI along with background information on the proposed Colorado Roadless Rule and an offer for additional information or meetings was sent to the following Tribes and committees: Hopi Tribal Council, Navajo Nation, Northern Cheyenne Tribal Council, Pueblo of Jemez, Pueblo of Nambé, Ohkay Owingeh, Pueblo of Picuris, Pueblo of Pojoaque, Pueblo of San Ildefonso, Pueblo of Santa Clara, Pueblo of Taos, Pueblo of Tesuque, Pueblo of Zuni, Jicarilla Apache Nation, Cheyenne and Arapaho Tribes of Oklahoma, Ute Business Committee, Shoshone Business Committee, and the Arapaho Business Committee. These 18 Tribes and committees were selected based on their current proximity to Colorado, their current use of lands in Colorado, and their historic use of lands within Colorado.

The 2008 Proposed Rule and DEIS were sent to each Tribe and each was contacted by phone to determine interest in meeting or obtaining information. The Tribes did not request additional government-to-government involvement, and no formal comments from any of the Tribes were received. A letter was sent outlining the key points of this revised proposed rule and the FS met with those Tribes requesting further consultation. Consultation efforts will continue throughout the process and for the final Rule.

Pursuant to Executive Order 13175 of November 6, 2000, "Consultation and Coordination with Indian Tribal Governments," the Department has assessed the impact of this proposed rule on Indian Tribal Governments and has determined that the proposed rule does not significantly or uniquely affect Indian Tribal Government communities. The proposed rule would establish direction governing the management and protection of Colorado Roadless Areas, however, the proposed rule respects prior existing rights, and it addresses discretionary Forest Service management decisions involving road construction, timber harvest, and some mineral activities. The Department has also determined that this proposed rule does not impose substantial direct compliance costs on Indian Tribal Governments. This proposed rule does not mandate Tribal participation in roadless management of the planning of activities in Colorado Roadless Areas. Rather, the Forest Service officials are obligated by other agency policies to consult early with Tribal governments and to work cooperatively with them where planning issues affect Tribal interests.

No Takings Implications

The proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630 issued March 15, 1988. It has been determined that the proposed rule does not pose the risk of a taking of private property.

Civil Justice Reform

The proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. After adoption of this proposed rule, (1) all State and local laws and regulations that conflict with this proposed rule or that would impede full implementation of this proposed rule will be preempted; (2) no retroactive effect would be given to this proposed rule; and (3) this proposed rule would not require the use of administrative proceedings before parties could file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Department has assessed the effects of this proposed rule on State, local, and Tribal governments and the private sector. This proposed rule does not compel the expenditure of $100 million or more by State, local, or Tribal governments or anyone in the private sector. Therefore, a statement under section 202 of the Act is not required.

Energy Effects

Based on guidance for implementing Executive Order 13211 (E.O. 13211) of

May 18, 2001, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use, issued by Office of Management and Budget (Memorandum for Heads of Executive Departments and Agencies, and Independent Regulatory Agencies (M–01–27), July 13, 2001), this proposed rule constitutes a "significant energy action" as defined in E.O. 13211 because projected reductions in coal production under the proposed rule are in excess of 5 million tons per year after 2024.

Projections of natural gas production are discussed in the RDEIS and the Regulatory Impact Analysis for the proposed Colorado Roadless Rule. Based on those projections, it has been determined that natural gas production varies across alternatives for only two National Forests (the Grand Mesa, Gunnison, and Uncompahgre (GMUG) and White River National Forests). It has also been determined that there is no appreciable difference in projected natural gas production between Alternatives 1 (2001 rule) and 2 (proposed rule) or alternative 4. The difference in potential natural gas production between alternatives 1, 2, or 4 (27 billion cubic feet per year) and alternative 3 (no action) (31 billion cubic feet per year) is a decrease of only 4 bcf/year, or 4 million mcf/year, which is well below the E. O. 13211 criterion for adverse effects of 25 million mcf.

Projected oil production ranges from approximately 50,000 barrels under Alternatives 1, 2, and 4 to approximately 110,000 barrels under Alternative 3 over a period of 15 to 30 years. The corresponding reduction in oil production per day under alternatives 1 or 2 or alternative 3 (no action) is inconsequential compared to the E. O. 13211 criterion of 10,000 barrels per day.

Based on *average* annual coal production rates estimated for economic impact analysis purposes, annual aggregate production across the three mines operating in the affected area is projected to be the same under the proposed rule and the no action alternative (*i.e.,* forest plans alternative) for the first 24 years after implementation (2011 to 2034). Coal production and production schedules are also projected to be the same for the proposed rule and alternative 4. It is only after 24 years (2035) that annual coal production is projected to decrease under the proposed rule compared to the no action alternative by an amount of 5.6 million tons per year which is the average annual production from the Elk Creek mine which ends after 2034. This estimated decrease is based on the known extent of coal resources and the exclusion of the Currant Creek area from the North Fork coal mining area. A decrease of 5.6 million tons is only slightly above the E. O. 13211 criterion of 5 million tons per year for significant adverse effects. Production is estimated to decrease by 6.0 million tons per year under the proposed rule compared to no action by 2058 when production ceases for all mines under the proposed rule. Coal production is projected to continue for an additional 22 years (until 2079) under the no action alternative.

The total reduction in recoverable coal reserves from roadless areas that are made accessible under the proposed rule, relative to no action alternative, is estimated to be 210 million tons (*i.e.,* 724 − 514 = 210 million ton reduction). In comparison, the recoverable coal reserves [1] reported for the State of Colorado by the U.S. Energy Information Administration ranges from 629 million tons in 2002 to 328 million tons by 2007,[2] recognizing that direct comparisons of accessible coal reserves under the alternatives with recoverable reserves estimated by USEIA are difficult due to differences in estimation procedures. However, the reduction of 210 million tons made accessible under the proposed rule is only 2% of the total estimated recoverable reserves [3] for the State of Colorado in 2007 (9,692 million tons) and less than 0.1% of total estimated recoverable reserves for the nation in 2007 (262,689 million tons).

The estimated reductions in the production life of affected mines under the proposed rule compared to the no action alternative may be significant, particularly when considering potential increases in demand for coal from western mines [4] and the Nation as a whole.[5] However, both the proposed rule and the no action alternatives are projected to sustain similar production rates over an extended period of 24 years after implementation of the rule, and there are many other factors that are likely to have a more significant effect on energy markets after that time, compared to the effect of reduced production under the proposed rule which begins 25 years after implementation of this rule would occur (*i.e.,* 2034). It is also noted that approximately 67% of all coal produced from Colorado in 2008 (32.7 million tons) was exported to other States, suggesting that regional markets and prices are likely to be heavily influenced by national prices, supplies, and market trends.

The reduction in coal production under the proposed rule (as well as alternative 4), relative to the no action alternative are not expected to have adverse effects on the productivity, competition, or prices in the energy sector regionally (or nationally) due to the following observations:

—Potential reductions in coal production under the proposed rule, relative to no action are not projected to occur until 24 years in the future (2035) and estimated reductions after year 24 (*i.e.,* 5.6 million tons/yr) exceed the criterion of 5.0 million tons per year by only a small fraction. A second decrease in production of similar magnitude (6.0 million tons per year) is projected to occur farther in the future (2059) when all mines cease operation under the proposed rule.

—The reduction in total accessible coal reserves under the proposed rule relative to the no action alternative amounts to a relatively small percentage of total estimated recoverable reserves in the State of Colorado (2%) and the nation (< 0.1%), and

—The reductions in reserves and production rates under the proposed rule compared to no action are estimated to occur well into the future (*e.g.,* 24 and 48 yrs), and the relative impact of these reductions is expected to be insignificant compared to the impact of other factors that could affect regional and national energy markets by that time.

The reductions in annual production under the 2001 rule, compared to the no

[1] "Recoverable Coal Reserves" consist of the quantity of coal that can be recovered (*i.e.,* mined) from existing coal reserves at reporting mines. Source: U.S. Energy Information Administration (EIA), Independent Statistics and Analysis (Table 14—Recoverable Coal Reserves and Average Recovery Percentage at Producing Mines by State, 2000—2007) *http://www.eia.doe.gov/cneaf/coal/reserves/reserves.html.*

[2] "2008 Coal Production and Employment for Colorado" Colorado Mining Association, Denver CO. *http://www.coloradomining.com.*

[3] "Estimated recoverable reserves" consist of coal in the demonstrated reserve base considered recoverable after excluding coal estimated to be unavailable due to land use restrictions or currently economically unattractive for mining. Source: U.S. Energy Information Administration (EIA), Independent Statistics and Analysis (Table 15—Recoverable Coal Reserves at Producing Mines, Estimated Recoverable Reserves, and Demonstrated Reserve Base by Mining Method, 2000–2007) *http://www.eia.doe.gov/cneaf/coal/reserves/reserves.html.*

[4] In 2007, the Energy Information Administration called for a 5% per year increase in coal production from western mines, but revised this statement in 2009, suggesting a slower rate of increase.

[5] Demand for coal is anticipated to increase as a consequence of 153 new coal-fired electricity plants to be built by 2025, many of which will be in States such as FL, TX, IL, KY that import Colorado coal. ("Colorado Mineral and Energy Industry Activities, 2006", Colorado Geological Survey, Department of Natural Resources, Denver CO.)

action (reductions range from 5.6 million tons per year beginning as early as 2013 and increase to 11.6 million tons by 2019) are somewhat greater than the reductions noted for the proposed rule (and Alternative 4), and production life is anticipated to extend for only 7 to 10 years under the 2001 rule compared to a longer production life under the no action alternative.

There is a substantial reduction in annual production under the 2001 rule alternative compared to the no action alternative (reductions range from 5.6 million tons per year beginning as early as 2013 and increase to 11.6 million tons by 2019), and production life is anticipated to extend for only 7 to 10 years under the 2001 rule compared to a longer production life under the no action alternative. The production reductions under the 2001 rule (*i.e.,* 11.6 million tons/yr beginning around 2019) exceed the criterion of 5 million tons per year for adverse effects (but reductions are still relatively small), and decreases in operating life of the mines as well as total reserves may suggest the potential for adverse effects to regional markets. The impacts of a number of other factors affecting energy markets and national market trends are still expected to outweigh the effects of implementing the 2001 rule alternative.

Alternative 1 has the greatest reduction in production, and alternatives 2 and 4 have some reduction compared to forest plans.

No novel legal or policy issues regarding adverse effects to supply, distribution or use of energy are anticipated beyond what has already been addressed in the RDEIS, or the Regulatory Impact Analysis (RIA). None of the proposed corridors designated for oil, gas, and/or electricity under Section 368 of the Energy Policy Act of 2005 are within Colorado Roadless Areas.

The proposed rule does not disturb existing access or mineral rights, and restrictions on saleable mineral materials are narrow. The proposed rule also provides regulatory mechanism for consideration of requests for modification of restrictions if adjustments are determined to be necessary in the future. As this action is a significant energy action, the above constitutes the Statement of Energy Effects.

List of Subjects in 36 CFR Part 294

National Forests, Recreation areas, Navigation (air), State petitions for inventoried roadless area management.

Therefore, for the reasons set forth in the preamble, the Forest Service proposes to amend part 294 of Title 36 of the Code of Federal Regulations by adding new subpart D to read as follows:

PART 294—SPECIAL AREAS

Subpart D—Colorado Roadless Area Management

Sec.

294.40 Purpose.
294.41 Definitions.
294.42 Prohibitions on tree-cutting, sale, or removal.
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Subpart D—Colorado Roadless Area Management

Authority: 16 U.S.C. 472, 529, 551, 1608, 1613; 23 U.S.C. 201, 205.

§ 294.40 Purpose.

The purpose of this subpart is to provide, within the context of multiple use management, State-specific direction for the protection of roadless areas on National Forest System lands in Colorado. The intent of this regulation is to protect roadless values by restricting tree cutting, sale, and removal, road construction and reconstruction, and linear construction zones within CRAs, with narrowly focused exceptions. Activities must be designed to conserve the roadless area characteristics listed in § 294 .41, although applying the exceptions in § 294.42, § 294.43, and § 294.44 may have effects to some roadless area characteristics.

§ 294.41 Definitions.

The following terms and definitions apply to this subpart.

At-risk community: As defined under section 101 of the Healthy Forest Restoration Act (Pub. L. 108–148).

Catchment: A watershed delineation beginning at the downstream point of occupation of native cutthroat trout and encompassing the upstream boundary of waters draining in the stream system.

Colorado Roadless Area Upper Tier Acres: A subset of Colorado Roadless Areas identified in a set of maps maintained at the national headquarters office of the Forest Service where not all exceptions for tree-cutting, sale, or removal and road construction/reconstruction would apply in order to provide a higher level of protection.

Colorado Roadless Areas: Areas designated pursuant to this subpart and identified in a set of maps maintained at the national headquarters office of the Forest Service. Colorado Roadless Areas established by this subpart shall constitute the exclusive set of National Forest System lands within the State of Colorado to which the provisions 36 CFR 220.5(a)(2) shall apply.

Community Protection Zone: An area extending one-half mile from the boundary of an at-risk community; or an area within one and a half miles from the boundary of an at-risk community, where any land:

(1) Has a sustained steep slope that creates the potential for wildfire behavior endangering the at-risk community;

(2) Has a geographic feature that aids in creating an effective fire break, such as a road or a ridge top; or

(3) Is in condition class 3 as defined by Healthy Forest Restoration Act (Pub. L. 108–148).

Community Wildfire Protection Plan: As defined under section 101 of the Healthy Forest Restoration Act (Pub. L. 108–148), and used in this subpart, the term "community wildfire protection plan" means a plan for an at-risk community that:

(1) Is developed within the context of the collaborative agreements and the guidance established by the Wildland Fire Leadership Council and agreed to by the applicable local government, local fire department, and State agency responsible for forest management, in consultation with interested parties and the Federal land management agencies managing land in the vicinity of the at-risk community;

(2) Identifies and prioritizes areas for hazardous fuel reduction treatments and recommends the types and methods of treatment on Federal and non-Federal land that will protect one or more at-risk communities and essential infrastructure; and

(3) Recommends measures to reduce structural ignitability throughout the at-risk community.

Condition Class 3: As defined under section 101 of the Healthy Forests Restoration Act (Pub. L. 108–148) the term "condition class 3" means an area of Federal land, under which:

(1) Fire regimes on land have been significantly altered from historical ranges;

(2) There exists a high risk of losing key ecosystem components from fire;

(3) Fire frequencies have departed from historical frequencies by multiple return intervals, resulting in dramatic changes to:

(i) The size, frequency, intensity, or severity of fires; or

(ii) Landscape patterns; and

(4) Vegetation attributes have been significantly altered from the historical range of the attributes.

Fire Hazard: A fuel complex defined by volume, type, condition, arrangement and location that determines the ease of ignition and the resistance to control; expresses the potential fire behavior for a fuel type, regardless of the fuel type's weather influenced fuel moisture condition.

Fire Occurrence: One fire event occurring in a specific place within a specific period of time; a general term describing past or current wildland fire events.

Fire Risk: The probability or chance that a fire might start, as affected by the presence and activities of causative agents.

Forest road: As defined at 36 CFR 212.1, the term means a road wholly or partly within or adjacent to and serving the National Forest System that the Forest Service determines is necessary for the protection, administration, and utilization of the National Forest System and the use and development of its resources.

Hazardous Fuels: Excessive live or dead wildland fuel accumulations that increase the potential for intense wildland fire and decrease the capability to protect life, property and natural resources.

Linear Construction Zone: A temporary linear area of surface disturbance over 50 inches wide that is used for motorized transport by vehicles or construction equipment to install a linear facility. It is not used as a motor vehicle route and is not engineered to road specifications.

Linear Facility: Linear facilities include pipelines, electrical power lines, telecommunications lines, ditches and canals.

Municipal Water Supply System: As defined under Section 101 of the Healthy Forests Restoration Act (Pub. L. 108–148), and used in this subpart, the term means the reservoirs, canals, ditches, flumes, laterals, pipes, pipelines, and other surface facilities and systems constructed or installed for the collection, impoundment, storage, transportation, or distribution of drinking water.

Native Cutthroat Trout: Collectively, all the native subspecies of cutthroat trout historically occurring in Colorado before European settlement which includes yellowfin, Rio Grande, Greenback, and Colorado River Trout.

Pre-existing Water Court Decree: A decree issued by the Colorado Water Courts prior to [final rule effective date] adjudicating as the point of a diversion or the place of use, a location within a Colorado Roadless Area. A pre-existing decree does not include decrees adjudicated prior to [final rule effective date] which right includes a point of diversion or place of use outside of a Colorado Roadless Area, the holder of which proposes to change or move the point of diversion or place of use within a Colorado Roadless Area. Nothing in this subpart shall be construed as affecting the jurisdiction or responsibilities of the Forest Service.

Responsible Official: The Forest Service line officer with the authority and responsibility to make decisions about protection and management of Colorado Roadless Areas pursuant to this subpart.

Road: As defined at 36 CFR 212.1, the term means a motor vehicle route over 50 inches wide, unless identified and managed as a trail.

Roadless Area Characteristics: Resources or features that are often present in and characterize Colorado Roadless Areas, including:

(1) High quality or undisturbed soil, water, and air;

(2) Sources of public drinking water;

(3) Diversity of plant and animal communities;

(4) Habitat for threatened, endangered, proposed, candidate, and sensitive species, and for those species dependent on large, undisturbed areas of land;

(5) Primitive, semi-primitive non-motorized, and semi-primitive motorized classes of dispersed recreation;

(6) Reference landscapes;

(7) Naturaly-appearing landscapes with high scenic quality;

(8) Traditional cultural properties and sacred sites; and

(9) Other locally identified unique characteristics.

Temporary Road: As defined at 36 CFR 212.1, the term means a road necessary for emergency operations or authorized by contract, permit, lease, or other written authorization that is not a forest road and that is not included in a forest transportation atlas.

Water Conveyance Structures: Facilities associated with the transmission, storage, impoundment, and diversion of water on and across National Forest System lands. Water conveyance structures include, but are not limited to: reservoirs and dams, diversion structures, headgates, pipelines, ditches, canals, and tunnels.

Water Influence Zone: The land next to water bodies where vegetation plays a major role in sustaining long-term integrity of aquatic systems. It includes the geomorphic floodplain (valley bottom), riparian ecosystem, and inner gorge. Its minimum horizontal width (from top of each bank) is 100 feet or the mean height of mature dominant late-seral vegetation, whichever is greater.

§ 294.42 Prohibition on tree-cutting, sale, or removal.

(a) *General.* Trees may not be cut, sold, or removed in Colorado Roadless Areas, except as provided in paragraph (b) and (c) of this section.

(b) *Upper Tier Acres.* Notwithstanding the prohibition in paragraph (a) of this section, trees may be cut, sold, or removed in Colorado Roadless Areas upper tier acres if the Responsible Official determines the activity is consistent with the applicable land management plan, and:

(1) Tree-cutting, sale, or removal is incidental to the implementation of a management activity not otherwise prohibited by this subpart; or

(2) Tree-cutting, sale, or removal is needed and appropriate for personal or administrative use, as provided for in 36 CFR part 223, subpart A.

(c) *Non-Upper Tier Acres.* Notwithstanding the prohibition in paragraph (a) of this section, trees may be cut, sold, or removed in Colorado Roadless Areas outside upper tier acres if the Responsible Official, unless otherwise noted, determines the activity is consistent with the applicable land management plan, one or more of the roadless area characteristics will be maintained or improved over the long-term with the exception of paragraphs (c)(5) and (6) of this section, and one of the following circumstances exists:

(1) The Regional Forester determines tree-cutting, sale, or removal is needed to reduce hazardous fuels to an at-risk community or municipal water supply system that is:

(i) Within the first one-half mile of the community protection zone, or

(ii) Within the next one-mile of the community protection zone, and is within an area identified in a Community Wildfire Protection Plan.

(iii) Projects undertaken pursuant to paragraphs (c)(1)(i) and (ii) of this section will focus on cutting and removing generally small diameter trees to create fuel conditions that modify fire behavior while retaining large trees to the maximum extent practical as appropriate to the forest type.

(2) The Regional Forester determines tree-cutting, sale, or removal is needed outside the community protection zone where there is a significant risk that a wildland fire disturbance event could adversely affect a municipal water

supply system or the maintenance of that system. A significant risk exists where the history of fire occurrence, and fire hazard and risk indicate a serious likelihood that a wildland fire disturbance event would present a high risk of threat to a municipal water supply system.

(i) Projects will focus on cutting and removing generally small diameter trees to create fuel conditions that modify fire behavior while retaining large trees to the maximum extent practical as appropriate to the forest type.

(ii) Projects are expected to be infrequent.

(3) Tree-cutting, sale, or removal is needed to maintain or restore the characteristics of ecosystem composition, structure and processes. These projects are expected to be infrequent.

(4) Tree-cutting, sale, or removal is needed to improve habitat for Federally threatened, endangered, proposed, or Agency designated sensitive species; in coordination with the Colorado Department of Natural Resources, including the Colorado Division of Wildlife.

(5) Tree-cutting, sale, or removal is incidental to the implementation of a management activity not otherwise prohibited by this subpart.

(6) Tree-cutting, sale, or removal is needed and appropriate for personal or administrative use, as provided for in 36 CFR part 223, subpart A.

§ 294.43 Prohibition on road construction and reconstruction.

(a) *General.* A road may not be constructed or reconstructed in a Colorado Roadless Area except as provided in paragraphs (b) and (c) of this section.

(b) *Upper Tier Acres.* Notwithstanding the prohibition in paragraph (a) of this section, a road may only be constructed or reconstructed in Colorado Roadless Area upper tier acres if the Responsible Official determines that:

(1) A road is needed pursuant to reserved or outstanding rights, or as provided for by statute or treaty.

(2) For any road construction/reconstruction authorized pursuant to this provision, the Responsible Official must determine:

(i) Motorized access, without road construction is not technically feasible;

(ii) When proposing to construct a forest road, that a temporary road would not provide reasonable access; and

(iii) Within a native cutthroat trout catchment or identified recovery watershed, whether road construction will diminish, over the long-term, conditions in the water influence zone and in the native cutthroat habitat.

(c) *Non-Upper Tier Acres.* Notwithstanding the prohibition in paragraph (a) of this section, a road or temporary road may only be constructed or reconstructed in Colorado Roadless Areas outside upper tier acres if the Responsible Official determines:

(1) That one of the following exceptions exists:

(i) A road is needed pursuant to reserved or outstanding rights, or as provided for by statute or treaty;

(ii) Road realignment is needed to prevent irreparable resource damage that arises from the design, location, use, or deterioration of a forest road and that cannot be mitigated by road maintenance. Road realignment may occur under this paragraph only if the road is deemed essential for administrative or public access, public health and safety, or other authorized use;

(iii) Road reconstruction is needed to implement a road safety improvement project on a forest road determined to be hazardous on the basis of accident experience or accident potential on that road;

(iv) The Regional Forester determines a road is needed to allow for the construction, reconstruction, or maintenance of an authorized water conveyance structure which is operated pursuant to a pre-existing water court decree (see also § 294.44(b)(1));

(v) A temporary road is needed to protect public health and safety in cases of threat of flood, fire, or other catastrophic event that, without intervention, would cause the loss of life or property;

(vi) The Regional Forester determines a temporary road is needed to facilitate tree-cutting, sale, or removal (§ 294.42(c)(1)) within the first one-half mile of the community protection zone to reduce the wildfire hazard to an at-risk community or municipal water supply system;

(vii) The Regional Forester determines a temporary road is needed to facilitate tree-cutting, sale or removal (§ 294.42(c)(3)) within the first one-half mile of the community protection zone to maintain or restore characteristics of ecosystem composition, structure and processes;

(viii) A temporary road is needed within a Colorado Roadless Area pursuant to the exploration or development of an existing oil and gas lease that does not prohibit road construction or reconstruction, including the construction of infrastructure necessary to transport the product, on National Forest System lands that are under lease issued by the Secretary of the Interior as of [final rule effective date]. The Forest Service shall not authorize the Bureau of Land Management to grant any request for a waiver, exception, or modification to any oil or gas lease if doing so would result in any road construction or tree cutting within a Colorado Roadless Area beyond that which was authorized by the terms and conditions of the lease at the time of issuance; or

(ix) A temporary road is needed for coal exploration and coal-related surface activities for certain lands within Colorado Roadless Areas in the North Fork coal mining area of the Grand Mesa, Uncompahgre, and Gunnison National Forests as defined by the North Fork coal mining area displayed on the final Colorado Roadless Areas map. Such roads may also be used for collecting and transporting coal mine methane. Any buried infrastructure, including pipelines, needed for the capture, collection, and use of coal mine methane will be located within the rights-of-way of temporary roads that are otherwise necessary for coal-related surface activities including the installation and operation of methane venting wells.

(2) If proposed road construction/reconstruction meets one of the exceptions, subject to the legal rights identified in 36 CFR 294.43(c)(1), the following must be determined:

(i) Motorized access, without road construction is not technically feasible;

(ii) When proposing to construct a forest road, that a temporary road would not provide reasonable access;

(iii) Road construction is consistent with the applicable land management plan direction;

(iv) Within a native cutthroat trout catchment or identified recovery watershed, road construction will not diminish, over the long-term, conditions in the water influence zone and in the native cutthroat habitat; and

(d) *Road construction/reconstruction project implementation and management.* Incorporate the following elements into any road construction/reconstruction projects implemented within Colorado Roadless Areas.

(1) *Road construction.* If it is determined that a road is authorized in a Colorado Roadless Area, conduct construction in a manner that reduces, to the extent practicable, effects on surface resources, and prevents unnecessary or unreasonable surface disturbance.

(2) *Road decommissioning.* Decommission any road and restore the affected landscape when it is determined that the road is no longer needed for the established purpose, or upon termination or expiration of a

contract, authorization, or permit, whichever is sooner. Require the inclusion of a road decommissioning provision in all such contracts or permits. Design decommissioning to stabilize, restore, and revegetate unneeded roads to a more natural state to protect resources and enhance roadless area characteristics.

(3) *Road designations.* The designation of a temporary road constructed or reconstructed pursuant to this subpart may not be changed to forest road except where a forest road is allowed under paragraphs (b) and (c) of this section.

(4) *Road use.* Use of motor vehicles for administrative purposes by the Forest Service and by fire, emergency, or law enforcement personnel is allowed. All roads constructed pursuant to paragraphs (b) and (c) of this section shall prohibit public motorized vehicles (including off-highway vehicles) except:

(i) Where specifically used for the purpose for which the road was established;

(ii) Motor vehicle use that is specifically authorized under an authorization issued under Federal law or regulation.

(5) *Road maintenance.* Maintenance of roads is permissible in Colorado Roadless Areas.

§ 294.44 Prohibition on linear construction zones.

(a) *General.* A linear construction zone may not be constructed or reconstructed in Colorado Roadless Areas except as provided in paragraph (b) of this section.

(b) *Linear Construction Zones.* Notwithstanding the prohibition in paragraph (a) of this section, the Regional Forester may authorize a linear construction zone within a Colorado Roadless Area for:

(1) The construction, reconstruction, or maintenance of an authorized water conveyance structure which is operated pursuant to a pre-existing water court decree (see § 294.43(c)(1)(iv));

(2) The construction, reconstruction, or maintenance of existing or future authorized electrical power lines or telecommunication lines. Authorize electrical power lines or telecommunication lines within Colorado Roadless Areas only if there is no opportunity for the project to be implemented outside of a Colorado Roadless Area without causing substantially greater environmental damage; or

(3) The construction or reconstruction of a pipeline associated with operation of an oil and gas lease that allows surface use within a Colorado Roadless Area or the construction or reconstruction of a pipeline needed to connect to infrastructure within a Colorado Roadless Area from outside a Colorado Roadless Area where such a connection would cause substantially less environmental damage than alternative routes. The construction of pipelines for the purposes of transporting oil or natural gas through a Colorado Roadless Area, where the source(s) and destination(s) of the pipeline are located exclusively outside of a Colorado Roadless Area, shall not be authorized.

(4) If a proposed linear construction zone meets one of the exceptions, then the following must be determined:

(i) Motorized access, without a linear construction zone, is not technically feasible;

(ii) A linear construction zone is consistent with the applicable land management plan direction;

(iii) Within a native cutthroat trout catchment or identified recovery watershed, a linear construction zone will not diminish, over the long-term, conditions in the water influence zone and in the native cutthroat habitat; and

(c) *Linear construction zone decommissioning.* Where a linear construction zone is constructed in a Colorado Roadless Area, installation of the linear facility will be done in a manner that minimizes ground disturbance, including placement within existing right-of-ways where feasible. All authorizations approving the installation of linear facilities through the use of a linear construction zone shall include a Responsible Official approved reclamation plan for reclaiming the affected landscape. Upon completion of the installation of a linear facility via the use of a linear construction zone, all areas of surface disturbance shall be reclaimed as prescribed in the authorization and the approved reclamation plan and may not be waived.

§ 294.45 Environmental documentation.

(a) Environmental documentation will be prepared pursuant to Section 102 of the National Environmental Policy Act, 40 CFR 1500, and 36 CFR part 220 for any proposed action within a Colorado Roadless Area. Proposals that substantially alter the undeveloped character of a Colorado Roadless Area require an Environmental Impact Statement (EIS).

(b) The Forest Service will offer cooperating agency status to the State of Colorado, for all proposed projects and planning activities to be implemented on lands within Colorado Roadless Areas. Where the Forest Service does not have the authority to offer formal cooperating agency status, the Forest Service shall offer to coordinate with the State.

§ 294.46 Other activities.

(a) *Oil and Gas Lease Stipulations.* Oil and gas leases issued within a Colorado Roadless Area after [final rule effective date] will prohibit road construction/reconstruction. The Forest Service shall not authorize the Bureau of Land Management to grant any request for a waiver, exception, or modification to any oil or gas lease if doing so would result in any road construction within a Colorado Roadless Area.

(b) *Oil and Gas Surface Use Plans of Operation.* Where applicable, during the review of any application for a surface use plan of operations affecting lands within a Colorado Roadless Area, the Responsible Official will:

(1) Locate, to the extent possible without compromising health and safety standards, roads, well sites, and facilities on pre-existing areas of surface disturbance. Project design shall minimize the amount of necessary temporary road construction or reconstruction.

(2) Consider an alternative for proposed operations that addresses locating directional drilling of multi-well sites on pre-existing areas of surface disturbance. Such an alternative can be dismissed from detailed analysis with clear justification.

(3) Restrict road construction for leases partially within Colorado Roadless Areas, to the extent practical, to portions of the lease outside of Colorado Roadless Areas except when doing so will be substantially more environmentally damaging, compromise safety standards, or is unfeasible due to topography or surface conditions.

(4) Perform, to the extent feasible, reclamation of surface disturbances incrementally, to minimize the total area of disturbance at any given point in time during the exploration or development of a lease.

(5) Design, to the extent feasible, temporary roads and facilities to blend with the terrain to minimize visual impacts and to facilitate restoration when the road is no longer needed.

(6) Co-locate, wherever possible and consistent with health and safety standards, power lines, flow lines and pipelines within the right-of-way of roads to minimize the area of surface disturbance.

(7) Consider new and developing low impact techniques and technologies and either apply or dismiss with justification.

(8) Utilize the best available technology, to the extent possible, to minimize noise and air emissions.

(c) *Trails.* Nothing in this subpart shall affect the current or future management of motorized and non-motorized trails in Colorado Roadless Areas. Decisions concerning the management or status of motorized and non-motorized trails within Colorado Roadless Areas under this subpart shall be made during the applicable forest travel management processes.

(d) *Motorized access.* Nothing in this subpart shall be construed as limiting the authority of the responsible official to approve existing and future motorized access not requiring road construction or reconstruction in Colorado Roadless Areas associated with grazing permits, special use authorizations, and other authorizations.

(e) *Livestock grazing.* The authority to issue livestock grazing permits on national forest system lands within a Colorado Roadless Area is not affected by this subpart; however no new temporary or forest roads shall be authorized through grazing permits issued after [final rule effective date].

§ 294.47 Modifications and administrative corrections.

Modifications and administrative corrections pursuant to this subpart, after coordination with the State, may be made under the following circumstances:

(a) *Modifications to boundaries.* The Chief of the Forest Service may modify the boundaries of any designated Colorado Roadless Area identified in § 294.49 or add new Colorado Roadless Areas based on changed circumstances. Modifications and additions will be reflected in the set of maps maintained at the national headquarters office of the Forest Service. The construction or reconstruction of a temporary road or tree-cutting, sale, or removal will not result in any boundary modification of a Colorado Roadless Area. Public notice with a minimum 90-day comment period will be provided for any proposed Colorado Roadless Area boundary modifications or additions.

(b) *Administrative corrections to boundaries.* The Chief of the Forest Service may issue administrative corrections after public notice and a 30-day comment period. Administrative corrections to the maps of any designated Colorado Roadless Areas identified in § 294.49 are adjustments to remedy errors such as clerical, topographical, or improvements in mapping technology. Other than clerical errors, an administrative correction is based on improved field data due to updated imagery, global positioning system data, or other collected field data.

(c) *Amendments to rule language.* Any amendment of this subpart will include coordination with the State and the appropriate level of NEPA analysis. A minimum 90-day comment period will be provided.

§ 294.48 Scope and applicability.

(a) This subpart does not revoke, suspend, or modify any permit, contract, lease, or other legal instrument authorizing or granting rights to the occupancy and use of National Forest system land issued prior to [final rule effective date] nor does it affect the authority or the discretion of the responsible official to reissue any such permit, contract, or other legal instrument upon its expiration or termination.

(b) This subpart does not revoke, suspend, or modify any project or activity decision made prior to [final rule effective date].

(c) The provisions set forth in this subpart provide the maximum level of tree-cutting, sale and removal, and road construction and reconstruction activity allowed within Colorado Roadless Areas. Land management plan components can be more restrictive than this subpart and will continue to provide direction and guidance for projects and activities within Colorado Roadless Areas. Nothing in this subpart shall prohibit a responsible official from further restricting activities allowed within Colorado Roadless Areas. This subpart does not compel the amendment or revision of any land management plan.

(d) The prohibitions and restrictions established in this subpart are not subject to reconsideration, revision, or rescission in subsequent project decisions or land management plan amendments or revisions undertaken pursuant to 36 CFR part 219.

(e) Nothing in this subpart waives any applicable requirements regarding site specific environmental analysis, public involvement, consultation with Tribes and other agencies, or compliance with applicable laws.

(f) If any provision in this subpart or its application to any person or to certain circumstances is held to be invalid, the remainder of the regulations in this subpart and their application remain in force.

(g) After [final rule effective date] the rule promulgated on January 12, 2001, (66 FR 3244) shall have no effect within the State of Colorado.

§ 294.49 List of designated Colorado Roadless Areas.

All National Forest System lands within the State of Colorado listed in this section are hereby designated as Colorado Roadless Areas.

Arapaho-Roosevelt National Forest

1. Bard Creek.
2. Byers Peak.
3. Cache La Poudre Adjacent Area.
4. Cherokee Park.
5. Comanche Peak Adjacent Area.
6. Copper Mountain.
7. Crosier Mountain.
8. Gold Run.
9. Green Ridge—East.
10. Green Ridge—West.
11. Grey Rock.
12. Hell Canyon.
13. Indian Peaks Adjacent Area.
14. James Peak.
15. Kelly Creek.
16. Lion Gulch.
17. Mount Evans Adjacent Area.
18. Mount Sniktau.
19. Neota Adjacent Area.
20. Never Summer Adjacent Area.
21. North Lone Pine.
22. North St. Vrain.
23. Rawah Adjacent Area.
24. Square Top Mountain.
25. Troublesome.
26. Vasquez Adjacent Area.
27. White Pine Mountain.
28. Williams Fork Ptarmigan Adjacent.

Grand Mesa, Uncompahgre, Gunnison National Forest

29. Agate Creek.
30. American Flag Mountain.
31. Baldy.
32. Battlements.
33. Beaver.
34. Beckwiths.
35. Calamity Basin.
36. Cannibal Plateau.
37. Canyon Creek—Antero.
38. Canyon Creek.
39. Carson.
40. Castle.
41. Cataract.
42. Cimarron Ridge.
43. Clear Fork.
44. Cochetopa.
45. Cochetopa Hills.
46. Cottonwoods.
47. Crystal Creek.
48. Crystal Peak.
49. Curecanti.
50. Currant Creek.
51. Deer Creek.
52. Dominguez.
53. Double Top.
54. East Elk.
55. Electric Mountain.
56. Failes Creek-Soldier Creek.
57. Flatirons.
58. Flattop Mountain.
59. Flattops—Elk Park.
60. Gothic.
61. Granite Basin.
62. Hightower.
63. Hope Lake.

64. Horse Ranch Park.
65. Horsefly Canyon.
66. Huntsman Ridge.
67. Italian Mountain.
68. Johnson Basin.
69. Kannah Creek.
70. Kelso Mesa.
71. Last Dollar—Sheep Creek.
72. Little Cimarron.
73. Long Canyon.
74. Matchless Mountain.
75. Matterhorn.
76. McClure Pass.
77. Mendicant.
78. Mineral Mountain.
79. Mirror Lake.
80. Mount Lamborn.
81. Munsey-Erickson.
82. Naturita Canyon.
83. North Henson.
84. Pilot Knob.
85. Poverty Gulch.
86. Salt Creek.
87. Sanford Basin.
88. Sawtooth.
89. Schofield Pass.
90. Soap Creek.
91. Steuben.
92. Sunnyside.
93. Sunset.
94. Texas Creek.
95. Tomahawk.
96. Turner Creek.
97. Turret Ridge.
98. Unaweep.
99. Union.
100. Whetstone.
101. Whitehouse Mountain.
102. Willow Creek.
103. Wilson.
104. Windy Point.

Manti-La Sal National Forest

105. Roc Creek.

Pike-San Isabel National Forest

106. Antelope Creek.
107. Aspen Ridge.
108. Babcock Hole.
109. Badger Creek.
110. Boreas.
111. Buffalo Peaks East.
112. Buffalo Peaks South.
113. Buffalo Peaks West.
114. Burning Bear.
115. Chicago Ridge.
116. Chipeta.
117. Cuchara North.
118. Cuchara South.
119. Elk Mountain—Collegiate North.
120. Elk Mountain—Collegiate South.
121. Elk Mountain—Collegiate West.
122. Farnum.
123. Green Mountain.
124. Greenhorn Mountain: Badito Cone to Dry Creek.
125. Greenhorn Mountain: Cisneros Creek to Upper Turkey Creek.
126. Greenhorn Mountain: Graneros Creek to Section 10.
127. Greenhorn Mountain: Little Saint Charles Creek to Greenhorn Creek.
128. Gunbarrel.
129. Hardscrabble.
130. Highline.
131. Holy Cross.
132. Hoosier Ridge.
133. Jefferson.
134. Kaufman Ridge.
135. Kreutzer—Princeton.
136. Little Fountain Creek.
137. Lost Creek East.
138. Lost Creek South.
139. Lost Creek West.
140. Methodist Mountain.
141. Mount Antero.
142. Mount Elbert.
143. Mount Evans.
144. Mount Massive.
145. Pikes Peak East.
146. Pikes Peak West.
147. Porphyry Peak.
148. Puma Hills.
149. Purgatoire.
150. Rampart East..
151. Rampart West.
152. Reveille Canyon.
153. Romley.
154. Sangre de Cristo: Alvarado Campground to Music Pass.
155. Sangre de Cristo: Blanca Peak to Slide Mountain.
156. Sangre de Cristo: Lake Creek to Hermit Creek.
157. Sangre de Cristo: Medano Pass to Carbonate Mountain.
158. Sangre de Cristo: Silverheels Gulch to Hunts Creek.
159. Sangre de Cristo: West Creek to Big Cottonwood.
160. Schoolmarm Mountain.
161. Scraggy Peaks.
162. Sheep Rock.
163. Silverheels.
164. Spanish Peaks.
165. Square Top Mountain.
166. St. Charles Peak.
167. Starvation Creek.
168. Tanner Peak.
169. Thirtynine Mile Mountain.
170. Thunder Butte.
171. Weston Peak.

Rio Grande National Forest

172. Alamosa River.
173. Antora Meadows-Bear Creek.
174. Beartown.
175. Beaver Mountain.
176. Bennet Mountain-Blowout-Willow Creek-Lion Point-Greenie Mountain.
177. Big Buck-Kitty-Ruby.
178. Box-Road Canyon.
179. Bristol Head.
180. Butterfly.
181. Chama Basin.
182. Conejos River-Lake Fork.
183. Copper Mountain-Sulphur.
184. Cotton Creek.
185. Crestone.
186. Cumbres.
187. Deep Creek-Boot Mountain.
188. Dorsey Creek.
189. Elkhorn Peak.
190. Four Mile Creek.
191. Fox Creek.
192. Fox Mountain.
193. Gibbs Creek.
194. Gold Creek-Cascade Creek.
195. Hot Springs.
196. Indian Ridge.
197. Kitty Creek.
198. La Garita.
199. Lake Fork.
200. Lower East Bellows.
201. Middle Alder.
202. Miller Creek.
203. Pole Creek.
204. Pole Mountain-Finger Mesa.
205. Red Mountain.
206. Ruby Lake.
207. Sawlog.
208. Sheep Mountain.
209. Silver Lakes-Stunner.
210. Snowshoe Mountain.
211. Spectacle Lake.
212. Spruce Hole-Sheep Creek.
213. Stunner Pass-Dolores Canyon.
214. Sulphur Tunnel.
215. Summit Peak-Elwood Pass.
216. Taylor Canyon.
217. Tewksberry.
218. Tobacco Lakes.
219. Trout Mountain-Elk Mountain.
220. Ute Pass.
221. Wason Park.
222. Wightman Fork—Upper Burro.
223. Wightman Fork—Lookout.
224. Willow Mountain.

Routt National Forest

225. Barber Basin.
226. Black Mountain.
227. Bunker Basin.
228. Bushy Creek.
229. Chatfield.
230. Chedsey Creek.
231. Dome.
232. Dome Peak.
233. Elkhorn.
234. Gold Creek.
235. Grizzly Helena.
236. Kettle Lakes.
237. Little Green Creek.
238. Long Park.
239. Mad Creek.
240. Morrison Creek.
241. Never Summer North.
242. Never Summer South.
243. Nipple Peak North.
244. Nipple Peak South.
245. Pagoda Peak.
246. Shield Mountain.
247. South Fork.
248. Sugarloaf North.
249. Sugarloaf South.
250. Troublesome North.
251. Troublesome South.
252. Walton Peak.
253. Whalen Creek.

San Juan National Forest

254. Baldy.
255. Blackhawk Mountain.
256. East Animas.
257. Fish Creek.
258. Florida River.
259. Graham Park.
260. HD Mountains.
261. Hermosa.
262. Lizard Head Adjacent.
263. Piedra Area Adjacent.
264. Runlett Park.
265. Ryman.

266. San Miguel.
267. South San Juan Adjacent.
268. Storm Peak.
269. Treasure Mountain.
270. Turkey Creek.
271. Weminuche Adjacent.
272. West Needles.
273. Winter Hills/Serviceberry Mountain.

White River National Forest

274. Adam Mountain.
275. Ashcroft.
276. Assignation Ridge.
277. Baldy Mountain.
278. Basalt Mountain A.
279. Basalt Mountain B.
280. Berry Creek.
281. Big Ridge to South Fork A.
282. Big Ridge to South Fork B.
283. Black Lake East.
284. Black Lake West.
285. Blair Mountain.
286. Boulder.
287. Budges.
288. Buffer Mountain.
289. Burnt Mountain.
290. Chicago Ridge.
291. Corral Creek.
292. Crystal River.
293. Deep Creek.
294. Dome Peak.
295. East Divide-Four Mile Park.
296. East Vail.
297. East Willow.
298. Elk Creek B.
299. Elliot Ridge.
300. Fawn Creek-Little Lost Park.
301. Freeman Creek.
302. Gallo Hill.
303. Game Creek.
304. Grizzly Creek.
305. Gypsum Creek.
306. Hardscrabble.
307. Hay Park.
308. Holy Cross City.
309. Homestake.
310. Hoosier Ridge.
311. Housetop Mountain.
312. Hunter.
313. Little Grand Mesa.
314. Lower Piney.
315. Mamm Peak.
316. Maroon East.
317. Maryland Creek.
318. McClure Pass.
319. McFarlane.
320. Meadow Mountain A.
321. Meadow Mountain B.
322. Morapos A.
323. Morapos B.
324. Mormon Creek.
325. No Name.
326. North Elk.
327. North Independent A.
328. North Independent B.
329. North Woody.
330. Pagoda Peak.
331. Piney Lake.
332. Porcupine Peak.
333. Ptarmigan A.
334. Ptarmigan B.
335. Ptarmigan C.
336. Ptarmigan Hill A.
337. Ptarmigan Hill B.
338. Red Dirt A.
339. Red Dirt B.
340. Red Mountain.
341. Red Table.
342. Reno Mountain.
343. Ripple Creek Pass-Trappers Lake.
344. Ryan Gulch.
345. Salt Creek.
346. Sloan Peak.
347. Spraddle Creek A.
348. Spraddle Creek B.
349. Sweetwater A.
350. Sweetwater B.
351. Tenderfoot Mountain.
352. Tenmile.
353. Thompson Creek.
354. Tigiwon.
355. Treasure Mountain.
356. West Brush Creek.
357. West Lake Creek.
358. Wildcat Mountain.
359. Wildcat Mountain B.
360. Wildcat Mountain C.
361. Williams Fork.
362. Willow.
363. Woods Lake.

Dated: April 11, 2011.

Jay J. Jensen,

Deputy Under Secretary, NRE.

[FR Doc. 2011–9119 Filed 4–14–11; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 158

[EPA–HQ–OPP–2010–0670; FRL–8857–7]

RIN 2070–AJ80

Pesticides; Microbial Pesticide Definitions and Applicability; Clarification and Availability of Draft Test Guideline for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: As promulgated, EPA's regulations distinguish "isolates" and "strains" in a confusing and non-obvious manner. This has resulted in significant uncertainty within the regulated industry. This proposed rule addresses this problem by proposing new regulatory language that clarifies the requirements applicable to new strains that are considered to be new active ingredients under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA is also soliciting comment on a draft microbial pesticide test guideline, explaining the deposition of a sample in a nationally recognized culture collection data requirement, for comment. The revisions proposed in this rule also include several other minor corrections to words and references. The changes should enhance the ability of industry to efficiently manage their microbial pesticide registration submissions.

DATES: Comments must be received on or before July 14, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0670, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0670. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form

of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rose Kyprianou, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5354; fax number: (703) 305–5884; e-mail address: *kyprianou.rose@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a producer or registrant of a microbial pesticide product. This proposal also may affect any person or company who might petition the Agency for a tolerance or an exemption from the requirement of a tolerance for the residues of a microbial pesticide, holds a pesticide registration with an existing tolerance or tolerance exemption for a microbial pesticide, or is interested in obtaining or retaining a tolerance or tolerance exemption in the absence of a registration (*i.e.,* an import tolerance or tolerance exemption for a microbial pesticide). Potentially affected entities may include, but are not limited to:

- Pesticide and Other Agricultural Chemical Manufacturing (NAICS code 325320), *e.g.,* pesticide manufacturers or formulators of pesticide products, importers, or any person or company who seeks to register a pesticide or to obtain a tolerance or tolerance exemption for a pesticide.
- Crop Production (NAICS code 111).
- Animal Production (NAICS code 112).
- Food Manufacturing and Processing (NAICS 311).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What is EPA's authority for taking this action?

This action is issued under the authority of sections 3, 5, 10, 12, and 25 of the Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

III. What action is EPA taking?

EPA is proposing several changes and corrections to the Microbial Pesticides data requirements (40 CFR part 158, subpart V). Two revisions are proposed to be made to text found in the Microbial Pesticides Definition and Applicability section (40 CFR 158.2100). The first is a correction, replacing "part" with "subpart" in 40 CFR 158.2100(c)(1). The other is a clarification, involving revisions to 40 CFR 158.2100(c)(2), and is in response to recent confusion over the distinction between isolates and strains and exactly how EPA is considering both of these terms. The clarification to 40 CFR 158.2100(c)(2) also proposes to include a requirement for the use of a unique identifier, as part of the microbial pesticide active ingredient taxonomic name, to allow for improved identification of company-specific registered isolates.

In conjunction with the change detailed for 40 CFR 158.2100(c)(2), EPA is also developing a draft microbial pesticide test guideline (OCSPP Guideline 885.1250) to explain the data requirement for the deposition of a sample in a nationally recognized culture collection, which is found in the tables in 40 CFR 158.2120(c) and 40 CFR 158.2171(c); presently, there is no test guideline referenced in the tables for this requirement. A copy of this draft test guideline is in the docket for this action to solicit public comment. Additionally, to clarify this microbial deposition data requirement, EPA is proposing to add a test note to the aforementioned tables, emphasizing the need for the continuing maintenance of a culture deposit to ensure it remains available in case EPA requests a sample. Finally, EPA is proposing to remove incorrect references, in 40 CFR 158.2120 and 40 CFR 158.2171, to a paragraph (e) that does not exist.

The improved clarity and transparency of the information proposed as changes to 40 CFR part 158, subpart V should enhance the ability of industry to efficiently manage their microbial pesticide registration submissions. Applicants may save time and money by understanding the

standards and interpretations of the definitions for the data that are needed. Having all required studies and information available to EPA at the time of application may reduce potential delays in the registration process, thereby enabling registration of microbial pesticides sooner and allowing microbial pesticide products to enter the market faster.

IV. Today's Proposed Revisions

A. Correcting the Statement in 40 CFR 158.2100(c)(1)

The Agency believes that 40 CFR 158.2100(c)(1), after replacing "part" with "subpart," should read as follows: "This subpart applies to microbial pesticides as specified in paragraphs (c)(2), (3), and (4) of this section." This section, as currently presented, could be misconstrued or interpreted to mean that all of 40 CFR part 158 applies to microbial pesticides and conflicts with the information presented in 40 CFR 158.1(c)(3).

B. Clarifying the Statement in 40 CFR 158.2100(c)(2)

The preamble of the final rule (71 FR 60988, October 26, 2007), codifying the provision found at 40 CFR 158.2100(c)(2), explained that registering a new isolate of an already registered microbial strain did not necessarily increase the amount of data needed to obtain such a registration. The following language is from that preamble:

> EPA carefully considered the comment raising the issue of whether an isolate occasionally could be evaluated to satisfy a subset of data requirements at a higher taxonomic level than strain level and whether an isolate might sometimes be included as part of a very similar strain. EPA believes the proposed microbial pesticide definition applicability provision is sufficiently flexible to ensure adequate consideration and data on new isolates, while allowing use of existing data to support registration if similar to an existing strain that is already registered. The wording of the provision relating to applicability of the microbial data requirements reads, "each new isolate of a microbial pesticide is treated as a new strain and must be registered independently of any similar registered microbial pesticide strain and supported by data required in this subpart." This wording does not preclude the possibility of using data from another isolate to support the assessment if it can be shown that the two isolates are sufficiently closely related. In this way, it ensures that each isolate will be independently considered for registration purposes. The differences in taxonomy between different microorganism classifications, particularly for baculoviruses, would make any attempt to further clarify this provision very complex and potentially confusing as the systematic nomenclature of these organisms change over time. The Agency intends to use its best scientific judgment in each instance to determine if one isolate is sufficiently closely related to another isolate to allow sharing of data or waiving of data requirements.

In this action, EPA is proposing new language for 40 CFR 158.2100(c)(2) to clarify that the use of the phrase "is treated as a new strain" was intended to illustrate that a new strain is considered to be a new active ingredient. EPA believes that this interpretation is consistent with its discussion in the 2007 final rule preamble and with how EPA has been implementing this regulation. Moreover, in order to allow for improved identification of company-specific registered isolates, these modifications will include a provision requiring use of a unique identifier as part of the microbial pesticide active ingredient taxonomic name (*e.g.,* a culture collection deposit identification number or another unique identifier, such as company initials followed by a number). Currently registered microbial pesticide active ingredients would not have to conform to this identification provision until they go through the registration review process.

C. Clarifying Particular Information Found in 40 CFR 158.2120 and 158.2171 Through Development of a Draft Test Guideline

In conjunction with the proposed change detailed for 40 CFR 158.2100(c)(2) (see Unit IV.B.), EPA is also developing a draft microbial pesticide test guideline (OCSPP Guideline 885.1250) to explain the deposition of a sample in a nationally recognized culture collection data requirement, which is currently found in the tables in 40 CFR 158.2120(c) and 40 CFR 158.2171(c). Presently, there is no test guideline referenced in the tables for this requirement. Instead, information on this data requirement is briefly mentioned at the end of the Microbial Pesticide Test Guideline for Manufacturing Process (OPPTS Guideline 885.1200): "A sample of registered [Microbial Pest Control Agents] MPCAs is to be maintained on deposit in a nationally recognized culture collection." In 1996, this particular statement was transferred from the 1989 revision of Subdivision M of the Pesticide Assessment Guidelines (specifically 151A–11) to the Microbial Pesticide Test Guideline for Manufacturing Process (OPPTS Guideline 885.1200). The term "maintained" was used because some culture collections will discard deposits after a certain time if they do not get subsequent requests to purchase samples from that deposit. In creating a distinct test guideline for the microbial deposition data requirement, EPA will provide a more easily found reference that can be added to the data requirement table. Furthermore, the draft test guideline will make clear that the deposition requirement is analogous to the submittal of samples data requirement (OPPTS Guideline 830.1900), which established that chemical pesticides must be deposited in the EPA National Pesticide Standard Repository. Some of this background information was explained in the preamble to the proposed rule for Data Requirements for Microbial and Biochemical Pesticides (71 FR 12072, March 8, 2006):

> f. *Submittal of samples.* This provision is typically intended to enable EPA to identify the active ingredient and provide standards to governmental agencies needing to monitor chemical pesticide residues and is conditionally required (CR). The Agency proposes to require (R) these data as a product analysis requirement to be deposited in a nationally recognized culture collection to allow EPA to validate strain identity if issues arise (guideline 885.1200).
>
> Since the Agency does not have capacity to store the variety of microbial pesticides that may be submitted, EPA did not set up a nationally recognized culture collection. There are several nationally recognized culture collections in this country (and abroad) such as the American Type Culture Collection and a microbial collection maintained in Peoria, Ill., by the USDA. These facilities have a vast number of microbial and cell cultures that [the facilities] are dedicated to transferring, maintaining and identifying. Rather than duplicate this effort, EPA chose to refer microbial pesticide producers to these facilities who have the routine expertise to keep and distribute (or protect) microbial cultures. There is a certain element of required expertise but really the cost and small number of our microbial pesticides would make it prohibitively expensive for the Agency to do this collection rather than direct the companies to these specialized facilities.

To clarify this microbial deposition data requirement, the Agency is proposing to add a test note to the tables in 40 CFR 158.2120 and 40 CFR 158.2171, emphasizing the need for the continuing maintenance of a culture deposit to ensure it remains available in case the Agency requests a sample.

D. Correcting Statements in 40 CFR 158.2120 and 158.2171

The current paragraphs (a) and (b) of both 40 CFR 158.2120 and 158.2171 incorrectly reference a paragraph (e) that does not exist. EPA proposes to remove these incorrect references. Specifically, EPA proposes to do the following in 40

CFR 158.2120 and 158.2171: (1) Revise the last sentence of paragraph (a) for each of these sections to read as "Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section" and (2) remove the last sentence in paragraph (b) for each of these sections.

V. FIFRA Review Requirements

Pursuant to FIFRA sections 25(a) and (d), EPA has submitted a draft of this proposed rule to the Committee on Agriculture in the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry in the United States Senate, and the U.S. Department of Agriculture (USDA).

The FIFRA Scientific Advisory Panel (SAP) and the USDA waived review of this proposed rule. The FIFRA SAP waived its review of this proposed rule because the significant scientific issues involved have already been reviewed by the SAP and additional review is not necessary. The SAP waived its review of this proposed rule on August 17, 2010.

VI. Statutory and Executive Order Reviews

This action only proposes to clarify the existing regulatory text to allow EPA and stakeholders a clearer understanding of 40 CFR part 158, subpart V. It does not otherwise propose to amend or impose any other requirements. The proposed rule will not otherwise involve any significant policy or legal issues and will not increase existing costs. As such, this action is not subject to review by the Office of Management and Budget (OMB) as a "significant regulatory action" under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Nor does it impose or change any information collection burden that requires additional review by OMB under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The information collection activities contained in the regulation are already approved under Information Collection Request (ICR) instruments related to the submission of data to EPA in order to establish a tolerance or an exemption from the requirement of a tolerance currently approved under OMB Control No. 2070–0024 (EPA ICR No. 0597), the activities associated with the application for a new or amended registration of a pesticide currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277), the activities associated with the application for an experimental use permit currently approved under OMB Control No. 2070–0040 (EPA ICR No. 0276), and the activities associated with the generation of data for regulatory review programs currently approved under OMB Control No. 2070–0174 (EPA ICR No. 2288). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), EPA hereby certifies that this proposed rule does not have a significant adverse economic impact on a substantial number of small entities. This action only proposes to clarify the existing regulatory text to allow EPA and stakeholders a clearer understanding of 40 CFR part 158, subpart V. It does not otherwise propose to amend or impose any other requirements. In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and the Agency. EPA solicits comments specifically about potential small business impacts.

State, local, and Tribal governments are rarely pesticide applicants or registrants, so this proposed rule is not expected to affect these governments. Accordingly, pursuant to Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538), EPA has determined that this action is not subject to the requirements in sections 202 and 205 because it does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or for the private sector in any one year. In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. For the same reasons, EPA has determined that this proposed rule does not have "federalism implications" as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), because it would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. Thus, Executive Order 13132 does not apply to this proposed rule. Nor does it have "Tribal implications" as specified in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 22951, November 9, 2000). EPA is not aware of any Tribal governments that are pesticide registrants. Thus, Executive Order 13175 does not apply to this action.

Since this action is not economically significant under Executive Order 12866, it is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), and Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). In addition, EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks, which is not the case in this proposed rule.

This action does not involve technical standards that would require the consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272).

This action does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, this action does not involve special consideration of environmental justice related issues as specified in Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 158

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 7, 2011.

Lisa P. Jackson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 158—[AMENDED]

1. The authority citation for part 158 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a.

2. Amend § 158.2100 as follows:

a. Revise paragraph (c)(1).

b. Revise paragraph (c)(2).

The revised text reads as follows:

§ 158.2100 Microbial pesticides definition and applicability.

* * * * *

(c) *Applicability.* (1) This subpart applies to microbial pesticides as specified in paragraphs (c)(2), (3) and (4) of this section.

(2) Because of the potential for variation in microorganisms, each new isolate of a microbial pesticide is treated as a new active ingredient and must be registered independently of any similarly designated and already registered microbial pesticide active ingredient. Each new isolate for which registration is sought must have a unique identifier following the taxonomic name of the microorganism, and the registration application must be supported by data required in this subpart. This does not preclude the possibility of using data from another isolate, provided sufficient similarity is established, to support registration.

* * * * *

3. Amend § 158.2120 as follows:

a. Revise paragraph (a).

b. Revise paragraph (b).

c. Revise paragraph (c).

d. In paragraph (d), redesignate test notes 1 through 4 as 2 through 5, respectively, and add new test note 1.

The revised and added text reads as follows:

§ 158.2120 Microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section.

(b) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; All = All of the above.

(c) *Table.* The following table shows the data requirements for microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—MICROBIAL PESTICIDES PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline No.	Data requirement	All use patterns	Test substance		Test notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product identity	R	MP	EP	
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	
885.1250	Deposition of a sample in a nationally recognized culture collection.	R	TGAI	TGAI	1
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2
885.1500	Certification of limits	R	MP	EP	
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	
830.6303	Physical state	R	TGAI	TGAI	
830.6304	Odor	R	TGAI	TGAI	
830.6313	Stability to normal and elevated temperatures, metals and metal ions.	R	TGAI	TGAI	
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	
830.6319	Miscibility	R	MP	EP	3
830.6320	Corrosion Characteristics	R	MP	EP	4
830.7000	pH	R	TGAI	TGAI	
830.7100	Viscosity	R	MP	EP	5
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	

(d) * * *

1. Required for each isolate of a microbial pesticide. New isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated registration(s).

* * * * *

4. Amend § 158.2171 as follows:

a. Revise paragraph (a).

b. Revise paragraph (b).

c. Revise paragraph (c).

d. In paragraph (d), redesignate test notes 3 through 6 as 4 through 7, respectively and add a new test note 3.

The revised and added text reads as follows:

§ 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are identified in paragraph (d) of this section.

(b) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TEP = Typical end-use product; TGAI = Technical grade of the active ingredient; All = All of the above.

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline No.	Data requirement	All use patterns	Test substance		Test notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product identity	R	MP	EP	
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	1, 2
885.1250	Deposition of a sample in a nationally recognized culture collection.	R	TGAI	TGAI	3
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	2
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	2, 4
885.1500	Certification of limits	R	MP	EP	
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	
830.6303	Physical state	R	TGAI	TGAI	
830.6304	Odor	R	TGAI	TGAI	
830.6313	Stability to normal and elevated temperatures, metals and metal ions.	R	TGAI	TGAI	
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	
830.6319	Miscibility	R	MP	EP	5
830.6320	Corrosion characteristics	R	MP	EP	6
830.7000	pH	R	TGAI	TGAI	
830.7100	Viscosity	R	MP	EP	7
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	

(d) * * *

3. Required for each isolate of a microbial pesticide. New isolates must be deposited with an agreement to ensure that the sample will be maintained and will not be discarded for the duration of the associated experimental use permit(s).

* * * * *

[FR Doc. 2011–9191 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 281

[EPA–R10–UST–2011–0097; FRL–9296–1]

Oregon: Tentative Approval of State Underground Storage Tank Program: Public Hearing Cancellation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; cancellation of notice of public hearing.

SUMMARY: This document cancels a public hearing on a proposed rulemaking relating to the State of Oregon's application for final approval of its Underground Storage Tank (UST) Program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency did not receive any comments or a request for a public hearing.

DATES: The public hearing originally scheduled for April 13, 2011 at 9 a.m. has been cancelled.

FOR FURTHER INFORMATION CONTACT: Katherine Griffith, U. S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Suite 900, *Mail Stop:* OCE–082, Seattle, WA 98101, *phone number:* (206) 553–2901, *e-mail: griffith.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and a notice of public hearing that appeared in the Federal Register on Wednesday, March 2, 2011 (76 FR 11404) announced that a public hearing was scheduled for April 13, 2011, at 9 a.m. at the United States Environmental Protection Agency, 805 SW. Broadway, Suite 500, Portland, Oregon 97205.

The public comment period for the proposed rulemaking expired on April 1, 2011. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request. As of Monday, April 4, 2011, no one has requested to speak. Therefore, the public hearing scheduled for April 13, 2011, is cancelled.

Dated: April 8, 2011.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2011–9184 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 355

[EPA–HQ–SFUND–2010–0586; FRL–9295–6]

RIN 2050–AF08

Emergency Planning and Notification; Emergency Planning and List of Extremely Hazardous Substances and Threshold Planning Quantities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revise the manner by which the regulated community would apply the threshold planning quantities (TPQs) for those extremely hazardous substances (EHSs) that are non-reactive solid chemicals in solution form. Specifically, facilities with a solid EHS in solution would be subject to the Emergency Planning requirements if the amount of the solid chemical on-site, when multiplied by 0.2, equaled or exceeded the lower published TPQ, based on data that shows less potential for the solid chemical in solution to remain airborne in the event of an accidental release. Previously, EPA assumed that 100% of the chemical could become airborne in the event of an accidental release.

DATES: Comments must be submitted on or before June 14, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–2010–0586, by one of the following methods:

- *http://www.regulations.gov:* Follow the online instructions for submitting comments.
- *E-mail: superfund.docket@epa.gov.*
- *Fax:* (202) 566–9744.
- *Mail:* Superfund Docket, Environmental Protection Agency, Mail code: [2822T], 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–SFUND–2010–0586. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to Section I.B of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically *http://www.regulations.gov/or* in hard copy at the Superfund Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Superfund Docket is (202) 566–0276.

FOR FURTHER INFORMATION CONTACT: Kathy Franklin, Office of Emergency Management, Mail Code 5104A, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0002; telephone number: (202) 564–7987; fax number: (202) 564–2625; e-mail address: *franklin.kathy@epa.gov*. You may also contact the Superfund, TRI, EPCRA, RMP and Oil Information Center at (800) 424–9346 or (703) 412–9810 (in the Washington, DC metropolitan area). The Telecommunications Device for the Deaf (TDD) number is (800) 553–7672 or (703) 412–3323 (in the Washington, DC metropolitan area). You may wish to visit the Office of Emergency Management (OEM) Internet site at *www.epa.gov/emergencies/content/epcra*.

SUPPLEMENTARY INFORMATION: Here are the contents of today's preamble.

I. General Information
A. Who is affected by this proposed rule?
B. What should I consider as I prepare my comments for EPA?
C. What is the statutory authority for this proposed rule?
D. What is the background for this proposed rule?
II. Summary of This Action
A. What is the scope of this proposed rule?
B. What is EPA's rationale for proposing the TPQ changes?
C. What alternative approaches were considered?
D. What are the peer review results?
E. What are the economic impacts of the TPQ changes?
III. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Energy Effects
I. National Technology Transfer and Advancement Act ("NTAA")
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Who is affected by this proposed rule?

Entities that would be affected by this proposed rule are those organizations and facilities subject to section 302 of the Emergency Planning and Community Right-to-Know Act (EPCRA) and its implementing regulations found in 40 CFR part 355, subpart B—Emergency Planning. To determine whether your facility is affected by this action, you should carefully examine the applicability provisions at 40 CFR part 355. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. What should I consider as I prepare my comments for EPA?

Tips for Preparing Your Comments. When submitting comments remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible.
- Make sure to submit your comments by the comment period deadline identified.

C. What is the statutory authority for this proposed rule?

This proposed rule is being issued under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), which was enacted as Title III of the Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99–499), (SARA). The Agency relies on EPCRA section 328 for general rulemaking authority.

D. What is the background of this proposed rule?

Title III of SARA (EPCRA) establishes authorities for emergency planning and preparedness, emergency release notification reporting, community right-to-know reporting, and toxic chemical release reporting. It is intended to encourage state and local planning for, and response to releases of, hazardous substances and to provide the public, local governments, fire departments, and other emergency officials with information concerning potential chemical hazards present in their communities. The implementing regulations for emergency planning, emergency release notification and the chemicals subject to these regulations (extremely hazardous substances (EHSs)) are codified in 40 CFR part 355. The implementing regulations for community right-to-know reporting (or hazardous chemical reporting) are codified in 40 CFR part 370.

Subtitle A of EPCRA establishes the framework for local emergency planning. The statute requires that EPA publish a list of EHSs. The EHSs list was established by EPA to identify chemical substances which could cause serious irreversible health effects from accidental releases (52 FR 13378). The Agency was also directed to establish threshold planning quantities (TPQs) for each extremely hazardous substance.

Under EPCRA section 302, a facility which has an EHS in excess of its TPQ on-site must notify the State Emergency Response Commission (SERC) and Local Emergency Planning Committee (LEPC), as well as participate in local emergency planning activities. Under EPCRA section 304, the facility owner or operator must report accidental releases of EHSs and hazardous substances listed under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) listed in 40 CFR 302.4 in excess of the reportable quantity (RQ) to the LEPC and SERC. Under EPCRA section 311 and 312, facilities which have a hazardous chemical defined under the Hazard Communication Standards (HCS) of the Occupational Safety and Health Act (OSHA) at or above 10,000 pounds or an EHS at or above its TPQ or 500 pounds, whichever is lower, are required to submit an Emergency and Hazardous Chemical Inventory form and Material Safety Data Sheet (MSDS) for that chemical to their SERC, LEPC and local fire department.

The purpose of the EHSs list is to focus initial efforts in the development of state and local contingency plans. Inclusion of a chemical on the EHSs list does not mean state or local communities should ban or otherwise restrict use of a listed chemical. Rather, such identification indicates a need for the community to undertake a program to investigate and evaluate the potential for accidental exposure associated with the production, storage or handling of the chemical at a particular site and develop a chemical emergency response plan around those risks.

1. Regulatory Background

The list of EHSs and their TPQs are codified in 40 CFR part 355, Appendices A & B. EPA first published the EHSs list and TPQs along with the methodology for determining TPQs as an interim final rule on November 17, 1986 (51 FR 41570). In the final rule of April 22, 1987 (52 FR 13378), EPA made a number of revisions. Among other things, the final rule republished the EHSs list, added four new chemicals and revised the methodology for some TPQs. The final rule also defined TPQs for EHS solids in solution, based on comments on the interim final rule. Details of the methodology used in determining whether to list a substance as an EHS and deriving the TPQs are found in the November 1986 and April 1987 **Federal Register** notices and in the technical support documents in the rulemaking record ("Threshold Planning Quantities Technical Support Document"; "Chemicals That Were Assigned Threshold Planning Quantities Different From the Calculated Index Value"; "Reactive Solids Whose Threshold Planning Quantities Should Be Less than 10,000 Pounds"; "Changes Made to Threshold Planning Quantities Between Proposed Rule and Final Rule": all dated April 7, 1987, and "Technical Support Document for Determination of Levels of Concern," November 11, 1986). These documents are found in the docket for this rulemaking.

EPA has since amended the EHSs list and deleted 51 chemicals. Ten chemicals were deleted based on the request of petitioners and the remaining 41 chemicals were deleted as a result of Agency review. The chemicals were deleted because they did not meet the toxicity criteria for the list and/or were originally listed in error. Petitions requesting deletion of two chemicals, paraquat dichloride (which is discussed below) and isophorone diisocyante have been denied. Isophorone diisocyanate was not deleted from the EHSs list because its inhalation toxicity met the EHSs listing criteria.

EPA has also changed the TPQs for some of the EHSs. In the April 22, 1987 final rule, EPA reduced the TPQs for 36 substances, while it raised the TPQs for 12 substances based on updated acute toxicity data. Since then, EPA has lowered the TPQ for muscimol because of a typographical error in a prior rulemaking; EPA has raised the TPQ for isophorone diisocyanate because it was mistakenly based on a physical state of reactive solid, when it is actually a liquid; and EPA has denied a petition to raise the TPQs for azinphos methyl and fenamiphos.

After a final rule was published on November 3, 2008 (73 FR 65452) which revised the footnotes to Appendix A and B, EPA found some printing errors in the Appendix A and B tables of the CFR affecting 11 EHS listings. This November 3, 2008 rule did not add, delete or revise any of the EHS names, RQs or TPQs. For the eleven EHSs listings, their RQ and TPQ values are correct, but just appear under the wrong column heading in the table and one EHS chemical name mistakenly appears in CAS No. column. The errors do not appear in the November 3, 2008 FR notice, but only in the 2009 and 2010 versions of the CFR. These errors to the CFR will be corrected in a future effort.

2. Petition for Paraquat Dichloride

Paraquat dichloride was originally listed as paraquat with a CAS No. 1910–42–5 on the final EHSs list. The lower TPQ was set at 10 pounds for paraquat dichloride with a particle size less than 100 microns in diameter, in molten form or as a solid in solution. The higher TPQ was set at 10,000 pounds for a particle size equal to or greater than 100 microns in diameter. ICI Americas submitted a petition in October 1989 that requested the Agency to remove paraquat from the EHSs list or alternatively, revise the TPQ. The TPQ for paraquat was based on an Immediately Dangerous to Life and Health (IDLH) value of 1.5 milligrams per cubic meter (mg/m^3). The petitioner requested that EPA base the TPQ on the LD_{50} or LC_{50} test results rather than the IDLH level. LD_{50} is the median lethal dose via dermal exposure or ingestion, defined as the dose at which 50 percent of the test animals died during exposure. LC_{50} is the median lethal concentration, defined as the concentration level at which 50

percent of the test animals died when exposed by inhalation within the stated study time. ICI Americas also noted that the CAS No. 1910–42–5 represented the chemical paraquat dichloride, not the paraquat cation, which can form many different salts.

On October 12, 1994 (59 FR 51816), EPA denied the petition to delete paraquat or modify the TPQ, but changed the listed chemical name from paraquat to paraquat dichloride. The oral toxicity for paraquat dichloride met the listing criteria based on the paraquat ion only, but did not meet the listing criteria based on total paraquat dichloride weight. Therefore, EPA changed the basis of the listing from an oral LD_{50} of 22 milligrams paraquat ion per kg of body weight (mg/kg) to an inhalation LC_{50} of 0.00138 milligrams paraquat dichloride per liter of air (mg/L). Because this inhalation toxicity met the EHSs listing criteria, paraquat dichloride was not deleted from the EHSs list. Further explanation of EPA's rationale for denying the petition can be found in the October 12, 1994 final rule (59 FR 51816).

3. Zeneca's Request To Reconsider the Paraquat Dichloride Petition

In November 1999, Zeneca (formerly ICI Americas) requested that EPA reconsider either removing paraquat dichloride from the EHSs list or raising its TPQ. Zeneca claimed that the form of the chemical used in inhalation toxicity tests (temporarily atomized powder under laboratory conditions) is not relevant data to use for listing paraquat dichloride. Zeneca believed that it was highly unlikely that inhalable particles or vapors of paraquat dichloride could become airborne during an accidental release. Zeneca did not agree with the rationale EPA used to assign a TPQ of 10 pounds to paraquat dichloride, which is only manufactured, processed and used in solution form. Zeneca claimed that EPA did not explain why a greater potential for airborne dispersion for solids in solution exists as opposed to liquid chemicals.

On October 11, 2000, Syngenta (formerly Zeneca) filed an action in U.S. District Court for the District of Columbia under the Administrative Procedures Act seeking judicial review of EPA's decisions regarding paraquat dichloride. In this complaint, Syngenta requested EPA to either delete paraquat dichloride from the EHSs list or raise its TPQ. On January 23, 2003, EPA filed a Motion for Voluntary Remand in order to reconsider the petition. The court granted EPA's motion and dismissed Syngenta's complaint on January 31, 2003. By order of February 24, 2003, the court denied Syngenta's Motion to Amend Judgment. EPA again reviewed the request to delete paraquat dichloride and/or to raise its TPQ. In a November 21, 2003 letter to the petitioner, EPA reaffirmed its denial to delete paraquat dichloride from the EHSs list. EPA concluded that the acute toxicity of paraquat dichloride meets the criteria for listing it as an EHS chemical. In the same letter to the petitioner, however, EPA agreed to consider a revision to the TPQ for paraquat dichloride in the context of a proposed rule to amend the TPQ for all EHS chemicals handled as solids in solution. This letter is in the docket for today's rulemaking.

II. Summary of This Action

A. What is the scope of this proposed rule?

The scope of this proposed rule is to revise the manner by which the regulated community would apply the TPQ for EHS chemicals that are handled as solids in solution. There are 157 EHS chemicals that are non-reactive solids at ambient temperature, which could potentially be affected by this change, if they are handled by facilities in a solution form. The affected chemicals are identified in Appendix C in the "Technical Support Document for Revised TPQ Method for Solids in Solution," which is in the Docket to this rulemaking. These 157 chemicals appear with two TPQs, (the higher TPQ is 10,000 pounds) in Appendix A and B of 40 CFR part 355. However, this change will not apply to the 12 solid EHS chemicals that are reactive solids (noted by footnote "a" in Appendix A and B of 40 CFR part 355). Reactive solids are highly reactive with air or water or are explosive. Because of this, they are more likely than other solids to be dispersed into the air due to the energy or heat created when they react. Other reactive solids form toxic gases when they react with air or water. The explanation for not assigning a 10,000 pound TPQ to each of the reactive solids is discussed in the document, "Reactive Solids Whose Threshold Planning Quantities Should Be Less Than 10,000 Pounds," April 7, 1987, which can be found in the docket to this rulemaking.

Additionally, the proposed methodology of applying TPQs for solids in solution does not affect the reporting requirements for Sections 311 and 312 of EPCRA (40 CFR part 370). Specifically, emergency planning notification under Section 302 helps LEPCs identify those facilities whose accidental releases pose risks to the surrounding community so they can develop emergency plans that identify the location and number of affected populations, evacuation or shelter-in-place procedures, etc. On the other hand, Sections 311 and 312 require submission of MSDSs and an on-site inventory of hazardous chemicals to help emergency responders assess how to respond to an emergency release or fire. Responders need the amounts, manner of storage and locations of the chemical on-site, not only the amount released off-site. They need information on the chemical and physical properties, hazard ratings, toxicity information and incompatibilities of the chemical, as well as measures needed to contain the spill or fire at the facility. They need to know what type of protective equipment is needed to protect them from exposure, not only airborne, but dermal.

Solid EHSs (except reactive solids) have a 10,000 pound TPQ or a specified lower TPQ for certain forms. For purposes of complying with the emergency planning notification requirements of Section 302 of EPCRA, EPA is proposing that facilities multiply the amount of EHS chemical handled as a solid in solution on-site by 0.2 and then determine if this amount equals or exceeds the established lower TPQ. If the amount of the solid EHS in solution on-site multiplied by 0.2 does not equal or exceed the lower TPQ for that solid EHS, then the facility is not subject to the EPCRA Section 302 emergency planning notification requirements for that substance. This amount includes only the weight of the chemical and not the solvent or other chemicals in solution. The amount of solid in solution may be determined by multiplying the weight percent of the solid in solution in a particular container by the weight of the solution. Solutions include aqueous or organic solutions, slurries, viscous solutions, suspensions, emulsions, and pastes. The revised TPQ methodology for solids in solution is similar to the use of the TPQ for EHS chemicals that are molten solids.[1]

The emergency release notification requirements under EPCRA Section 304 are not affected by this proposal. Section 304 requires facilities to notify the community emergency coordinator for the LEPC of any area likely to be affected by the release and the SERC of any area likely to be affected by the release (defined in 40 CFR 355.42) at or above the reportable quantity (RQ) of

[1] The TPQ for EHSs that are in a molten form on-site is calculated by multiplying the weight of the chemical by 0.3 to determine if the lower TPQ is met or exceeded.

any EHS or CERCLA hazardous substance. The RQ is not the same as the TPQ. TPQs are based on acute mammalian toxicity and potential for airborne dispersion. RQs, on the other hand, are developed using several criteria, including aquatic toxicity, mammalian toxicity, ignitability, reactivity, chronic toxicity, potential carcinogenicity, biodegradation, hydrolysis, and photolysis (50 FR 13468, April 4, 1985).

As an example, a facility has 4,000 pounds of a solution of 37% by weight paraquat dichloride on-site. Therefore, this solution contains 1,480 pounds of paraquat dichloride (0.37 × 4,000 pounds). The facility would multiply 1,480 pounds by 0.2 which equals 296 pounds. This amount is then compared to the TPQ for paraquat dichloride, which is 10 pounds. Because this amount exceeds the 10 pound TPQ, the facility is required to comply with the emergency notification requirements of Section 302 of EPCRA. As another example, a facility has 10 gallons of a solution of 37% by weight paraquat dichloride on-site. The density of the solution is 9.33 pounds per gallon. Therefore, this solution contains 34.5 pounds of paraquat dichloride (10 gal × 9.33 lb/gal × 0.37). The facility would multiply 34.5 pounds by 0.2 which equals 6.9 pounds. This amount is then compared to the TPQ for paraquat dichloride, which is 10 pounds. Because this amount is less than the 10 pound TPQ, the facility is not required to comply with the emergency notification requirements of Section 302 of EPCRA.

Facilities that handle both the powdered and solution forms of a particular solid EHS will have to consider the quantities of each form and the particle size to determine whether they exceed a TPQ. Below are several examples of how to apply the revised TPQ methods in various cases.[2]

Solid in solution exceed lower TPQ, powder below 10,000 pounds. A facility has 5,000 pounds of a pure EHS powder form on-site which is less than the 10,000 pound TPQ. However, they have 1,000 gallons of a 35% by weight EHS solid in solution with a density of 9 pounds per gallon. The amount of solids in solution on-site is 3,150 pounds (1000 gallons × 9 pounds per gallon × 0.35). Multiplying the 3,150 pounds of solid in solution by 0.2 equates to 630 pounds, which exceeds the lower TPQ of 500 pounds. Thus, the facility must report under Section 302 of EPCRA based on exceeding the lower TPQ for the solid in solution form.

Solid in solution below lower TPQ, powder exceeds 10,000 pounds. A facility has 11,000 pounds of a pure EHS solid powder on-site which is more than the 10,000 pound TPQ. They also have 2,000 gallons of a 10% by weight EHS solid in solution with a density of 9 pounds per gallon. The amount of solids in solution on-site is 1,800 pounds (2,000 gallons × 9 pounds per gallon × 0.10). Multiplying the 1,800 pounds of solid in solution by 0.2 equates to 360 pounds, which is less than the lower TPQ of 500 pounds. Thus, the facility must report under Section 302 of EPCRA based on exceeding the 10,000 pound TPQ for the solid in powder form.

Solid in solution below lower TPQ, powder below 10,000 pounds. A facility has 5,000 pounds of a pure EHS solid powder which is less than the 10,000 pound TPQ. They also have 1,500 gallons of a 15% by weight EHS solid in solution with a density of 9 pounds per gallon. The amount of solids in solution on-site is 2,025 pounds (1.500 gallons × 9 pounds per gallon × 0.15). Multiplying the 2,025 pounds of solid in solution by 0.2 equates to 405 pounds, which is less than the lower TPQ of 500 pounds. Thus, the facility is not required to report under Section 302 of EPCRA because it does not exceed the lower 500 pound TPQ for the solid in solution form or the 10,000 pound TPQ for the powder with particle size greater than 100 microns.

Powdered product less than 100 microns, processed into solution. If the same amounts of solid EHS were involved as the same scenarios above, except the powder has a particle size of less than 100 microns, then the lower 500 pound TPQ would apply to the powder instead of the 10,000 pounds. If either the amount of powder or solid in solution exceeds the lower TPQ, the facility would be required to report under Section 302 of EPCRA.

EPA is proposing this change based on data in the literature that shows the original assumption of 100% potential airborne release for solids in solution is inappropriate because it appears to overestimate the amount of chemical that would remain airborne after release. Review of the literature for accidental releases of liquid aerosols suggests a new methodology for applying the TPQs for solids in solution is warranted. The data shows that no more than 20% of the release is expected to remain airborne. More detailed discussion can be found in Section II.B.4.a of this preamble and in the technical support document in the docket to this proposed rule.

EPA's revised TPQ methodology for EHS solids in solution and supporting data was peer reviewed and the technical support document was revised based on peer review comments. The results of the peer review and response to peer review comments are found in a separate document, "Peer Review of Technical Support Document for Revised TPQ Method for EHS Solids in Solution," which is available in the docket to this rulemaking. A summary of the peer reviewer's comments and EPA responses to them are presented in Section II.D of this preamble.

B. What is EPA's rationale for the TPQ changes?

1. Development of Existing TPQs

The TPQs were initially assigned based on a ranking scheme using a Level of Concern (LOC) based on acute toxicity and the potential for airborne dispersion. The TPQ methodology is described in detail in the "Threshold Planning Quantities Technical Support Document" dated April 7, 1987, which can be found in the docket for this rulemaking. For each chemical, a ranking index was calculated which equaled the LOC divided by an air dispersion factor (V). For gases, V = 1, while for liquids, V was based on a volatilization model using the molecular weight and boiling point of the chemical.

Solid EHS chemicals with a particle size less than 100 microns in diameter, molten solids, solids in solution, and solids with a National Fire Protection Association (NFPA) reactivity rating of 2, 3, or 4 were assigned a V equal to 1. If the EHS solid does not have a particle size less than 100 microns, is not molten or handled in solution form, and does not have an NFPA reactivity rating of 2, 3, or 4, then the EHS chemical was assigned a TPQ of 10,000 pounds, which corresponds to the highest index value. Solids with an NFPA reactivity rating of 2, 3, or 4 are noted with footnote "b" in the EHSs list.

Between one and 10,000 pounds, chemicals were assigned to the intermediate TPQ categories of 10, 100, 500 or 1,000 pounds based on the order of magnitude ranges of the index values. Also, for solids in molten form, before applying the TPQ, the amount of chemical on-site at any time is multiplied by an adjustment factor of 0.3 to conservatively account for the maximum volatilization of the spilled molten substance that is likely to take place.

[2] For these examples, the EHS is not paraquat dichloride, but an unspecified solid EHS.

2. Petitioner's Arguments for Changing Paraquat Dichloride's TPQ

In their complaint, Syngenta did not agree with EPA's rationale to assign a lower TPQ of 10 pounds to paraquat dichloride, which is only manufactured, processed and used in solution form. Syngenta claimed that EPA did not explain why it assumed a greater potential for airborne dispersion for solids in solution as opposed to liquid chemicals. In addition, Syngenta argued that Paraquat Dichloride solution is basically a non-volatile salt dissolved in water, and that the physical and chemical characteristics of many solids like paraquat dichloride limit their capacity to become airborne. Pure paraquat dichloride has a very low vapor pressure and decomposes at about 340° Celsius (C) before it reaches a boiling point. Syngenta further argued that using a liquid volatilization model to set a TPQ for paraquat dichloride is inappropriate.[3] Moreover, Syngenta stated that "the laws of physics preclude the possibility of a release of paraquat dichloride becoming completely airborne. Regardless of the emergency release scenario (extreme temperature, explosion, etc.), the amount to become airborne would not only be less than 100%, it would be virtually zero." Syngenta also stated that although paraquat dichloride can be temporarily atomized under laboratory conditions for testing animals, they do not believe that inhalable particles or vapors of paraquat dichloride can become airborne during an accidental release.

In discussions with EPA, Syngenta also raised the issue of aerosol size as a factor to be considered in developing the TPQ methodology for EHS solids in solution.

3. Basis for Existing Solids in Solution TPQs

In the April 7, 1987 "Threshold Planning Quantities Technical Support Document" (page 27), EPA noted that "solids may also be handled in solution and molten form and could potentially follow a liquid release scenario. However, even at molten temperatures, significant amounts of vapor are not likely to be generated." On page 24 of the same technical support document, when discussing liquid releases, EPA assumed that a spill of a liquid could occur as a result of an accidental situation that involves heat (e.g. fire, exothermic runaway reaction, or reactions with air or water).

More specifically, when a solid chemical is in solution form, the solution can behave like a liquid during an accidental release and be dispersed into the air due to overheating, overpressure or anything that can cause a loss of containment from a vessel or piece of equipment. An accident involving a release of energy could create a liquid aerosol type of release into the air. Such liquid aerosol droplets, if small enough, can be dispersed into the air and remain airborne beyond the facility boundary, resulting in EHS exposure to the surrounding community. Environmental conditions and the properties of the specific chemical will dictate the behavior and dispersion of the chemical after a release or spill has occurred. For example, the solvent can evaporate from solution (especially at higher temperature) and small particulates of solid remaining after evaporation of the solvent can potentially be carried off-site. EPA recognized that the solid EHS (dissolved or suspended in a liquid solution) will not be dispersed into the air based on volatilization of the solid, but because of the energy released from the accident, or by wind.

At the time of the April 1987 rulemaking, EPA did not have sufficient information to determine how much of the solid EHS in solution could be dispersed airborne off-site and conservatively used V=1 for this release scenario. Furthermore, although paraquat dichloride decomposes at a temperature of 340° C (644° Fahrenheit, F), EPA believed that accidents involving aerosol releases of paraquat dichloride solution could potentially occur at temperatures less than 340° C. Boiling solutions containing non-volatile solids result in vaporization of the solvent, but not the solid. However, the turbulence of boiling the solution can entrain liquid aerosol droplets containing the solid into the air.

4. Airborne Dispersion of Solids in Solution.

Based on more recent information, EPA has re-evaluated the assumption of 100% airborne releases when setting the TPQ for solids in solution, not just for paraquat dichloride solution, but for all EHS solids in solution, except for the 12 solid EHS chemicals that are reactive solids.

a. Liquid Aerosol Release Data

EPA reviewed data in the literature on releases of aerosols to evaluate their potential use for revising the application of the TPQs for EHS solids in solution. EPA was specifically looking for data on how much of a solution containing a dissolved or suspended solid would remain airborne after an accidental release. One problem encountered in reviewing the literature was some studies only involved chemicals that are pure liquids and which have vapor pressures much higher than solid chemicals. That data would likely not represent the release and dispersion of a solid chemical that normally has a very low vapor pressure. However, the U.S. Department of Energy (USDOE) used experimental liquid aerosol release data involving metal salt solutions to estimate the Airborne Release Fraction (ARF) of metal salt solutions for a wide variety of release scenarios. This information was collected in a 1994 report, which is available in the docket to this rulemaking.[4] Many of the USDOE scenarios had very low ARFs; EPA considered the scenarios with higher release potential to best serve the purposes of emergency planning. Also, scenarios which required hypothetical input data to compute the ARF were not used. When median and bounding (maximum) values of ARFs were provided for a scenario, EPA used the maximum ARF in order to be conservative and cover the worst case scenario. EPA summarized the data from those DOE aerosol release scenarios with the highest (ARFs) in the table below. (The ARF values, release scenarios from the USDOE report and other data are discussed in greater detail in the technical support document for this rulemaking, which is available in the docket to this rulemaking.) From this data, EPA determined that a worst case estimate of the ARF for a solution containing non-volatile solids would be 0.2. This particular ARF is based on the scenarios of an aqueous solution or air dried salts under gasoline fire on a metal surface. The airborne fractions from the USDOE report generally contained aerosol sizes less than or equal to 100 microns. Droplets larger than 100 microns in diameter are expected to fall out before they reach a community outside a facility.

Aerosol release scenario	Maximum airborne release fraction (ARF)
Thermal Stress from Boiling	0.002

[3] EPA agrees with the petitioner that using the liquid volatilization model to set a TPQ for paraquat dichloride, whether handled as a pure chemical or in solution, is inappropriate. However, the TPQ for paraquat dichloride was not set using the volatilization method.

[4] USDOE. 1994. DOE Handbook, *Airborne Release Fractions/Rates and Respirable Fractions for Nonreactor Nuclear Facilities.* December 1994. US Department of Energy, Washington, DC 20585 DOE–HDBK–3010–94. Volume 1—Analysis of Experimental Data and Volume II—Appendices.

Aerosol release scenario	Maximum airborne release fraction (ARF)
High Pressure Venting Below Liquid Level	0.12
Pressure Venting Above the Liquid Level	0.002
Superheated Liquid Temp ≥ 50 °C and ≤ 100 °C	0.1
Superheated Liquid Temp ≤ 50 °C	0.01
Burning Organic Layer Over Aqueous Solution	0.1
Aqueous Solution or Dry Salt Under Gasoline Fire on Metal	0.2
Aerodynamic Entrainment and Re-Suspension	0.1

Using the highest airborne release fraction rather than an average result of the scenarios is consistent with the intent of the emergency planning program to plan for a reasonable worst case scenario. This data is a good surrogate to use to predict the maximum potential aerosol release fraction of EHS solids in solution in the event of an accidental release. Water is probably the most common solvent that would be used with most of the EHS solids, whether they are dissolved, suspended or emulsified in water. Many of the EHS solids are pesticides and pesticides are commonly applied as water solutions or emulsions.

EPA also looked at experimental data collected by the Center for Chemical Process Safety (CCPS) for aerosol releases of water and cyclohexane. CCPS, a directorate of the American Institute of Chemical Engineers (AICHE), was established in 1985 to develop and disseminate technical information for use in the prevention of major chemical process incidents. CCPS develops and publishes guidelines, conducts seminars, symposia, training programs and meetings on chemical process-safety matters; CCPS also cooperates with other organizations, both internationally and domestically, to promote process safety. CCPS's activities are supported by funding and expertise from over 100 entities including, industry, consulting firms and governmental organizations. USEPA is a member of this organization.

In 1989, the CCPS Vapor Cloud Modeling Subcommittee began an "Aerosol Project" to meet some of the research objectives proposed to the U.S. National Vapor Cloud Research Committee, which included developing a superheated liquid release model and developing experimental data to validate the model. The experimental field data was the result of field controlled-release experimentation by CCPS with financial assistance by special grants from some of the CCPS sponsors and from the USEPA and USDOE. The experimental superheated liquid release data was developed, documented, peer reviewed and, where necessary, corrected. The Vapor Cloud Modeling Subcommittee contracted a review of the fundamental basis for the RELEASE model and to make model improvements to reconcile the cyclohexane, chlorine and methylamine test data. The results of the model development and the experimental field data used was published in 1999 in a CCPS concept book "RELEASE: A Model with Data to Predict Aerosol Rainout in Accidental Releases" by David W. Johnson and John L. Woodward.

EPA did not use the aerosol release fraction from the CCPS data because these liquids did not contain any solid material in solution. Specifically, the reported airborne release fraction for water varied from 0.03 to 0.54 and for cyclohexane varied from 0.36 to 0.94. Cyclohexane with a vapor pressure of 95 millimeters (mm) mercury (Hg) is more volatile than water with its vapor pressure of 24 mm Hg. It is not a good comparison to use aerosol release fractions of volatile liquids to estimate the aerosol release fractions of a solid in solution because solids generally are not very volatile. The water aerosol data might be a close surrogate for estimating a release of an aqueous solution of the solid, but it does not have the important constituent of a dissolved solid, which might influence the amount of aerosol remaining entrained in the air. However, the CCPS data for water supports EPA's belief that assuming a 100% airborne liquid aerosol release is inappropriate because the water aerosol fractions measured in the experiments were less than one. CCPS also had experimental release data for CFC–11 and chlorine (both gases) and methylamine (a highly volatile chemical with a vapor pressure of 300 mg Hg), but EPA did not consider this data for use as a good analogy because of their high volatility and they did not contain any solids.

USDOE was interested in applying the experimental aerosol release data to estimate airborne fractions of liquid aerosol releases that were below respirable size, which they defined as particles of 10 micron Aerodynamic Equivalent Diameter (AED) or less. By USDOE's definition, respirable size particles are those that can be transported through the air and inhaled into the human respiratory system.

For purposes of establishing TPQs, EPA chose a distance of 100 meters (330 feet) to represent the distance from a source inside a chemical facility to the point where the community might be exposed. This decision was based on data indicating that a particle size greater than 100 microns is not likely to be deposited more than 100 meters from the source ("Threshold Planning Quantities Technical Support Document," USEPA April 7, 1987, Public Docket 300PQ, Document No. 300PQ–2–21). The 100-micron cutoff is also consistent with CERCLA regulations (for reportable quantities) which also uses a 100 micron particle size for powdered materials.

Most of the USDOE experimental aerosol release data had median aerosol diameters of less than 100 microns. This size is consistent with what EPA believes is the size of aerosols to which the community could be exposed. On the other hand, the water and cyclohexane aerosol release data compiled by CCPS had much larger mean aerosol diameter sizes, generally over 100 microns. For the reasons already discussed and because it is likely that aerosol releases with diameters larger than 100 microns will fall out of the air before they reach a community, the water and cylcohexane aerosol release fractions were not used in determining the TPQs for solids in solution.

b. Liquid and Solution TPQ Comparison

Pure EHS liquids could also be released accidentally as aerosols via the same catastrophic scenarios (overpressure, superheating). It could be argued that perhaps the TPQ method for solids in solution could also apply to liquids. However, this goes against the ranking used for setting TPQs based on the extent of airborne releases by physical state as being high for gases, less for liquids and even less for solids in solution. Currently, the release scenario used for developing the liquid TPQs considers a spill of the liquid due to a loss of containment. The liquid then escapes into the air by volatilization. An airborne release of solids in solution will require more than a failure of containment to have appreciable airborne dispersion. An energy source, such as overpressure or high temperature would be required to disperse the solution into the air and create aerosol droplets. Not all of the droplets will stay airborne (unlike volatilized vapors) and affect the community, whose exposure depends on droplet size and distance from the facility fence line.

If one assumes that there is an equal potential for airborne releases for gases, liquids, small particulate solids and solids in solution, then the TPQ ranking scheme would change radically and rely

almost entirely on the toxicity of the chemical. However, EPA believes that airborne dispersibility is a critical factor in determining TPQs. Limited state and local resources should be focused on those EHS chemicals that can potentially cause the greatest harm and less on those that might be toxic, but less likely to be released to the air and carried beyond the facility boundary.

As a hypothetical scenario, EPA determined if the current TPQ method for liquids gives more conservative (or at least as conservative) TPQs (lower thresholds) as compared to the proposed TPQ methodology for solids in solution. To do this, EPA estimated the TPQs for liquids by assuming that V = 1, and then divided it by 0.2 (based on an expected 20% maximum airborne dispersion) to determine the amount of EHS on-site that would trigger emergency planning notification. These amounts or "effective TPQs" were then compared to the current listed TPQs for liquids. For 116 of the 163 EHS liquids, the current TPQs for liquids based on volatilization were equal to or lower than the new effective TPQs based on aerosolization. Most of the other 47 liquids had current TPQs that were about twice the effective TPQ. This comparison with a table of results for the EHS liquids is discussed in the technical support document for this rulemaking. Based on this analysis, EPA believes that using the volatilization model to establish V for liquid TPQs is still appropriate. The spilled liquid using a boiling point scenario is probably the most prevalent worst-case scenario that is reasonable to use for establishing TPQs for liquids.

Further examination of the 47 liquid chemicals was undertaken to see why these had TPQs greater than the effective TPQs—that is, about twice the effective TPQ. Many of these liquids had effective TPQ values of 5, 50 and 5,000 pounds. However, there are no TPQs of 5, 50 or 5,000 pounds. Rather, the use of order of magnitude index ranges assigned to various TPQ levels resulted in assigned TPQ values of 1, 10, 100, 500, 1,000 and 10,000 pounds. Thus, where the effective TPQs are either 5, 50, or 5,000 pounds, the comparison of a current TPQ versus an effective TPQ may not be valid. More discussion on this can be found in the technical support document.

C. What alternative approaches were considered?

Given the data in the literature available on aerosol releases of solids in solution, EPA considered various alternative approaches. One alternative was using an index ranking method with an assigned V similar to the original method of assigning TPQs. Another alternative was to apply the ARF to the existing lower TPQ for solids to develop a new TPQ for solids in solution for each solid EHS. A third alternative was similar to the approach of multiplying the maximum ARF by the amount on-site, except that the ARF would only represent aerosol sizes less than respirable size. Below we discuss these alternatives, as well as the basis for not selecting them.

1. Index Ranking Method With V Less Than 1

This alternative would establish TPQs using a ranking approach based on each chemical's physical state, acute toxicity and, the potential for the chemical to become airborne (V). For this alternative, V would be set to 0.2 for EHS solids in solution.

For the original development of the TPQs, the ranking index was defined as the LOC divided by V, where V was set equal to 1 for gases and solids in powder form with a particle size less than 100 microns, molten solids and solids in solution. For liquid EHSs, V (the potential to become airborne) depended upon the property of volatility (evaporation of liquid into the gas phase). In the development of V for use in setting TPQs for liquids, V represented the mass per time evolved to the air per mass of the spill. This is explained in further detail in the April 1987 "Threshold Planning Quantities Technical Support Document" available in the docket.

Most of the values for V for liquids are approximately 0.1 (see Appendix B in the "Technical Support Document for Revising TPQ Method for Solids in Solution" for this rule). Using a higher V equal to 0.2 for solids in solution implies that in the event of an accidental release, more of the solution would become airborne than if it were volatilized from a liquid spill. Even if a liquid were accidentally released via aerosol form, the volatility of the liquid chemical will increase the fraction that remains dispersed in the air. Therefore, it would not be a fair representation to have a solid in solution with a V higher than that used for a volatile liquid. Also, because there are different mechanisms involved in the two types of releases, it may not be comparable to use the 0.2 as a substitute for V for solids in solution.

2. Existing TPQ and Aerosol Release Fraction

Another alternative is to apply the ARF to the existing lower TPQ for solids to develop a new TPQ. For example, the lower TPQ for paraquat dichloride is 10 pounds. Dividing 10 pounds by 0.2, the maximum expected aerosol release fraction for a solution would result in a new TPQ of 50 pounds for paraquat dichloride in solution form. For each of the 157 non-reactive solids on the EHSs list, a new TPQ for the solution form of the EHS solid could be determined and listed. However, for each solid non-reactive chemical, there are already two TPQs, one developed based on the ranking index methodology of (Index = Level of Concern/V) and one based on the default TPQ of 10,000 pounds for non-molten, non-reactive, non-solution solids with a particle size equal to or greater than 100 microns. Including a third set of TPQs for EHS solids in solution could be confusing to the regulated community. Thus, EPA believes that using the existing lower TPQ for solids and comparing that to the product of the amount on-site multiplied by 0.2 is a better approach, and similar to the approach used for the molten solids form.

3. Using ARF Limited to Smaller Aerosol Sizes

Another approach considered is similar to the proposed approach of multiplying the maximum ARF by the amount on-site, except that the ARF would only represent the fraction of aerosols with particles less than respirable size. Through discussions with the petitioner and EPA's November 2003 response to the petition, EPA has considered whether aerosol size should be used as a factor in developing new TPQs for solids in solution. A consultant for Syngenta believes that EPA should only consider the dispersion of aerosols with particle sizes less than or equal to 4 microns because these smaller aerosols are the size that can enter the lung and because the inhalation toxicity tests used for the basis of the EHSs listing only used very small particles.

This approach would require sufficient data on the aerosol size distribution for each release scenario to develop a new ARF that would include only aerosols of 4 microns and lower. The ARFs currently cited for the scenarios used for the preferred approach include aerosol sizes of 100 microns and lower. For some of the USDOE accident scenarios, it is possible to recalculate the airborne aerosol fractions using the raw experimental data to include only aerosols less than or equal to 4 microns in diameter. This results in smaller airborne release fractions.

EPA does not believe this approach should be used for a number of reasons, including:

• Inhalation toxicity tests are designed to use small particles to ensure that the lung is exposed. However, EPA is not using the inhalation toxicity for risk assessment, but only as a screening tool.

• Although the EHSs listing for paraquat dichloride is based on inhalation toxicity, EPA also has concerns regarding dermal and ingestion exposure via swallowing for the larger aerosols.

• Solvent evaporation from larger aerosols can also create smaller aerosols which can enter the lung.

Each of these is discussed below.

a. Aerosol Size in Toxicity Tests

Aerosols may be defined as a suspension of solid or liquid particles in air. Inhalation acute toxicity tests are purposely designed with very small diameter particles in order to ensure that particles are small enough to enter the rodent's lungs and test the toxicity in the lungs. Larger particles may not enter deep areas of the lungs and thus, test results may be misinterpreted if little inhalation toxicity is shown. EPA is not attempting to use the airborne aerosol fraction for purposes of risk assessment, but only as a tool to set screening levels for the amount of chemicals on-site which may potentially cause harm if accidentally released. Also, the size of the aerosols used in an animal laboratory test cannot be assumed to be the same as those that people may be exposed to during an accidental release.

b. Particle Size and Exposure

Inhalable size particles enter the respiratory tract, including the head airways and are generally equal to or less than 100 microns. Thoracic size particles (generally equal to or less than 10 microns) travel past the larynx and reach the lung airways and the gas-exchange regions of the lung. Respirable size particles (generally less than or equal to 4 microns) are a subset of thoracic particles that are more likely to reach the gas-exchange region of the lung.[5]

Most particles that enter the upper airways are trapped in mucous that moves to the throat and is swallowed within a few hours. Thus, instead of inhalation exposure deep in the lungs, exposure to larger particles of chemicals may occur through dermal exposure to mucous membranes or ingestion exposure through swallowing. Emergency planning for EHS chemicals is not limited to inhalation exposure only, although many of the EHS chemical listings are based on studies which meet the EHSs listing criteria for inhalation toxicity. Although airborne exposure is the most likely route of exposure, it is not the only route of exposure. In the event of an accidental release, EPA is concerned about all routes of exposure (inhalation, dermal and ingestion) to the community. Thus, exposure to larger size aerosols (e.g. those above 4 or 10 microns) by any route, such as through the skin or mucous membranes) should not be ignored when setting TPQs.

c. Solvent Evaporation From Aerosols

Even after liquid aerosol droplets are released, some of the solvent may evaporate in the air. This would result in even smaller size aerosols or solid EHS particulates in the air to which a community would be exposed. One concern is that droplets of size greater than 100 microns could settle quickly, dry into a smaller particle size and then become airborne again (re-suspension). In the event of an accidental release, the responsible party should clean up chemicals deposited on the facility grounds before additional exposure to the community would take place. The USDOE report did include data on re-suspension of particulates from soil after an aerosol release. However, the amount re-suspended did not add much to the reasonable worst case aerosol release fraction of 0.2. This scenario is explained further in the technical support document for this rule.

D. What are the peer review results?

EPA's revised TPQ methodology for EHS solids in solution and supporting data was peer reviewed and the technical support document was revised based on the peer review comments. The description of the peer review process, the results of the peer review and EPA's response to the peer review comments are found in a separate document, "Peer Review of Technical Support Document for Revised TPQ Method for EHS Solids in Solution," which is available in the docket to this rulemaking. Below are the questions posed to the peer reviewers, a summary of the peer reviewers' comments and EPA's responses.

1. Based on your reading and analysis of the information provided, do you find the revised TPQ method to be logical with a sound scientific basis?

Two of the three reviewers agreed that the revised TPQ method was logical with a sound scientific basis using the USDOE experimental aerosol release data. However, one reviewer thought the revised TPQ method may not be based on the most sound science because the LOC is based on Immediately Dangerous to Health and Life values (IDLH) and animal lethality data that he believes may not be appropriate. Nonetheless, this reviewer did think that a cursory review of the effective TPQ list (Appendix B in technical support document) appears to have appropriately listed the ranking of chemicals by potential hazard to the public.

EPA recognizes that use of the IDLH was an imperfect measure for determining the LOC, but believes the approach provides a consistent relative ranking of the EHS. Where animal lethality data were substituted, safety factors were applied to the data to estimate the LOC. Human data were taken into account for some chemicals, such as chemical warfare agents, and adjustments were made to the TPQ initially based on index values. EPA realizes that better data are being developed that could be used for the LOC (such as AEGLs—Acute Exposure Guideline Levels). However, a re-evaluation of the LOC for all EHS chemicals would best be undertaken by a separate rulemaking effort, given the extent and complexity of this issue.

2. Is the writing clear and concise? Has EPA provided the right level of detail? Is the method understandable? Are the results clearly presented?

Two of the three reviewers thought that the revised method was not clear and understandable and suggested improvements. For example, it was recommended that EPA clarify the definition of a solution, as well as include a flowchart of the method or a graph to help describe the approach.

EPA agrees that improvements were needed in order to present the information in a better way for the regulated community to understand and apply, and the revised technical support document addresses those concerns. Thus, additional supporting background information, discussion about the development of TPQs, and examples and calculations of how to apply the TPQs for EHS solids in solution have been added to the technical support document and has been further

[5] USEPA. October 2004. Air Quality Criteria for Particulate Matter. Vol I, Chapter 2 and Volume II, Chapter 6. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. Research Triangle Park, NC. EPA/600/P–00/002aF and EPA/600/P–00/002bF

explained in the preamble to the proposed rule. The proposed rule, which was not provided to the peer reviewers, is written more clearly and is less technical than the materials given to the peer reviewers to review.

One reviewer thought that EPA had provided the right amount of detail, and thought the method is understandable, and the text is for the most part readable. However, the reviewer had several clarifications and corrections he thought EPA should make. These clarifications have been made to the technical support document, including improving a description of background on TPQ development, clarifying some terms used in the document, and adding some references and other editorial comments.

This same reviewer thought the argument against the alternative approach of using V=0.2 for developing TPQ for solids in solutions was not that convincing. EPA has revised the discussion of this alternative approach by stating that EPA believes that this approach would result in TPQs that would be too low as compared to TPQs for liquids of similar toxicity because most of the liquids have approximately V=0.1. EPA believes that liquids have a higher potential for airborne dispersion because of their inherently higher volatility. Also, the mechanism for airborne dispersion for liquids using the spill model is volatilization, whereas solids in solution will be dispersed via aerosolization, so using V=0.2 for solutions may be not comparable.

3. Is the revised method consistent with the overall approach used for setting TPQs for other EHS chemicals?

All three reviewers thought that the revised method was fairly consistent with the approach used for setting other TPQs. However, one reviewer thought that EPA should consider lowering the TPQs for 46 of 163 EHS liquids based on the comparison of using the revised TPQ method versus the current method. EPA believes that using a V of 0.2 to recalculate the TPQ indexes would result in conservatively low TPQs for solids in solution as compared to liquids of the same toxicity. Given that volatilization requires only the loss of containment of a chemical, whereas aerosolization requires the loss of containment and usually an energy release, EPA believes the higher potential for airborne dispersion should be assigned to liquids as compared to a non-volatile solid in solution. Because there are different mechanisms (volatilization versus aerosolization) involved in the two types of releases, it may not be comparable to use 0.2 as a substitute for V for solids in solution. Based on the comments, EPA has revised the discussion in the preamble to the rule and Section VI.A—Use Original Ranking Method to Develop New TPQs of the document, "Technical Support Document for Revised TPQ Method for EHS Solids in Solution." EPA has also provided a more logical and clearer explanation for TPQs for different forms in Appendix A: Assigning Threshold Planning Quantities (TPQs) for Extremely Hazardous Substances, in the above document.

4. Is the revised method sufficiently protective for fulfilling accident prevention purposes of section 302 of EPCRA?

The reviewers all agreed that the method was sufficiently conservative to fulfill the accident prevention purposes of section 302 of EPCRA.

5. Is the revised method presented in a straightforward and uncomplicated way for the regulated community to understand and apply?

One reviewer thought that the revised method is not particularly straightforward and uncomplicated and that the regulated community will have difficulty understanding and applying it. Another reviewer suggested that examples be provided of how to apply the method when both powdered and solution form of a solid EHS is on-site. One reviewer thought a flow chart might be helpful to summarize the TPQ approach for the full spectrum of chemical forms.

To address these concerns, EPA has provided in the technical support document and the preamble to the proposed rule, a number of examples of how to apply the new TPQ method for solids in solution.

6. Are you aware of any other approaches or significant data/studies that are relevant and should be included or referenced in this document? Please explain

The reviewers were not able to provide any other approaches or data that should be used to revise the TPQ method for solids in solution, although one did provide other recommendations regarding the EHS chemical listing process and the toxicity values used for TPQs. Some of these comments address issues that are outside the scope of the current effort, which focuses only on TPQs for solids in solution.

7. Please Provide Any Other Suggestions You May Have About How To Strengthen the Document

To address other comments and concerns of the reviewers, EPA has clarified that the 12 reactive EHS solids are not subject to the revised TPQ method for solids in solution. EPA has also added several technical references as suggested into the technical support document.

E. What are the economic impacts of the TPQ changes?

Currently, facilities, who have an EHS present in an amount equal to or greater than the EHS's TPQ, are required to:

- Notify the SERC and LEPC that the facility is subject to emergency planning notification.
- Notify the SERC and LEPC of a facility representative to participate in the local emergency planning process.
- Notify the LEPC of any relevant facility changes that affect emergency planning.
- Provide the LEPC with the necessary information for developing a local emergency plan, as requested.

For facilities with an EHS that exists as solids in solution, emergency planning notification is required if the amount of solids by weight meets or exceeds the lower published TPQ for that chemical. Solid EHSs have another higher TPQ of 10,000 pounds that applies only if the EHS is not in solution, has a particle size equal to or greater than 100 microns, is not molten and does not have an NFPA reactivity rating of 2, 3, or 4.

The proposed rule would subject facilities with an EHS solid in solution to the emergency planning requirements if the amount of solid chemical on-site, when multiplied by 0.2, equals or exceeds the lower published TPQ. The effect would be to allow facilities to have up to five times larger amounts of EHS solids in solution on-site than before without being subject to the above emergency planning requirements.

Facilities who already had EHS solids in solution on-site above the TPQ and who have already (or should have already) completed emergency planning notification should notify their LEPC if they no longer exceed the TPQ as a result of this rulemaking. Section 303(d)(2) of EPCRA requires facilities to promptly provide to their LEPC any changes relevant to emergency planning. Regulations at 40 CFR 355.21 clarify that relevant changes to emergency planning should be reported within 30 days. EPA expects that this notification will be a minimal burden.

The emergency planning notification requirement is not required annually. Facilities, who are handling an EHS solid in solution for the first time, may benefit from the changes. However, if they have other EHSs on-site which trigger the reporting requirements, they would still have to make the necessary notifications.

EPA believes that the changes proposed by this rule can benefit SERCs and LEPCs to better focus their limited resources on those amounts of EHS chemicals that will potentially cause the greatest harm and to spend fewer resources on those that pose less harm, when released. The EHSs list has a total of 355 chemicals, of which 157 are non-reactive solids. This proposed rule applies only to those 157 non-reactive solids and only when they exist in solution form. While the Agency does not collect information to quantify the number of facilities that may be impacted by this rule, we suspect it will likely be a minimal number of facilities that are impacted since we believe that many of these facilities handle other EHS chemicals that will trigger the emergency planning requirements. However, the Agency solicits comment and data on the number of facilities that may be impacted, and the extent of the impact.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" because it raises novel policy issues arising out of litigation on the listing of paraquat dichloride as an EHS. EPA has decided to modify the manner by which the TPQ is applied for paraquat dichloride, as well as any other EHS that exists as a non-reactive solid in solution. Specifically, facilities with a non-reactive solid EHS in solution would be subject to the Emergency Planning requirements of 40 CFR part 355, subpart B—Emergency Planning only if the amount of non-reactive EHS solids in solution on-site multiplied by 0.2 equals or exceeds the lower published TPQ. Accordingly, EPA submitted this action to the Office of Management and Budget for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

The proposed regulation will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

B. Paperwork Reduction Act

This proposed rule does not impose any new information collection burden. Rather, this proposed rule, in effect, raises the amount of chemical on-site required before triggering emergency planning reporting under 40 CFR part 355 for EHS non-reactive solids in solution. Facilities with this form of EHS chemical would have already (or should have already) reported their presence to their SERC and LEPC and identified a Facility Emergency Coordinator and necessary information for development of a local emergency plan to their LEPC. If as a result of this rulemaking, facilities find that they have an EHS solid in solution on-site which no longer equals or exceeds the TPQ, the facility should notify their LEPC. Section 303(d)(2) of EPCRA requires facilities to promptly provide to their LEPC any changes relevant to emergency planning. Regulations at 40 CFR 355.21 clarify that relevant changes to emergency planning should be reported within 30 days. EPA expects that this notification will be a minimal burden. The emergency planning notification requirement is not required annually. There may be a slight burden reduction for facilities who are reporting EHS non-reactive solids in solution for the first time under the Section 302 requirements.

The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR part 355 under the provisions of the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2050–0092, EPA ICR number 1395.07. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the rule on small entities." 5 USC 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

This proposed rule changes the manner by which facilities apply the TPQs for those EHSs that are solid chemicals in solution form. Specifically, facilities with a non-reactive solid EHS in solution would be subject to the Emergency Planning requirements of 40 CFR part 355, subpart B—Emergency Planning only if the amount of non-reactive EHS solids in solution on-site, multiplied by 0.2 equals or exceeds the lower published TPQ. We have therefore concluded that today's proposed rule will relieve regulatory burden for some affected small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532–1538 for state, local, or tribal governments or the private sector. This proposed rule does not impose any new requirements on state, local or tribal governments. Facilities currently with EHS non-reactive solids in solution on-site have already (or should have already) reported these chemicals to their SERC and LEPC and identified a

Facility Emergency Coordinator and the necessary information for developing an emergency plan to their LEPC. We expect that this proposed action will neither increase nor decrease the requirements for SERCs or LEPCs. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This proposed action does not impose any new requirements on state, local or tribal governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

This proposed rule would reduce the reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning. We also expect that this proposed action will neither increase nor decrease the requirements for SERCs or LEPCs. This rule does not impose any requirements on state or local governments. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed action from state and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, (65 FR 67249, November 9, 2000). This proposed rule would reduce reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning. This action also does not impose any new requirements on tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866 and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed rule would reduce reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning.

H. Executive Order 13211: Energy Effects

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Rather, this proposed rule would reduce reporting burden on any facilities that would have an EHS non-reactive solid in solution on-site for the first time and could be subject to the emergency planning requirements for that chemical under 40 CFR part 355, subpart B—Emergency Planning.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or would otherwise be impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations of when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve technical standards. Therefore, EPA does not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (February 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. That is, based on new information and data, the Agency believes that amounts of EHS non-reactive solids in solution that would remain airborne from a potential release into the environment from an accident would be lower than previously considered, and thus, would have less impact on the local community. This in turn will allow SERCs and LEPCs to better focus their limited resources on the amounts of EHS chemicals that will potentially cause the greatest harm, including those affecting minority or low-income populations and to spend fewer resources on those that pose less harm, when released.

List of Subjects in 40 CFR Part 355

Environmental protection, Air pollution control, Chemicals, Disaster assistance, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: April 8, 2011.

Lisa P. Jackson,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 355—EMERGENCY PLANNING AND NOTIFICATION

1. The authority citation for part 355 continues to read as follows:

Authority: Sections 302, 303, 304, 325, 327, 328, and 329 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11002, 11003, 11004, 11045, 11047, 11048, and 11049).

2. Section 355.16 is amended by revising paragraph (b) to read as follows:

§ 355.16 How do I determine the quantity of extremely hazardous substances present for certain forms of solids?

* * * * *

(b) *Solids in solution.* Multiply the weight percent of non-reactive solids in solution in a particular container by the total weight of solution in the container. Then multiply by 0.2.

* * * * *

3. Section 355.61 is amended by adding in alphabetical order the definition of "Solution" to read as follows:

§ 355.61 How are key words in this part defined?

* * * * *

Solution means any aqueous or organic solutions, slurries, viscous solutions, suspensions, emulsions, or pastes.

* * * * *

[FR Doc. 2011–9096 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 441

[CMS–2296–P]

RIN 0938–AP61

Medicaid Program; Home and Community-Based Services (HCBS) Waivers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the regulations implementing Medicaid home and community-based services (HCBS) waivers under section 1915(c) of the Social Security Act by providing States the option to combine the existing three waiver targeting groups as identified in § 441.301. In addition, we are proposing other changes to the HCBS waiver provisions to convey expectations regarding person-centered plans of care, to provide characteristics of settings that are not home and community-based, to clarify the timing of amendments and public input requirements when States propose modifications to HCBS waiver programs and service rates, and to describe the additional strategies available to CMS to ensure State compliance with the statutory provisions of section 1915(c) of the Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 14, 2011.

ADDRESSES: In commenting, please refer to file code CMS–22296–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2296–P, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2296–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Kathryn Poisal, (410) 786–5940.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 1915(c) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain Medicaid statutory requirements so that a State may offer Home and Community-Based Services (HCBS) to State-specified group(s) of Medicaid beneficiaries who otherwise would require services at an institutional level of care. This provision was added to the Act by the Omnibus Budget and Reconciliation Act of 1981 (Pub. L. 97–35, enacted August 13, 1981) (OBRA'81) (with a number of subsequent amendments). Regulations were published to effectuate this statutory provision, with final regulations issued on July 25, 1994 (59 FR 37719). In the June 22, 2009 **Federal Register** (74 FR 29453), we published the Medicaid Program; Home and Community-Based Services (HCBS) advance notice of proposed rulemaking (ANPRM) that proposed to initiate rulemaking on a number of areas within the section 1915(c) program. We received 313 comments (which can be accessed at *http://www.regulations.gov/*) and held teleconferences with stakeholders. The correspondence included comments from States, health care and community support providers and associations, consumer groups, and social workers, and others. In the following sections, we discuss comments relating to questions

posed by the ANPRM and addressed in this proposed rule.

Along with our overarching interest in making improvements to the Medicaid HCBS program, we seek to ensure that Medicaid is providing needed strategies for States in their efforts to meet their obligations under the Americans with Disabilities Act (ADA) and Supreme Court's decision in *Olmstead* v. *L.C.,* 527 U.S. 581 (1999). In the *Olmstead* decision, the Court affirmed a State's obligations to serve individuals in the most integrated setting appropriate to their needs. A State's obligations under the ADA and section 504 of the Rehabilitation Act are not defined by, or limited to, the scope or requirements of the Medicaid program; however, the Medicaid program provides an opportunity to obtain partial Federal funding to assist in compliance with these laws through the provision of Medicaid services to Medicaid-eligible individuals.

We believe that these proposed changes will have numerous benefits for individuals and States alike. In addition to providing clarity around individual and stakeholder input, these proposed changes will move the system forward by enabling services to be planned and delivered in a manner driven by individual needs rather than diagnosis. These changes will enable States to realize administrative and program design simplification, as well as improve efficiency of operation. The changes related to clarification of HCBS settings will support the use of waiver authority to maximize the opportunities for waiver participants to have access to the benefits of community living and the opportunity to receive services in the most integrated setting appropriate.

A. Responses to Comments Received on ANPRM

1. Target Groups

Under section 1915(c) of the Act, the Secretary is authorized to waive section 1902(a)(10)(B) of the Act, allowing States not to apply comparability requirements and target an HCBS waiver program to a specified Medicaid-eligible group or sub-group of individuals who would otherwise require institutional care. A single section 1915(c) waiver may, under current regulation, serve one of the three target groups identified in § 441.301(b)(6). As provided in the rule, these three target groups are: "Aged or disabled, or both; Mentally retarded or developmentally disabled, or both; and Mentally ill.[1]" States must currently develop separate section 1915(c) waivers in order to serve more than one of the specified target groups. A Federal regulatory change that permits combining targeted groups within one waiver would remove a barrier for States that wish to design a waiver that meets the needs of more than one target population. This regulatory change would enable States to design programs to meet the needs of Medicaid-eligible individuals. For example, a growing number of Medicaid-eligible individuals with intellectual disabilities reside with aging caregivers who are also eligible for Medicaid. The proposed change would enable the State to design a coordinated section 1915(c) waiver structure that meets the needs of the entire family that, in this example, includes both an aging parent and a person with intellectual disabilities. In this illustration, the family would occupy two waiver slots, but with the proposed change, both could now be served under the same waiver program. We also believe the capacity to combine multiple target groups in one waiver may offer some administrative efficiencies for States.

Through the ANPRM, we proposed to initiate rulemaking to allow States the flexibility to combine any or all of the three target groups in one HCBS waiver (74 FR 29453). We sought public comments on how we may establish criteria related to the removal of an existing regulatory barrier that currently prevents States from designing cross-disability section 1915(c) HCBS waiver programs. The comments provided on this provision were largely positive, advising CMS to consider carefully quality elements and protections needed to ensure that all target groups are protected sufficiently in such a structure. Through this proposed rule, we include expectations that each individual within the waiver, regardless of target group, has equal access to the services necessary to meet their unique needs.

2. HCBS Settings

Through the ANPRM, we also sought public input on strategies to define home and community-based settings where waiver participants may receive services. Additionally, the request for input was in response to isolated situations that have emerged where States or other stakeholders are expressing interest in using HCBS waivers to serve individuals in segregated settings or settings with a strong institutional nature. For example, some proposed settings are on campuses of institutional facilities, segregated from the larger community, and do not allow individuals to choose whether or with whom they share a room, limit individuals' freedom of choice on daily living experiences such as meals, visitors, activities, and limit individuals' opportunities to pursue community activities.

We received several comments to the ANPRM strongly urging CMS to clarify in regulations that HCBS funding is not intended to be used for people in segregated facilities. One comment referenced large, campus-based programs and stated "[s]uch settings clearly do not meet the basic understanding of home and community-based settings." Another comment, expressing concern about segregated, residential campuses, added, "that HCBS funding is not intended to be used for these segregated facilities."

More recently, we received a significant amount of correspondence from stakeholders across the country in response to a specific State proposal contemplating a campus-based, segregated setting for HCBS. One correspondent wrote "* * * congregate settings are being planned on the grounds of existing Intermediate Care Facilities for Individuals with Mental Retardation (ICF/MRs) or in other segregated settings in several States, with the intent of using Home and Community-Based (Services) Waiver (HCBW) funding. This type of effort is incompatible with the goals * * * as defined by CMS. Both ADA and *Olmstead* require that services are provided in the most integrated settings appropriate to an individual's needs." Another writer expressed the following concern: "[My son] is very well known in the community and we know he is much safer in the community than in an institution. There are simply more eyes and ears in the community who would certainly telephone us if they even suspected abuse of any kind. The success of my son, and my desired success for those 5000 people * * * with developmental disabilities who are desperately waiting for services, is my motivation to oppose the use of the HCBW for a cluster of large group homes on a campus. They simply will not have the opportunities for growth as human beings * * *."

As a result of the significant comments we received and the subsequent feedback through correspondence and other stakeholder input opportunities, we propose that HCBS settings: must be integrated in the

[1] Although this terminology is still used in the statute and regulations, it is not consistent with the preferred language to describe target groups. In the spirit of Rosa's Law [Pub. L. 111–256], CMS will use the term, "individuals with intellectual disabilities" instead of "mentally retarded or developmentally disabled" where possible.

community; must not be located in a building that is also a publicly or privately operated facility that provides institutional treatment or custodial care; must not be located in a building on the grounds of, or immediately adjacent to, a public institution; or, must not be a housing complex designed expressly around an individual's diagnosis or disability, as determined by the Secretary. In addition, we propose that the settings must not have qualities of an institution, as determined by the Secretary. Such qualities may include regimented meal and sleep times, limitations on visitors, lack of privacy and other attributes that limit individual's ability to engage freely in the community. We invite comments on this portion of the regulations.

Through the ANPRM, we received comments suggesting that we carefully consider any adverse impact that a rule change may have on American Indians and Alaska Natives who reside on Tribal lands where living settings may differ according to cultural norms. To that end, we were advised to be careful that the language of a regulation does not unintentionally prohibit normative cultural living practices. We note that this proposed rule change does not exclude from home and community-based settings culturally appropriate settings on Tribal lands when the individual is an Indian or resides on Tribal lands where culturally acceptable group living arrangements are an integral aspect of the Tribal community. Specifically, Indian means any individual defined at 25 U.S.C. 1601(c), 1603(f), or 1679(b), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(1) Is a member of a Federally-recognized Indian Tribe;

(2) Resides in an urban center and meets one or more of the four criteria:

(a) Is a member of a Tribe, band, or other organized group of Indians, including those Tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(b) Is an Eskimo or Aleut or other Alaska Native;

(c) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(d) Is determined to be an Indian under regulations promulgated by the Secretary.

(3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

The comments noted that persons who are older with and without disabilities may choose to live together in assisted living facilities and urged CMS to allow them to exercise this preference and receive waiver services. Similarly, some persons who are older may desire to live in retirement communities, such as continuing care retirement communities. As a result, in accordance with a person-centered plan, we will allow such settings to be permissible under the section 1915(c) HCBS program for older persons under certain circumstances, which are noted below.

However, as previously noted, the Medicaid program's rules do not define or limit other obligations States may have under the ADA and section 504 of the Rehabilitation Act for individuals who seek more integrated settings than assisted living settings (ALS) or other settings not covered by this regulation.

For the purposes of this regulation, we note that ALS for persons who are older, without regard to disability, would not be excluded from home and community-based settings when the following conditions are met:

- Individual has a lease.
- Setting is an apartment with individual living, sleeping, bathing and cooking areas, and individuals can choose whether to share a living arrangement and with whom.
- Individuals have lockable access to and egress from their own apartments.
- Individuals are free to receive visitors and leave the setting at times and for durations of their own choosing.
- Aging in place, or allowing individuals to remain where they live as they age and/or support needs change, must be a common practice of the ALS.
- Leases may not reserve the right to assign apartments or change apartment assignments.
- Access to the greater community is easily facilitated based on the individual's needs and preferences.
- An individual's compliance with their person-centered plan (in the event that the individual has shared his/her plan or the landlord is also the provider of services) is not in and of itself a condition of the lease.

We are particularly interested in gaining comments on these aspects of the proposed rule. In addition, we note that this proposal in no way preempts broad Medicaid requirements, such as an individual's right to obtain services from any willing and qualified provider of a service.

Recognizing the imperative to provide clear guidance to States and in consideration of recent proposals that have clearly exceeded reasonable standards for HCBS, we are proposing to clarify now that certain settings are not home and community-based because they are not integrated in the community. A setting that is integrated in the community is a setting that enables individuals with disabilities to interact with individuals without disabilities to the fullest extent possible. Further, we believe that such settings do not preclude individuals' ability to access community activities at times, frequencies and with persons of their choosing. Such settings are not segregated based on disability, either physically or because of setting characteristics, from the larger community. In addition, such settings will afford individuals choice in their daily life activities, such as eating, bathing, sleeping, visiting and other typical daily activities. We will continue our dialogue with a wide variety of stakeholders on other issues related to the characteristics of HCBS settings.

3. Person-Centered Planning

Underpinning all aspects of successful HCBS is the importance of a complete and inclusive person-centered planning process that addresses health and long-term services and support needs in a manner that reflects individual preferences. To fully meet individual needs and ensure meaningful access to their surrounding community, systems that deliver HCBS must be based upon a strong foundation of person-centered planning and approaches to service delivery. Through the ANPRM process, we received favorable comments regarding our interest in ensuring a person-centered approach to services and support plan development, with recommendations that we articulate expectations for such an approach.

The person-centered approach is a process, directed by the individual with long-term support needs, and may also include a representative whom the individual has freely chosen. The person-centered plan shall identify the strengths, preferences, needs (clinical and support), and desired outcomes of the individual. The person-centered process enables the individual to choose others to serve as important contributors and members of the team in the planning process.

These participants in the person-centered planning process enable and

assist the individual to identify and access a personalized mix of paid and non-paid services. This process and the resulting service and support plan, also called a plan of care, will assist the individual in achieving personally defined outcomes in the most integrated community setting. The process is conducted in a manner that reflects what is important for the individual to meet identified clinical and support needs determined through a person-centered functional needs assessment process and what is important to the individual to ensure delivery of services in a manner that reflects personal preferences and choices and contributes to the assurance of health and welfare. The person-centered plan may also reflect whether and what services an individual may choose to self-direct. The plan should act as the basis for the building of an individual's budget, and the individual's ability to make decisions regarding the resources available to him or her. In collaboration with those that the individual has identified, he or she chooses planning goals to achieve these personal outcomes and to meet personal clinical and support needs. The identified personally-defined outcomes, preferred methods for achieving them, and the training supports, therapies, treatments, and other services the individual needs to achieve those outcomes become part of the written services and support plan.

In addition to being driven by the individual receiving services, the person-centered planning process would—

- Include people chosen by the individual;
- Provide necessary support to ensure that the individual has a meaningful role in directing the process;
- Occur at times and locations of convenience to the individual;
- Reflect cultural considerations of the individual;
- Include strategies for solving conflict or disagreement within the process, including strategies to address any conflict of interest concerns among planning participants;
- Include opportunities for periodic and ongoing plan updates as needed and/or requested by the individual; and,
- Offer choices to the individual regarding the services and supports they receive and from whom.

The plan resulting from this process should reflect the individual strengths and preferences, as well as clinical and support needs (as identified through a person-centered functional assessment). The plan should include individually identified goals, which may include goals and preferences related to relationships, community participation, employment, income and savings, health care and wellness, education, and others. The plan should reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals and who provides them. The plan should reflect risk factors and measures in place to minimize them. The plan must be signed by all individuals and providers responsible for its implementation, and should reflect the approach in place to ensure that it is implemented as intended. A copy of the plan must be provided to the individual and their representative(s). We invite comment on the person-centered process and planning elements of this proposed rule.

4. Summary

It is in this context and with the valuable input from the ANPRM that we propose modifications and additions to the regulations governing section 1915(c) HCBS waiver programs. We further seek to use this opportunity to clarify expectations regarding timing of amendments and public input requirements when States propose modifications to HCBS waiver programs and service rates, and strategies available to CMS to ensure State compliance with the statutory assurances of section 1915(c) of the Act.

B. Strategies To Ensure Compliance With Statutory Assurances

Our primary concern in the oversight of the section 1915(c) waivers is the health and welfare of the individuals served within the programs. Section 1915(f) of the Act requires the Secretary to monitor implementation of waivers to assure compliance with all requirements and provides for termination of waivers where the Secretary has found noncompliance. This authority and the process for termination of waivers is currently addressed in the regulations at § 441.304(d), § 441.307, and § 441.308. We seek to add provisions describing other strategies CMS may employ only after all other efforts have not yielded necessary results, to ensure compliance, short of termination or nonrenewal. At present, when we identify serious quality issues, such as potential harm to individual health and welfare or significant financial concerns, and States fail to take appropriate remedial action, the only enforcement options addressed in the regulations are for CMS to refuse to renew the waiver or terminate the waiver, as described at current § 441.304(d). Such action could have a significant detrimental impact on the individuals served (for example, loss of waiver services or Medicaid eligibility). We are interested in specifying a broader array of approaches CMS may take to achieve and maintain full State compliance with the requirements specified in or under section 1915(c) of the Act in addition to waiver termination. We invite comment on the discussion of compliance strategies in this proposed rule.

CMS issues these proposed rules to address issues that are pressing in the design, operation, and oversight of the section 1915(c) waiver program. However, we are committed to continuing a dialogue with all interested stakeholders on issues related to designing services and supports that meet individual needs, and that offer meaningful community participation opportunities.

II. Provisions of the Proposed Regulations

The provisions of this proposed rule would apply to all States offering Medicaid HCBS waivers under section 1915(c) of the Act.

As noted above, our ANPRM encompassed three main areas: Removal of regulatory barriers to serve more than one target group in a single waiver; definition of home and community characteristics; and, underpinning each of those areas, requirements for person-centered planning. Comments were supportive of our interest in setting forth our expectations regarding person-centered service and support plans that reflect what is important for the individual and to the individual. The proposed revisions to § 441.301(b)(1)(i) would require that a written services and support plan be based on the person-centered approach. This provision includes minimum requirements for this approach.

In new paragraph, § 441.301(b)(1)(iv), we would include clarifying language regarding settings that would not be considered home and community-based under section 1915(c) of the Act. We clarify that HCBS settings are integrated in the community and may not include: facilities located in a building that is also a publicly or privately-operated facility that provides inpatient institutional treatment or custodial care; or in a building on the grounds of, or immediately adjacent to, a public or private institution; or a disability-specific housing complex designed expressly around an individual's diagnosis, that is segregated from the larger community, as determined by the Secretary.

We note that this proposed rule change does not exclude living settings on Tribal lands that reflect cultural norms, or ALS for persons who are older

regardless of disability, when the conditions noted above in the background section are met.

The proposed revisions to § 441.301(b)(6) would allow States to combine target groups. We recognize that some States and stakeholders want additional flexibility to combine target groups in order to provide services based upon needs rather than diagnosis or condition, and for administrative relief from operating and managing multiple section 1915(c) waiver programs. Under this proposal, States must still determine that without the waiver, participants would require institutional level of care, in accordance with section 1915(c) of the Act. The proposal will not affect the cost neutrality requirement for section 1915(c) waivers, which requires the State to assure that the average per capita expenditure under the waiver for each waiver year not exceed 100 percent of the average per capita expenditures that would have been made during the same year for the level of care provided in a hospital, nursing facility, or ICF/MR under the State plan had the waiver not been granted. We will provide States with guidance on how to demonstrate cost neutrality for a waiver serving multiple target groups.

In an effort to ensure that safeguards are in place to protect the health and welfare of each waiver participant, we are proposing in a new paragraph § 441.302(a)(4) that to choose the option of more than one target group under a single waiver, States must assure CMS that they are able to meet the unique service needs that each individual may have regardless of target group, and that each individual in the waiver has equal access to all needed services. In addition, to ensure that services are provided in settings that are home and community-based, we are proposing in a new paragraph § 441.302(a)(5) that States provide assurance that the settings where services are provided are home and community based, and comport with new paragraph § 441.301(b)(1)(iv). While we are not changing the existing quality assurances through this rule, we are proposing to clarify that States must continue to assure health and welfare of all participants when target groups are combined under one waiver, and assure that they have the mechanisms in place to demonstrate compliance with that assurance.

At § 441.304, we would make minor revisions to the heading to indicate the rules addressed under this section.

We are proposing to revise § 441.304(d) and redesignate current § 441.304(d) as new § 441.304(g). The new § 441.304(d) would codify and clarify our guidance (*Application for a section 1915(c) Home and Community-Based Waiver, V. 3.5, Instructions, Technical Guide and Review Criteria, January 2008*) regarding the effective dates of waiver amendments with substantive changes, as determined by CMS. Substantive changes may include, but are not limited to changes in eligible populations, constriction of service amount, duration, or scope, or other modifications as determined by the Secretary. We would add regulatory language reflective of our guidance that waiver amendments with changes that we determine to be substantive may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal adverse impact on individuals impacted by the change.

Additionally, given the important requirement at § 447.205, which describes States' responsibilities to provide public notice when States propose significant changes to their methods and standards for setting payment rates for services, we propose to add a new paragraph § 441.304(e) to remind States of their obligations under § 447.205. We would further include a requirement at a new proposed paragraph § 441.304(f) that States establish public input processes specifically for HCBS changes. These processes, commensurate with the proposed change, could include formalized information dissemination approaches, conducting focus groups with affected parties, and establishing a standing advisory group to assist in waiver policy development. These processes must be identified expressly within the waiver document and utilized for waiver policy development. The input process must be accessible to the public (including individuals with disabilities) and States must make significant efforts to ensure that those who want to participate in the process are able to do so. These processes must include consultation with Federally-recognized Indian Tribes in accordance with Federal requirements and the State must seek advice from Indian health programs or Urban Indian Organizations prior to submission of a waiver request, renewal, amendment or action that would have a direct effect on Indians or Indian health providers or Urban Indian Organizations in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted on February 17, 2009). We would be interested in comments on this proposed addition to strengthen the public input process on changes proposed to services and other changes to the structure and operation of the section 1915(c) waivers.

In new paragraph, § 441.304(g), we propose to add language describing additional strategies CMS may employ to ensure State compliance with the requirements of a waiver, short of termination or non-renewal. Our proposed regulation at the new § 441.304(g) reflects an approach to encourage State compliance. We are interested in working with States to achieve full compliance without having to resort to termination of a waiver. Therefore, we are proposing strategies to ensure compliance in serious situations short of termination. These strategies include use of a moratorium on waiver enrollments or withholding of a portion of Federal payment for waiver services or for administration of waiver services in accordance with the seriousness and nature of the State's noncompliance (that is, health and welfare concerns and significant financial issues). These strategies could continue, if necessary, as the Secretary determines whether termination is warranted. Our primary objective is to use such strategies rarely, only after other efforts to resolve issues have not succeeded as necessary to ensure the health and welfare of individuals served.

Once CMS employs a strategy to ensure compliance, the State must submit an acceptable corrective action plan in order to resolve all areas of noncompliance. The corrective action plan must include detail on the actions and timeframe the State will take to correct each area of noncompliance, including necessary changes to the quality improvement strategy and a detailed timeline for the completion and implementation of corrective actions. CMS will determine if the corrective action plan is acceptable.

Selecting Strategies To Ensure Compliance

In consideration of whether and which strategies will be used to ensure compliance, and in accordance with the seriousness and nature of the State's noncompliance (that is, health and welfare concerns and significant financial issues), we will consider such areas as the following:

- The areas of noncompliance and whether they pose immediate concerns or otherwise compromise the State's ability to assure participant's health and welfare.
- The nature and duration of the identified area of serious noncompliance.

• The State's history of noncompliance in general, and specifically with reference to the cited area of serious noncompliance.

• The significance of the deficiencies and whether they indicate a system-wide failure to provide quality services.

III. Collection of Information Requirements

This proposed rule does not contain any new information collection requirements; however, it does make reference to information collection requirements currently approved by OMB. Specifically, the burden associated with the information collection requirements contained in this proposed rule (HCBS Waivers) is currently approved under OMB control number 0938–0499 with a July 31, 2012, expiration date.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–2296–P] Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This rule will have no consequential effect on State, local, or Tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 441

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

1. The authority citation continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart G—Home and Community-Based Services: Waiver Requirements

2. Section 441.301 is amended by—

A. Revising paragraphs (b)(1)(i) and (b)(6).

B. Adding new paragraph (b)(1)(iv).

The revisions and addition read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

(b) * * *

(1) * * *

(i) Under a written services and support plan (also called plan of care) that is based on a person-centered approach and is subject to approval by the Medicaid agency.

(A) *Person-Centered Planning Process.* In addition to being led by the individual receiving services, the person-centered planning process:

(*1*) Includes people chosen by the individual.

(*2*) Provides necessary support to ensure that the individual has a meaningful role in directing the process.

(*3*) Occurs at times and locations of convenience to the individual.

(*4*) Reflects cultural considerations of the individual.

(*5*) Includes strategies for solving conflict or disagreement within the process, including any conflict of interest concerns.

(*6*) Offers choices to the individual regarding the services and supports they receive and from whom.

(*7*) Includes a method for the individual to request updates to the plan as needed.

(B) *The Person-Centered Plan.* The person-centered plan must reflect the services that are important for the individual to meet individual services and support needs as assessed through a person-centered functional assessment as well as what is important to the person with regard to preferences for the delivery of such supports. Commensurate with the level of need of the individual, the plan must:

(*1*) Reflect the individual's strengths and preferences.

(*2*) Reflect clinical and support needs as identified through a person-centered functional assessment.

(*3*) Include individually identified goals, which may include, as desired by the individual, items related to relationships, community living, community participation, employment, income and savings, health care and wellness, education, and others.

(*4*) Reflect the services and supports (paid and unpaid) that will assist the individual to achieve identified goals and the providers of those services and supports.

(*5*) Reflect risk factors and measures in place to minimize them, including back-up strategies when needed.

(*6*) Be signed by all individuals and providers responsible for its implementation.

(*7*) Be understandable to the individual receiving services and the individuals important in supporting him or her.

(*8*) Include a timeline for review.

(*9*) Identify the individual and/or entity responsible for monitoring the plan.

(*10*) Be distributed to everyone involved (including the participant) in the plan.

(*11*) Be directly integrated into self-direction where individual budgets are used.

(*12*) Prevent the provision of unnecessary or inappropriate care.

* * * * *

(iv) Only in settings that are home and community based, integrated in the community, provide meaningful access to the community and community activities, and choice about providers, individuals with whom to interact, and daily life activities. A setting is not integrated in the community if it is:

(A) Located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment or custodial care; in a building on the grounds of, or immediately adjacent to, a public institution; or a housing complex designed expressly around an individual's diagnosis or disability, as determined by the Secretary; or

(B) Has qualities of an institutional setting, as determined by the Secretary.

* * * * *

(6) Be limited to one or more of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Individuals with Intellectual or Developmental Disabilities, or both.

(iii) Mentally ill.

3. Section 441.302 is amended by adding paragraphs (a)(4) and (a)(5) to read as follows:

§ 441.302 State Assurances.

* * * * *

(a) * * *

(4) Assurance that the State is able to meet the unique service needs that particular target groups may present when the State selects to serve more than one target group under a single waiver, as specified in § 441.301(b)(6) of this subpart.

(5) Assurance that services are provided in home and community based settings, as specified in § 441.301(b)(1)(iv) of this subpart.

* * * * *

4. Section 441.304 is amended by—

A. Revising the section heading as set forth below.

B. Redesignating paragraph (d) as new paragraph (g).

C. Adding new paragraphs (d), (e), and (f).

D. Revising newly designated paragraph (g).

The additions and revisions read as follows:

§ 441.304 Duration, extension, and amendment of a waiver.

* * * * *

(d) The agency may request that waiver modifications be made effective retroactive to the first day of a waiver year, or another date after the first day of a waiver year, in which the amendment is submitted, unless the amendment involves substantive changes as determined by CMS.

(1) Substantive changes may include, but are not limited to, revisions to services available under the waiver including elimination or reduction in services, and changes in the scope, amount, and duration of the services. Substantive changes may also include a change in the qualifications of service providers, changes in rate methodology or a change in the eligible population.

(2) A request for an amendment that involves a substantive change as determined by CMS, may only take effect on or after the date when the amendment is approved by CMS, and must be accompanied by information on how the State has assured smooth transitions and minimal adverse impact on individuals impacted by the change.

(e) The agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services in accordance with § 447.205 of this chapter.

(f) The agency must establish and use a public input process, for any changes in the services or operations of the waiver.

(1) This process must be described fully in the State's approved waiver application and be sufficient in light of the scope of the changes proposed, to ensure meaningful opportunities for input for individuals served, or eligible to be served, in the waiver.

(2) This process must include consultation with Federally recognized Tribes, and in accordance with section 5006(e) of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), Indian health programs and Urban Indian Organizations.

(g)(1) If CMS finds that the Medicaid agency is not meeting one or more of the requirements for a waiver contained in this subpart, the agency is given a notice of CMS' findings and an opportunity for a hearing to rebut the findings.

(2) If CMS determines that the agency is substantively out of compliance with this subpart after the notice and any hearing, CMS may employ strategies to ensure compliance as described in § 441.304(g)(1) of this paragraph or terminate the waiver.

(3)(i) Strategies to ensure compliance may include the imposition of a moratorium on waiver enrollments, other corrective strategies as appropriate to ensure the health and welfare of waiver participants, or the withholding of a portion of Federal payment for waiver services until such time that compliance is achieved, or, ultimately, termination. When a waiver is terminated, the State must comport with § 441.307 of this subpart.

(ii) CMS will provide States with a written notice of the impending strategies to ensure compliance for a waiver program. The notice of CMS' intent to utilize strategies to ensure compliance would include the nature of the noncompliance, the strategy to be employed, the effective date of the compliance strategy, the criteria for removing the compliance strategy and the opportunity for a hearing.

Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.

Dated: December 1, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 28, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–9116 Filed 4–14–11; 8:45 am]

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Notices

Federal Register
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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Funds Availability; Inviting Applications for the Quality Samples Program

Announcement Type: New.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.605.

SUMMARY: The Commodity Credit Corporation (CCC) announces it is inviting proposals for the 2012 Quality Samples Program (QSP). The intended effect of this notice is to solicit applications from eligible applicants and to award funds in October 2011. QSP is administered by personnel of the Foreign Agricultural Service (FAS).

DATES: To be considered for funding, applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. Any applications received after this time will be considered only if funds are still available.

FOR FURTHER INFORMATION CONTACT: Entities wishing to apply for funding assistance should contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.* Information is also available on the FAS Web site at *http://www.fas.usda.gov/mos/programs/QSP.asp.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Authority: QSP is authorized under Section 5(f) of the CCC Charter Act, 15 U.S.C. 714c(f).

Purpose: QSP is designed to encourage the development and expansion of export markets for U.S. agricultural commodities by assisting U.S. entities in providing commodity samples to potential foreign importers to promote a better understanding and appreciation for the high quality of U.S. agricultural commodities.

QSP participants will be responsible for procuring (or arranging for the procurement of) commodity samples, exporting the samples, and providing the on-site technical assistance necessary to facilitate successful use of the samples by importers. Participants that are funded under this announcement may seek reimbursement from QSP for the sample purchase price, the cost of transporting the samples domestically to the port of export, and then to the foreign port or point of entry. Transportation costs from the foreign port or point of entry to the final destination will not be eligible for reimbursement. CCC will not reimburse the costs incidental to purchasing and transporting samples, for example, inspection or documentation fees. Although providing technical assistance is required for all projects, QSP will not reimburse the costs of providing technical assistance. A QSP participant will be reimbursed after CCC reviews its reimbursement claim and determines that the claim is complete.

General Scope of QSP Projects: QSP projects are the activities undertaken by a QSP participant to provide an appropriate sample of a U.S. agricultural commodity to a foreign importer, or a group of foreign importers, in a given market. The purpose of the project is to provide information to an appropriate target audience regarding the attributes, characteristics, and proper use of the U.S. commodity. A QSP project addresses a single market/commodity combination.

As a general matter, QSP projects should conform to the following guidelines:

- Projects should benefit the represented U.S. industry and not a specific company or brand;
- Projects should develop a new market for a U.S. product, promote a new U.S. product, or promote a new use for a U.S. product, rather than promote the substitution of one established U.S. product for another;
- Sample commodities provided under a QSP project must be in sufficient supply and available on a commercial basis;
- The QSP project must either subject the commodity sample to further processing or substantial transformation in the importing country, or the sample must be used in technical seminars in the importing country designed to demonstrate to an appropriate target audience the proper preparation or use of the sample in the creation of an end product;
- Samples provided in a QSP project shall not be directly used as part of a retail promotion or supplied directly to consumers. However, the end product, that is, the product resulting from further processing, substantial transformation, or a technical seminar, may be provided to end-use consumers to demonstrate to importers consumer preference for that end product; and
- Samples shall be in quantities less than a typical commercial sale and limited to the amount sufficient to achieve the project goal (*e.g.,* not more than a full commercial mill run in the destination country).

QSP projects shall target foreign importers and audiences who:

- Have not previously purchased the U.S. commodity that will be transported under QSP;
- Are unfamiliar with the variety, quality attribute, or end-use characteristic of the U.S. commodity;
- Have been unsuccessful in previous attempts to import, process, and market the U.S. commodity (*e.g.,* because of improper specification, blending, formulation, sanitary, or phytosanitary issues);
- Are interested in testing or demonstrating the benefits of the U.S. commodity; or
- Need technical assistance in processing or using the U.S. commodity.

II. Award Information

Under this announcement, the number of projects per participant will not be limited. However, individual projects will be limited to $75,000 of QSP reimbursement. Projects comprised of technical preparation seminars, that is, projects that do not include further processing or substantial transformation, will be limited to $15,000 of QSP reimbursement as these projects require smaller samples. Financial assistance will be made available on a reimbursement basis only; cash advances will not be made available to any QSP participant.

All proposals will be reviewed against the evaluation criteria contained herein and funds will be awarded on a competitive basis. Funding for

successful proposals will be provided through specific agreements between the applicant and CCC. These agreements will incorporate the proposal as approved by FAS. FAS must approve in advance any subsequent changes to the project.

III. Eligibility Information

1. *Eligible Applicants:* Any United States private or government entity with a demonstrated role or interest in exporting U.S. agricultural commodities may apply to the program. Government organizations consist of Federal, State, and local agencies. Private organizations include non-profit trade associations, universities, agricultural cooperatives, State regional trade groups, and profit-making entities.

2. *Cost Sharing:* FAS considers the applicant's willingness to contribute resources, including cash, goods, and services of the U.S. industry and foreign third parties, when determining which proposals are approved for funding.

3. Proposals should include a justification for funding assistance from the program—an explanation as to what specifically could not be accomplished without Federal funding assistance and why the participating organization(s) would be unlikely to carry out the project without such assistance. Applicants may submit more than one proposal.

IV. Application and Submission Information

1. *Address to Request Application Package:* Organizations are strongly encouraged to submit their QSP applications to FAS through the Uniform Export Strategy (UES) application Internet Web site. The UES allows applicants to submit a single consolidated and strategically coordinated proposal that incorporates requests for funding and recommendations for virtually all of the FAS marketing programs, financial assistance programs, and market access programs. The suggested UES format encourages applicants to examine the constraints or barriers to trade that they face, identify activities that would help overcome such impediments, consider the entire pool of complementary marketing tools and program resources, and establish realistic export goals.

Applicants planning to use the Internet-based system must contact the FAS/Program Operations Division to obtain Web site access information. The Internet-based application may be found at the following URL address: *https://www.fas.usda.gov/ues/webapp/.*

Although FAS highly recommends applying via the Internet-based application, as this format virtually eliminates paperwork and expedites the FAS processing and review cycle, applicants also have the option of submitting an electronic version of their application to FAS at *podadmin@fas.usda.gov.*

2. *Content and Form of Application Submission:* To be considered for QSP, an applicant must submit to FAS information detailed in this notice. Additionally, in accordance with the Office of Management and Budget's policy directive (68 FR 38402 (June 27, 2003)) regarding the need to identify entities that are receiving government awards, all applicants must submit a Dun and Bradstreet Data Universal Numbering System (DUNS) number. An applicant may request a DUNS number at no cost by calling the dedicated toll-free DUNS number request line at 1–866–705–5711. Incomplete applications and applications that do not otherwise conform to this announcement will not be accepted for review.

FAS recommends that proposals contain, at a minimum, the following:

(a) Organizational information, including:

- Organization's name, address, Chief Executive Officer (or designee), Federal Tax Identification Number (TIN), and DUNS number;
- Type of organization;
- Name, telephone number, fax number, and e-mail address of the primary contact person;
- A description of the organization and its membership;
- A description of the organization's prior export promotion experience; and
- A description of the organization's experience in implementing an appropriate trade/technical assistance component;

(b) Market information, including:

- An assessment of the market;
- A long-term strategy in the market; and
- U.S. export value/volume and market share (historic and goals) for 2005–2011;

(c) Project information, including:

- A brief project title;
- Amount of funding requested;
- A brief description of the specific market development trade constraint or opportunity to be addressed by the project, performance measures for the years 2012–2014 which will be used to measure the effectiveness of the project, a benchmark performance measure for 2010, the viability of long-term sales to this market, the goals of the project, and the expected benefits to the represented industry;
- A description of the activities planned to address the constraint or opportunity, including how the sample will be used in the end-use performance trial, the attributes of the sample to be demonstrated and its end-use benefit, and details of the trade/technical servicing component (including who will provide and who will fund this component);
- A sample description (*i.e.,* commodity, quantity, quality, type, and grade), including a justification for selecting a sample with such characteristics (this justification should explain in detail why the project could not be effective with a smaller sample);
- An itemized list of all estimated costs associated with the project for which reimbursement will be sought;
- Beginning and end dates for the proposed project; and
- The importer's role in the project regarding handling and processing the commodity sample.
- Explanation as to what specifically could not be accomplished without Federal funding assistance and why the participating organization(s) would be unlikely to carry out the project without such assistance

(d) Information indicating all funding sources and amounts to be contributed by each entity that will supplement implementation of the proposed project. This may include the organization that submitted the proposal, private industry entities, host governments, foreign third parties, CCC, FAS, or other Federal agencies. Contributed resources may include cash, goods or services.

3. *Submission Dates and Times:* QSP funding is reviewed on a rolling basis during the fiscal year as long as remaining QSP funding is available. That is:

- Proposals received by, but not later than 5 p.m. Eastern Daylight Time, May 16, 2011, will be considered for funding with other proposals received by that date;
- Proposals not approved for funding during the review period will be reconsidered for funding after the review period only if the applicant specifically requests such reconsideration in writing, and only if funding remains available;
- Proposals received after 5 p.m. Eastern Daylight Time, May 16, 2011, will be considered for funding only if funding remains available.

4. *Funding Restrictions:* Proposals that request more than $75,000 of CCC funding for individual projects will not be considered. Projects comprised of technical preparation seminars will be limited to $15,000 in QSP funding. CCC will not reimburse expenditures made prior to approval of a proposal or unreasonable expenditures.

V. Application Review Information

1. *Criteria and Review Process:* Following is a description of the FAS process for reviewing applications and the criteria for allocating available QSP funds.

FAS will use the following criteria in evaluating proposals:

- The ability of the organization to provide an experienced staff with the requisite technical and trade experience to execute the proposal;
- The extent to which the proposal is targeted to a market in which the United States is generally competitive;
- The potential for expanding commercial sales in the proposed market;
- The nature of the specific market constraint or opportunity involved and how well it is addressed by the proposal;
- The extent to which the importer's contribution in terms of handling and processing enhances the potential outcome of the project;
- The amount of reimbursement requested and the organization's willingness to contribute resources, including cash, goods and services of the U.S. industry, and foreign third parties; and
- How well the proposed technical assistance component assures that performance trials will effectively demonstrate the intended end-use benefit.

Proposals will be evaluated by the Commodity Branch offices in the FAS' Cooperator Programs Division. The Commodity Branches will review each proposal against the factors described above. The purpose of this review is to identify meritorious proposals, recommend an appropriate funding level for each proposal based upon these factors, and submit proposals and funding recommendations to the Deputy Administrator, Office of Trade Programs.

2. *Anticipated Announcement Date:* Announcements of funding decisions for QSP are anticipated during October 2011.

VI. Award Administration Information

1. *Award Notices:* FAS will notify each applicant in writing of the final disposition of the submitted application. FAS will send an approval letter and agreement to each approved applicant. The approval letter and agreement will specify the terms and conditions applicable to the project, including the levels of QSP funding, and any cost-share contribution requirements.

2. *Administrative and National Policy Requirements:* The agreements will incorporate the details of each project as approved by FAS. Each agreement will identify terms and conditions pursuant to which CCC will reimburse certain costs of each project. Agreements will also outline the responsibilities of the participant, including, but not limited to, procurement (or arranging for procurement) of the commodity sample at a fair market price, arranging for transportation of the commodity sample within the time limit specified in the agreement (organizations should endeavor to ship commodities within 6 months of effective date of agreement), compliance with cargo preference requirements (shipment on United States flag vessels, as required), compliance with the Fly America Act requirements (shipment on United States air carriers, as required), timely and effective implementation of technical assistance, and submission of a written evaluation report within 90 days of expiration of the agreement.

QSP projects are subject to review and verification by FAS' Compliance, Security and Emergency Planning Division. Upon request, a QSP participant shall provide to CCC the original documents that support the participant's reimbursement claims. CCC may deny a claim for reimbursement if the claim is not supported by adequate documentation.

3. *Reporting:* A written evaluation report must be submitted within 90 days of the expiration of each participant's QSP agreement. Evaluation reports should address all performance measures that were presented in the proposal.

VII. Agency Contact(s)

For additional information and assistance, contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.*

Signed at Washington, DC, on the 25th of March, 2011.

John D. Brewer,

Administrator, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 2011–9213 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Funds Availability: Inviting Applications for the Emerging Markets Program

Announcement Type: New.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.603.

SUMMARY: The Commodity Credit Corporation (CCC) announces that it is inviting proposals for the 2012 Emerging Markets Program (EMP). The intended effect of this notice is to solicit applications from the private sector and from government agencies for FY 2012 and to award funds in October 2011. The EMP is administered by personnel of the Foreign Agricultural Service (FAS).

DATES: To be considered for funding, applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. Any applications received after this time will be considered only if funds are still available.

FOR FURTHER INFORMATION CONTACT: Entities wishing to apply for funding assistance should contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.* Information is also available on the Foreign Agricultural Service Web site at *http://www.fas.usda.gov/mos/em-markets/em-markets.asp.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Authority: The EMP is authorized by section 1542(d)(1) of the Food, Agriculture, Conservation and Trade Act of 1990 (The Act), as amended. The EMP regulations appear at 7 CFR part 1486.

1. *Purpose.* The EMP assists U.S. entities in developing, maintaining, or expanding exports of U.S. agricultural commodities and products by funding activities that improve emerging markets' food and rural business systems, including reducing potential trade barriers in such markets. The EMP is intended primarily to support export market development efforts of the private sector, but EMP resources may also be used to assist public organizations.

All U.S. agricultural commodities, except tobacco, are eligible for consideration. Agricultural product(s) should be comprised of at least 50 percent U.S. origin content by weight,

exclusive of added water, to be eligible for funding. Proposals that seek support for multiple commodities are also eligible. EMP funding may only be used to develop, maintain, or expand emerging markets for U.S. agricultural commodities and products through generic activities. EMP funding may not be used to support the export of another country's products to the United States, or to promote the development of a foreign economy as a primary objective.

2. *Appropriate Activities.* All EMP projects must fall into at least one of the following four categories:

(a) Assistance to teams consisting primarily of U.S. individuals expert in assessing the food and rural business systems of other countries. This type of EMP project must include all three of the following:

- Conduct an assessment of the food and rural business system needs of an emerging market;
- Make recommendations on measures necessary to enhance the effectiveness of these systems; and
- Identify opportunities and projects to enhance the effectiveness of the emerging market's food and rural business systems.

To be eligible, such proposals must clearly demonstrate that experts are primarily agricultural consultants, farmers, other persons from the private sector, and government officials, and that they have expertise in assessing the food and rural business systems of other countries.

(b) Assistance to enable individuals from emerging markets to travel to the United States so that these individuals can, for the purpose of enhancing the food and rural business systems in their countries, become familiar with U.S. technology and agribusiness and rural enterprise operations by consulting with food and rural business system experts in the United States.

(c) Assistance to enable U.S. agricultural producers and other individuals knowledgeable in agricultural and agribusiness matters to travel to emerging markets to assist in transferring their knowledge and expertise to entities in emerging markets. Such travel must be to emerging markets. Travel to developed markets is not eligible under the program even if the traveler's targeted market is an emerging market.

(d) Technical assistance to implement the recommendations, projects, and/or opportunities identified under 2(a) above. Technical assistance that does not implement the recommendations, projects, and/or opportunities identified by assistance under 2(a) above is not eligible under the EMP.

Proposals that do not fall into one or more of the four categories above, regardless of previous guidance provided regarding the EMP, are not eligible for consideration under the program.

EMP funds may not be used to support normal operating costs of individual organizations, nor as a source to recover pre-award costs or prior expenses from previous or ongoing projects. Proposals that counter national strategies or duplicate activities planned or already underway by U.S. non-profit agricultural commodity or trade associations ("cooperators") will not be considered. Other ineligible expenditures include: branded product promotions (in-store, restaurant advertising, labeling, *etc.*); advertising, administrative, and operational expenses for trade shows; Web site development; equipment purchases; and the preparation and printing of brochures, flyers, and posters (except in connection with specific technical assistance activities such as training seminars). For a more complete description of ineligible expenditures, please refer to the EMP regulations.

3. *Eligible Markets.* The Act defines an emerging market as any country that the

Secretary of Agriculture determines:

(a) Is taking steps toward developing a market-oriented economy through the food, agriculture, or rural business sectors of the economy of the country; and

(b) Has the potential to provide a viable and significant market for U.S. agricultural commodities or products of U.S. agricultural commodities.

Because EMP funds are limited and the range of potential emerging market countries is worldwide, consideration will be given only to proposals that target countries or regional groups with per capita income of less than $12,195 (the current ceiling on upper middle income economies as determined by the World Bank [World Development Indicators; December 2010, *http://siteresources.worldbank.org/DATASTATISTICS/Resources/CLASS.XLS]*) and populations of greater than 1 million.

Income limits and their calculation can change from year to year with the result that a given country may qualify under the legislative and administrative criteria one year but not the next. Therefore, CCC has not established a fixed list of emerging market countries.

A few countries technically qualify as emerging markets but may require a separate determination before funding can be considered because of political sensitivities.

II. Award Information

In general, all qualified proposals received before the application deadline will compete for EMP funding. Priority consideration will be given to proposals that directly support or address at least one of the goals and objectives in the USDA and FAS Strategic Plans. The USDA Strategic Plan can be accessed at the following link: *http://www.ocfo.usda.gov/usdasp/sp2010/sp2010.pdf.* The FAS strategic plan can be accessed at the following link: *http://www.fas.usda.gov/admin/FAS%20StrategicPlan2010-15finalClearedFFAS.pdf.* The applicants' willingness to contribute resources, including cash, goods and services will be a critical factor in determining which proposals are funded under the EMP. Proposals will also be judged on the potential benefits to the industry represented by the applicant and the degree to which the proposal demonstrates industry support.

The limited funds and the range of eligible emerging markets worldwide generally preclude CCC from approving large budgets for individual projects. While there is no minimum or maximum amount set for EMP-funded projects, most projects are funded at a level of less than $500,000 and for a duration of approximately one year. Private entities may submit multi-year proposals requesting higher levels of funding that may be considered in the context of a detailed strategic implementation plan. Funding in such cases is generally limited to three years and provided one year at a time with commitments beyond the first year subject to interim evaluations and funding availability. Government entities are not eligible for multi-year funding.

Funding for successful proposals will be provided through specific agreements. The CCC, through FAS, will be kept informed of the implementation of approved projects through the requirement to provide interim progress reports and final performance reports. Changes in the original project timelines and adjustments within project budgets must be approved in advance by FAS.

Note: EMP funds awarded to government agencies must be expended or otherwise obligated by close of business, September 30, 2012.

III. Eligibility and Qualification Information

1. *Eligible Applicants:* Any U.S. private or government entity (e.g., universities, non-profit trade associations, agricultural cooperatives, State regional trade groups (SRTGs),

State departments of agriculture, Federal agencies, profit-making entities, and consulting businesses) with a demonstrated role or interest in exports of U.S. agricultural commodities or products may apply to the program. Proposals from research and consulting organizations will be considered if they provide evidence of substantial participation by and financial support from the U.S. industry. For-profit entities are also eligible but may not use program funds to conduct private business, promote private self-interests, supplement the costs of normal sales activities or promote their own products or services beyond specific uses approved by CCC in a given project.

U.S. export market development cooperators and SRTGs may seek funding to address priority, market specific issues and to undertake activities not suitable for funding under other CCC market development programs, *e.g.,* the Foreign Market Development Cooperator (Cooperator) Program and the Market Access Program (MAP). Foreign organizations, whether government or private, may participate as third parties in activities carried out by U.S. organizations, but are not eligible for funding assistance from the program.

2. *Cost Sharing:* No private sector proposal will be considered without the element of cost-share from the applicant and/or U.S. partners. The EMP is intended to complement, not supplant, the efforts of the U.S. private sector. There is no minimum or maximum amount of cost-share, though the range in recent successful proposals has been between 35 and 75 percent. The degree of commitment to a proposed project, represented by the amount and type of private funding, is one factor used in determining which proposals will be approved for funding. Cost-share may be actual cash invested or professional time of staff assigned to the project. Proposals for which private industry is willing to commit cash, rather than in-kind contributions, such as staff resources, will be given priority consideration.

Cost-sharing is not required for proposals from government agencies, but is mandatory for all other eligible entities, even when they may be party to a joint proposal with a government agency. Contributions from USDA or other government agencies or programs may not be counted toward the stated cost-share requirement of other applicants. Similarly, contributions from foreign (non-U.S.) organizations may not be counted toward the cost-share requirement, but may be counted in the total cost of the project.

3. *Other:* Proposals should include a justification for funding assistance from the program—an explanation as to what specifically could not be accomplished without Federal funding assistance and why the participating organization(s) would be unlikely to carry out the project without such assistance. Applicants may submit more than one proposal.

IV. Application and Submission Information

1. *Address to Request Application Package:* EMP applicants have the opportunity to utilize the Unified Export Strategy (UES) application process, an online system that provides a means for interested applicants to submit a consolidated and strategically coordinated single proposal that incorporates funding requests for any or all of the market development programs administered by FAS.

Applicants are strongly encouraged to submit their applications to FAS through the UES application Internet Web site. The Internet-based format reduces paperwork and expedites the FAS processing and review cycle. Applicants planning to use the on-line UES system must contact the Program Operations Division to obtain site access information. The Internet-based application is located at the following URL address: *https://www.fas.usda.gov/ues/webapp/.*

Although FAS highly recommends applying via the Internet-based application, applicants also have the option of submitting an electronic version to FAS at *podadmin@fas.usda.gov.*

2. *Content and Form of Application Submission:* To be considered for the EMP, an applicant must submit to FAS information required by this Notice of Funds Availability and the EMP regulations at 7 CFR part 1486. EMP regulations and additional information are available at the following URL address: *http://www.fas.usda.gov/mos/em-markets/em-markets.asp.*

In addition, in accordance with the Office of Management and Budget's issuance of a final policy (68 FR 38402 (June 27, 2003)) regarding the need to identify entities that are receiving government awards, all applicants must submit a Dun and Bradstreet Data Universal Numbering System (DUNS) number. An applicant may request a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1–866–705–5711.

Applications should be no longer than ten (10) pages and include the following information:

(a) Date of proposal;

(b) Name of organization submitting proposal;

(c) Organization address, telephone and fax numbers;

(d) Tax ID number;

(e) DUNS number;

(f) Primary contact person;

(g) Full title of proposal;

(h) Target market(s);

(i) Current conditions in the target market(s) affecting the intended commodity or product;

(j) Description of problem(s) (*i.e.,* constraint(s)) to be addressed by the project, such as the need to assess and enhance food and rural business systems of the emerging market, lack of awareness by foreign officials of U.S. technology and business practices, impediments (infrastructure, financing, regulatory or other non-tariff barriers) to the effectiveness of emerging market's food and rural business systems previously identified by an EMP project that are to be implemented by the applicant, *etc.;*

(k) Project objectives;

(l) Performance measures: Benchmarks for quantifying progress in meeting the objectives;

(m) Rationale: Explanation of the underlying reasons for the project proposal and its approach, the anticipated benefits, and any additional pertinent analysis;

(n) Clear demonstration that successful implementation will benefit an emerging market's food and rural business system and/or reduce potential trade barriers, and will benefit a particular industry as a whole, not just the applicant(s);

(o) Explanation as to what specifically could not be accomplished without Federal funding assistance and why the participating organization(s) would be unlikely to carry out the project without such assistance;

(p) Specific description of activity/activities to be undertaken;

(q) Timeline(s) for implementation of activity, including start and end dates;

(r) Information on whether similar activities are or have previously been funded with USDA resources in the target country or countries (*e.g.,* under MAP and/or Cooperator programs); and

(s) Detailed line item activity budget:

- Cost items should be allocated separately to each participating organization; and
- Expense items constituting a proposed activity's overall budget (*e.g.*, salaries, travel expenses, consultant fees, administrative costs, *etc.*), with a line item cost for each, should be listed, clearly indicating:

(1) Which items are to be covered by EMP funding;

(2) Which by the participating U.S. organization(s); and

(3) Which by foreign third parties (if applicable).

Cost items for individual consultant fees should show calculation of daily rate and number of days. Cost items for travel expenses should show number of trips, destinations, cost, and objective for each trip.

Qualifications of applicant(s) should be included as an attachment.

3. *Funding Restrictions:* Certain types of expenses are not eligible for reimbursement by the program, and there are limits on other categories of expenses, such as indirect overhead charges, travel expenses, and consulting fees. CCC will also not reimburse unreasonable expenditures or expenditures made prior to approval of a proposal. Full details of the funding restrictions are available in the EMP regulations.

4. *Submission Dates and Times:* EMP funding is reviewed on a rolling basis during the fiscal year as long as remaining EMP funding is available. That is:

- Proposals received by, but not later than, 5 p.m. Eastern Daylight Time, May 16, 2011, will be considered for funding with other proposals received by that date;
- Proposals not approved for funding during the review period will be reconsidered for funding after the review period only if the applicant specifically requests such reconsideration in writing, and only if funding remains available;
- Proposals received after 5 p.m. Eastern Daylight Time, May 16, 2011, will be considered for funding only if funding remains available.

5. *Other Submission Requirements:* All Internet-based applications must be properly submitted by 5 p.m., Eastern Daylight Time, May 16, 2011, in order to be considered for funding; late submissions received after the deadline will be considered only if funding remains available. All applications submitted by e-mail must be received by 5 p.m. Eastern Daylight Time, May 16, 2011, at *podadmin@fas.usda.gov* in order to receive the same consideration.

V. Application Review Information

1. *Criteria:* Key criteria used in judging proposals include:

- The objective of the activities is to develop, maintain, or expand markets for U.S. agricultural exports by improving the effectiveness of the food and rural business systems in emerging markets;
- Appropriateness of the activities for the targeted market(s) and the extent to which the project identifies market barriers (*e.g.,* a fundamental deficiency in the emerging market's food and rural business systems, and/or a recent change in those systems);
- Potential of the project to expand U.S. market share, increase U.S. exports or sales;
- Quality of the project's performance measures, and the degree to which they relate to the objectives, deliverables, and proposed approach and activities;
- Justification for Federal funding;
- Overall cost of the project and the amount of funding provided by the applicant and any partners; and
- Evidence that the organization has the knowledge, expertise, ability, and resources to successfully implement the project, including timeliness and quality of reporting on past EMP activities.

Please see 7 CFR part 1486 for additional evaluation criteria.

2. *Review and Selection Process:* All applications undergo a multi-phase review within FAS, by appropriate FAS field offices, and, as needed, by the private sector Advisory Committee on Emerging Markets to determine the qualifications, quality, appropriateness of projects, and reasonableness of project budgets.

VI. Award Administration Information

1. *Award Notices:* FAS will notify each applicant in writing of the final disposition of the submitted application. FAS will send an approval letter and project agreement to each approved applicant. The approval letter and agreement will specify the terms and conditions applicable to the project, including the levels of EMP funding and cost-share contribution requirements.

2. *Administrative and National Policy Requirements:* Interested parties should review the EMP regulations, which are available at the following URL address: *http://www.fas.usda.gov/mos/em-markets/em-markets.asp.*

3. *Reporting.* Quarterly progress reports for all programs 1 year or longer in duration are required. Projects of less than 1 year generally require a mid-term progress report. Final performance reports are due 90 days after completion of each project. Content requirements for both types of reports are contained in the Project Agreement. Final financial reports are also due 90 days after completion of each project as attachments to the final reports. Please see 7 CFR part 1486 for additional reporting requirements.

VII. Agency Contact(s)

For additional information and assistance, contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or by *e-mail: podadmin@fas.usda.gov.*

Signed at Washington, DC, on the 25th day of March, 2011.

John D. Brewer,

Administrator, Foreign Agricultural Service and Vice President, Commodity Credit Corporation.

[FR Doc. 2011–9216 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Funds Availability: Inviting Applications for the Technical Assistance for Specialty Crops Program

Announcement Type: New.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.604.

SUMMARY: The Commodity Credit Corporation (CCC) announces that it is inviting proposals for the 2012 Technical Assistance for Specialty Crops (TASC) program. The intended effect of this notice is to solicit applications from the private sector and from government agencies for FY 2012 and to award funds in October 2011. The TASC program is administered by personnel of the Foreign Agricultural Service (FAS).

DATES: To be considered for funding, applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. Any applications received after this time will be considered only if funds are still available.

FOR FURTHER INFORMATION CONTACT: Entities wishing to apply for funding assistance should contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.* Information is also available on the FAS Web site at *http://www.fas.usda.gov/mos/tasc/tasc.asp.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Authority: The TASC program is authorized by section 3205 of Public Law 107–171. TASC regulations appear at 7 CFR part 1487.

Purpose: The TASC program is designed to assist U.S. organizations by

providing funding for projects that address sanitary, phytosanitary, or related technical barriers that prohibit or threaten the export of U.S. specialty crops. U.S. specialty crops, for the purpose of the TASC program, are defined to include all cultivated plants, or the products thereof, produced in the United States, except wheat, feed grains, oilseeds, cotton, rice, peanuts, sugar, and tobacco.

As a general matter, TASC program projects should be designed to address the following criteria:

- Projects should identify and address a sanitary, phytosanitary, or related technical barrier that prohibits or threatens the export of U.S. specialty crops;
- Projects should demonstrably benefit the represented industry rather than a specific company or brand;
- Projects must address barriers to exports of commercially-available U.S. specialty crops for which barrier removal would predominantly benefit U.S. exports; and
- Projects should include an explanation as to what specifically could not be accomplished without Federal funding assistance and why the participating organization(s) would be unlikely to carry out the project without such assistance.

Examples of expenses that CCC may agree to reimburse under the TASC program include, but are not limited to: initial pre-clearance programs, export protocol and work plan support, seminars and workshops, study tours, field surveys, development of pest lists, pest and disease research, database development, reasonable logistical and administrative support, and travel and per diem expenses.

II. Award Information

In general, all qualified proposals received before the specified application deadline will compete for funding. The limited funds and the range of barriers affecting the exports of U.S. specialty crops worldwide preclude CCC from approving large budgets for individual projects. Proposals requesting more than $500,000 in any given year will not be considered. Additionally, the maximum duration of an activity is 5 years. In order to validate funding eligibility, proposals must specify previous years of TASC funding for each proposed activity/title/market/constraint combination.

Applicants may submit multiple proposals, and applicants with previously approved TASC proposals may apply for additional funding. The number of approved projects that a TASC participant can have underway at any given time is five. Please see 7 CFR part 1487 for additional restrictions.

FAS will consider providing either grant funds as direct assistance to U.S. organizations or technical assistance on behalf of U.S. organizations, provided that the organization submits timely and qualified proposals. FAS will review all proposals against the evaluation criteria contained in the program regulations.

Funding for successful proposals will be provided through specific agreements. These agreements will incorporate the proposal as approved by FAS. FAS must approve in advance any subsequent changes to the project. FAS or another Federal agency may be involved in the implementation of approved projects.

III. Eligibility Information

1. Eligible Applicants: Any U.S. organization, private or government, with a demonstrated role or interest in exporting U.S. agricultural commodities may apply to the program. Government organizations consist of Federal, State, and local agencies. Private organizations include non-profit trade associations, universities, agricultural cooperatives, state regional trade groups, and private companies.

Foreign organizations, whether government or private, may participate as third parties in activities carried out by U.S. organizations, but are not eligible for funding assistance from the program.

2. Cost Sharing or Matching: FAS considers the applicant's willingness to contribute resources, including cash, goods, and services of the U.S. industry and foreign third parties, when determining which proposals are approved for funding.

3. Proposals should include a justification for funding assistance from the program—an explanation as to what specifically could not be accomplished without Federal funding assistance and why the participating organization(s) would be unlikely to carry out the project without such assistance.

IV. Application and Submission Information

1. Application through the Unified Export Strategy (UES): Organizations are strongly encouraged to submit their applications to FAS through the UES application Internet Web site. Using the UES application process reduces paperwork and expedites FAS's processing and review cycle. Applicants planning to use the UES Internet-based system must contact FAS/Program Operations Division to obtain site access information, including a user ID and password. The UES Internet-based application may be found at the following URL address: *https://www.fas.usda.gov/ues/webapp/.*

Although FAS highly recommends applying via the Internet-based UES application, as this format virtually eliminates paperwork and expedites the FAS processing and review cycle, applicants also have the option of submitting an electronic version to FAS at *podadmin@fas.usda.gov.*

2. Content and Form of Application Submission: All TASC proposals must contain complete information about the proposed projects as described in § 1487.5(b) of the TASC program regulations. In addition, in accordance with the Office of Management and Budget's policy directive (68 FR 38402 (June 27, 2003)) regarding the need to identify entities that are receiving government awards, all applicants must submit a Dun and Bradstreet Data Universal Numbering System (DUNS) number. An applicant may request a DUNS number at no cost by calling the dedicated toll-free DUNS number request line at 1–866–705–5711. Incomplete applications and applications that do not otherwise conform to this announcement will not be accepted for review.

3. Submission Dates and Times: TASC funding is reviewed on a rolling basis during the fiscal year as long as remaining TASC funding is available. That is:

- Proposals received by, but not later than, 5 p.m. Eastern Daylight Time, May 16, 2011, will be considered for funding with other proposals received by that date;
- Proposals not approved for funding during the review period will be reconsidered for funding after the review period only if the applicant specifically requests such reconsideration in writing, and only if funding remains available;
- Proposals received after 5 p.m. Eastern Daylight Time, May 16, 2011, will be considered for funding only if funding remains available.

Notwithstanding the foregoing, a proposal may be submitted for expedited consideration under the TASC Quick Response process if, in addition to meeting all requirements of the TASC program, a proposal clearly identifies a time-sensitive activity. In these cases, a proposal may be submitted at any time for an expedited evaluation. Such a proposal must include a specific request for expedited evaluation.

FAS will track the time and date of receipt of all proposals.

4. Funding Restrictions: Although funded projects may take place in the

United States or abroad, all eligible projects must specifically address sanitary, phytosanitary, or related technical barriers to the export of U.S. specialty crops.

Certain types of expenses are not eligible for reimbursement by the program, such as the costs of market research, advertising, or other promotional expenses, as set forth in the written program agreement between CCC and the participant. CCC will also not reimburse unreasonable expenditures or any expenditure made prior to approval of a proposal.

5. Other Submission Requirements: All Internet-based applications must be properly submitted by 5 p.m., Eastern Daylight Time, May 16, 2011, in order to be considered for funding; late submissions received after the deadline will be considered only if funding remains available. All applications submitted by email must be received by 5 p.m. Eastern Daylight Time, May 16, 2011, at *podadmin@fas.usda.gov* in order to receive the same consideration.

V. Application Review Information

1. Criteria: FAS follows the evaluation criteria set forth in § 1487.6 of the TASC regulations.

2. Review and Selection Process: FAS will review proposals for eligibility and will evaluate each proposal against the criteria referred to above. The purpose of this review is to identify meritorious proposals, recommend an appropriate funding level for each proposal based upon these factors, and submit the proposals and funding recommendations to the Deputy Administrator, Office of Trade Programs. FAS may, when appropriate, request the assistance of other U.S. government subject area experts in evaluating the merits of a proposal.

VI. Award Administration Information

1. Award Notices: FAS will notify each applicant in writing of the final disposition of the submitted application. FAS will send an approval letter and agreement to each approved applicant. The approval letter and agreement will specify the terms and conditions applicable to the project, including levels of funding, timelines for implementation, and written evaluation requirements.

2. Administrative and National Policy Requirements: The agreements will incorporate the details of each project as approved by FAS. Each agreement will identify terms and conditions pursuant to which CCC will reimburse certain costs of each project. Agreements will also outline the responsibilities of the participant. Interested parties should review the TASC program regulations found at 7 CFR part 1487 in addition to this announcement. TASC program regulations are available at the following URL address: *http:www.fas.usa.gov/mos/programs/TASC_1487_regulations_1-1-06.pdf.* Hard copies may be obtained by contacting the Program Operations Division at (202) 720–4327.

3. Reporting: TASC participants will be required to submit separate interim reports at 3, 6, and 9 months for each program year, and a final report, each of which evaluates their TASC project using the performance measures presented in the approved proposal, as set forth in the written program agreement.

VII. Agency Contact

For additional information and assistance, contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.*

Signed at Washington, DC, on the 25th of March, 2011.

John D. Brewer,

Administrator, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 2011–9219 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Funds Availability: Inviting Applications for the Market Access Program

Announcement Type: New.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.601.

SUMMARY: The Commodity Credit Corporation (CCC) announces that it is inviting proposals for the 2012 Market Access Program (MAP). The intended effect of this notice is to solicit applications from eligible applicants and to award funds in October 2011. The MAP is administered by personnel of the Foreign Agricultural Service (FAS).

DATES: All applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. Applications received after this date will not be considered.

FOR FURTHER INFORMATION CONTACT: Entities wishing to apply for funding assistance should contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.* Information is also available on the FAS Web site at *http://www.fas.usda.gov/mos/programs/map.asp.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Authority: The MAP is authorized under Section 203 of the Agricultural Trade Act of 1978, as amended. MAP regulations appear at 7 CFR part 1485.

Purpose: The MAP is designed to create, expand, and maintain foreign markets for U. S. agricultural commodities and products through cost-share assistance. Financial assistance under the MAP will be made available on a competitive basis, and applications will be reviewed against the evaluation criteria contained herein and in the MAP regulations. All U.S. agricultural commodities, except tobacco, are eligible for consideration.

The FAS allocates funds in a manner that effectively supports the strategic decision-making initiatives of the Government Performance and Results Act (GPRA) of 1993. In deciding whether a proposed project will contribute to the effective creation, expansion, or maintenance of foreign markets, the FAS considers whether the applicant provides a clear, long-term agricultural trade strategy and a program effectiveness time line against which results can be measured at specific intervals using quantifiable product or country goals. The FAS also considers the extent to which a proposed project targets markets with the greatest growth potential. These factors are part of the FAS resource allocation strategy to fund applicants who can demonstrate performance and address the objectives of the GPRA.

II. Award Information

Under the MAP, the CCC enters into agreements with eligible participants to share the cost of certain overseas marketing and promotion activities. MAP participants may receive assistance for generic or brand promotion activities. For generic activities, funding priority is given to organizations that have the broadest possible producer representation of the commodity being promoted and that are nationwide in membership and scope. Only non-profit U.S. agricultural trade organizations, nonprofit State regional

trade groups (SRTGs), non-profit U.S. agricultural cooperatives, and State government agencies can participate directly in the brand program. The MAP generally operates on a reimbursement basis.

III. Eligibility Information

1. *Eligible Applicants:* To participate in the MAP, an applicant must be a nonprofit U.S. agricultural trade organization, a nonprofit SRTG, a nonprofit U.S. agricultural cooperative, or a State government agency. A small-sized U.S. commercial entity may participate through a MAP participant.

2. *Cost Sharing:* To participate in the MAP, an applicant must agree to contribute resources to its proposed promotional activities. The MAP is intended to supplement, not supplant, the efforts of the U.S. private sector. In the case of generic promotion, the contribution must be at least 10 percent of the value of resources provided by CCC for such generic promotion. In the case of brand promotion, the contribution must be at least 50 percent of the total cost of such brand promotion.

The degree of commitment of an applicant to the promotional strategies contained in its application, as represented by the agreed cost-share contributions specified therein, is considered by FAS when determining which applications will be approved for funding. Cost-share may be actual cash invested or in-kind contributions, such as professional staff time spent on design and execution of activities. The MAP regulations, in section 1485.13(c), provide detailed discussion of eligible and ineligible cost-share contributions.

3. *Other:* Applications should include a justification for funding assistance from the program—an explanation as to what specifically could not be accomplished without Federal funding assistance, and why participating organization(s) are unlikely to carry out the project without such assistance.

IV. Application and Submission Information

1. *Address to Request Application Package:* Organizations are encouraged to submit their MAP applications to FAS through the Unified Export Strategy (UES) application Internet Web site. The UES allows interested applicants to submit a single consolidated and strategically coordinated proposal that incorporates requests for funding and recommendations for virtually all of the FAS marketing programs, financial assistance programs, and market access programs. The suggested UES format encourages applicants to examine the constraints or barriers to trade that they face, identify activities that would help overcome such impediments, consider the entire pool of complementary marketing tools and program resources, and establish realistic export goals. Applicants planning to use the Internet-based system must contact the FAS/Program Operations Division to obtain Web site access information. The Internet-based application may be found at the following URL address: *https://www.fas.usda.gov/ues/webapp/.*

The FAS highly recommends applying via the Internet-based application, as this format virtually eliminates paperwork and expedites the FAS processing and review cycle. However, applicants also have the option of submitting an electronic version of their application to FAS at *podadmin@fas.usda.gov.*

2. *Content and Form of Application Submission:* To be considered for the MAP, an applicant must submit to FAS information required by the MAP regulations in section 1485.13. In addition, in accordance with the Office of Management and Budget's policy (68 FR 38402 (June 27, 2003)) regarding the need to identify entities that are receiving government awards, all applicants must submit a Dun and Bradstreet Data Universal Numbering System (DUNS) number. An applicant may request a DUNS number at no cost by calling the dedicated toll-free DUNS number request line at 1–866–705–5711. Incomplete applications and applications that do not otherwise conform to this announcement will not be accepted for review.

The FAS administers various other agricultural export assistance programs including the Foreign Market Development Cooperator (Cooperator) program, the Emerging Markets Program, the Quality Samples Program, and the Technical Assistance for Specialty Crops program. Any organization that is not interested in applying for the MAP, but would like to request assistance through one of the other programs mentioned should contact the Program Operations Division.

3. *Submission Dates and Times:* All applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. All MAP applicants, regardless of the method of submitting an application, must also submit by the application deadline, an original signed certification statement as specified in 7 CFR 1485.13(a)(2)(i)(G) to the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024. Applications or certifications received after this date will not be considered.

4. *Funding Restrictions:* Certain types of expenses are not eligible for reimbursement by the program, and there are limits on other categories of expenses. CCC also will not reimburse unreasonable expenditures or expenditures made prior to approval. Full details are available in the MAP regulations in section 1485.16.

V. Application Review Information

1. *Criteria and Review Process:* Following is a description of the FAS process for reviewing applications and the criteria for allocating available MAP funds.

(1) Phase 1—Sufficiency Review and FAS Divisional Review:

Applications received by the closing date will be reviewed by FAS to determine the eligibility of the applicants and the completeness of the applications. These requirements appear in sections 1485.12 and 1485.13 of the MAP regulations. Applications that meet the requirements then will be further evaluated by the appropriate Commodity Branch office of the FAS/Cooperator Programs Division. The Commodity Branch will review each application against the criteria listed in section 1485.14 of the MAP regulations. The purpose of this review is to identify meritorious proposals and to recommend an appropriate funding level for each application based upon these criteria.

(2) Phase 2—Competitive Review: Meritorious applications then will be passed on to the Office of the Deputy Administrator, Office of Trade Programs, for the purpose of allocating available funds among the applicants. Applicants will compete for funds on the basis of the following allocation criteria (the number in parentheses represents a percentage weight factor):

(a) Applicant's Contribution Level (40)

- The applicant's 4-year average share (2009–2012) of all contributions (cash and goods and services provided by U.S. entities in support of overseas marketing and promotion activities) compared to;
- The applicant's 4-year average share (2009–2012) of the funding level for all MAP participants.

(b) Past Performance (30)

- The 3-year average share (2008–2010) of the value of exports promoted by the applicant compared to;
- The applicant's 2-year average share (2010–2011) of the funding level for all

MAP applicants plus, for those groups participating in the Cooperator program, the 2-year average share (2010–2011) of Cooperator marketing plan budgets.

(c) Projected Export Goals (15)

- The total dollar value of projected exports promoted by the applicant for 2012 compared to;
- The applicant's requested funding level;

(d) Accuracy of Past Projections (15)

- Actual exports for 2010 as reported in the 2012 MAP application compared to;
- Past projections of exports for 2010 as specified in the 2010 MAP application.

The Commodity Branches' recommended funding levels for each applicant are converted to percentages of the total MAP funds available and then multiplied by each weight factor as described above to determine the amount of funds allocated to each applicant.

2. *Anticipated Announcement Date:* Announcements of funding decisions for the MAP are anticipated during October 2011.

VI. Award Administration Information

1. *Award Notices:* The FAS will notify each applicant in writing of the final disposition of its application. The FAS will send an approval letter and program agreement to each approved applicant. The approval letter and program agreement will specify the terms and conditions applicable to the project, including the levels of MAP funding and cost-share contribution requirements.

2. *Administrative and National Policy Requirements:* Interested parties should review the MAP regulations, which are available at the following URL address: *http://www.fas.usda.gov/mos/programs/map.asp.* Hard copies may be obtained by contacting the Program Operations Division.

3. *Reporting:* The FAS requires various reports and evaluations from MAP participants. Reporting requirements are detailed in the MAP regulations in section 1485.20(b) and (c).

VII. Agency Contact(s)

For additional information and assistance, contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture at: Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or by phone: (202) 720–4327, or by fax: (202) 720–9361, or by e-mail: *podadmin@fas.usda.gov.*

Signed at Washington, DC, on the 25th of March, 2011.

John D. Brewer,

Administrator, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 2011–9217 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Funds Availability: Inviting Applications for the Foreign Market Development Cooperator Program

Announcement Type: New.

Catalog of Federal Domestic Assistance (CFDA) Number: 10.600.

SUMMARY: The Commodity Credit Corporation (CCC) announces that it is inviting proposals for the 2012 Foreign Market Development Cooperator (Cooperator) program. The intended effect of this notice is to solicit applications from eligible applicants for 2012 and to award funds in October 2011. The Cooperator program is administered by personnel of the Foreign Agricultural Service (FAS).

DATES: All applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. Applications received after this date will not be considered.

FOR FURTHER INFORMATION CONTACT: Entities wishing to apply for funding assistance should contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.* Information is also available on the FAS Web site at *http://www.fas.usda.gov/mos/programs/fmdprogram.asp.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Authority: The Cooperator program is authorized by title VII of the Agricultural Trade Act of 1978, as amended. Cooperator program regulations appear at 7 CFR part 1484.

Purpose: The Cooperator program is designed to create, expand, and maintain foreign markets for U.S. agricultural commodities and products through cost-share assistance. Financial assistance under the Cooperator program will be made available on a competitive basis and applications will be reviewed against the evaluation criteria contained herein and in the Cooperator program regulations. All U.S. agricultural commodities, except tobacco, are eligible for consideration.

The FAS allocates funds in a manner that effectively supports the strategic decision-making initiatives of the Government Performance and Results Act (GPRA) of 1993. In deciding whether a proposed project will contribute to the effective creation, expansion, or maintenance of foreign markets, the FAS considers whether the applicant provides a clear, long-term agricultural trade strategy, and a program effectiveness time line against which results can be measured at specific intervals using quantifiable product or country goals. The FAS also considers the extent to which a proposed project targets markets with the greatest growth potential. These factors are part of the FAS resource allocation strategy to fund applicants who can demonstrate performance and address the objectives of the GPRA.

II. Award Information

Under the Cooperator program, the FAS enters into agreements with eligible nonprofit U.S. trade organizations to share the cost of certain overseas marketing and promotion activities. Funding priority is given to organizations that have the broadest possible producer representation of the commodity being promoted and that are nationwide in membership and scope. Cooperators may receive assistance only for generic activities that do not involve promotions targeted directly to consumers. The program generally operates on a reimbursement basis.

III. Eligibility Information

1. *Eligible Applicants:* To participate in the Cooperator program, an applicant must be a nonprofit U.S. agricultural trade organization.

2. *Cost Sharing:* To participate in the Cooperator program, an applicant must agree to contribute resources to its proposed promotional activities. The Cooperator program is intended to supplement, not supplant, the efforts of the U.S. private sector. The contribution must be at least 50 percent of the value of resources provided by CCC for activities conducted under the project agreement.

The degree of commitment of an applicant to the promotional strategies contained in its application, as represented by the agreed cost-share contributions specified therein, is considered by the FAS when determining which applications will be approved for funding. Cost-share may be

actual cash invested or in-kind contributions, such as professional staff time spent on design and execution of activities. The Cooperator program regulations, including sections 1484.50 and 1484.51, provide detailed discussion of eligible and ineligible cost-share contributions.

3. *Other:* Applications should include a justification for funding assistance from the program—an explanation as to what specifically could not be accomplished without federal funding assistance and why participating organization(s) are unlikely to carry out the project without such assistance.

IV. Application and Submission Information

1. *Address to Request Application Package:* Organizations are encouraged to submit their FMD applications to the FAS through the Unified Export Strategy (UES) application Internet Web site. The UES allows applicants to submit a single consolidated and strategically coordinated proposal that incorporates requests for funding and recommendations for virtually all of the FAS marketing programs, financial assistance programs, and market access programs. The suggested UES format encourages applicants to examine the constraints or barriers to trade faced, identify activities that would help overcome such impediments, consider the entire pool of complementary marketing tools and program resources, and establish realistic export goals.

Applicants planning to use the Internet-based system must contact the FAS/Program Operations Division to obtain site access information. The Internet-based application may be found at the following URL address: *https://www.fas.usda.gov/ues/webapp/.*

The FAS highly recommends applying via the Internet-based application as this format virtually eliminates paperwork and expedites the FAS processing and review cycle. However, applicants also have the option of submitting an electronic version of their application to FAS at *podadmin@fas.usda.gov.*

2. *Content and Form of Application Submission:* To be considered for the Cooperator program, an applicant must submit to the FAS information required by the Cooperator program regulations in section 1484.20. In addition, in accordance with the Office of Management and Budget's policy (68 FR 38402 (June 27, 2003)) regarding the need to identify entities that are receiving government awards, all applicants must submit a Dun and Bradstreet Data Universal Numbering System (DUNS) number. An applicant may request a DUNS number at no cost by calling the dedicated toll-free DUNS number request line at 1–866–705–5711.

Incomplete applications and applications that do not otherwise conform to this announcement will not be accepted for review.

The FAS administers various other agricultural export assistance programs, including the Market Access Program (MAP), the Emerging Markets Program, the Quality Samples Program, and the Technical Assistance for Specialty Crops Program. Any organization that is not interested in applying for the Cooperator program but would like to request assistance through one of the other programs mentioned should contact the Program Operations Division.

3. *Submission Dates and Times:* All applications must be received by 5 p.m. Eastern Daylight Time, May 16, 2011. All Cooperator program applicants, regardless of the method of submitting an application, also must submit by the application deadline, an original signed certification statement as specified in 7 CFR section 1484.20(a)(14) to the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U.S. Department of Agriculture, Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024. Applications or certifications received after this date will not be considered.

4. *Funding Restrictions:* Certain types of expenses are not eligible for reimbursement by the program, and there are limits on other categories of expenses. CCC also will not reimburse unreasonable expenditures or expenditures made prior to approval. Full details are available in the Cooperator program regulations including sections 1484.54 and 1484.55.

V. Application Review Information

1. *Criteria and Review Process:* Following is a description of the FAS process for reviewing applications and the criteria for allocating available Cooperator program funds.

(1) Phase 1—Sufficiency Review and FAS Divisional Review

Applications received by the closing date will be reviewed by FAS to determine the eligibility of the applicants and the completeness of the applications. These requirements appear in sections 1484.14 and 1484.20 of the Cooperator program regulations. Applications that meet the requirements then will be further evaluated by the appropriate Commodity Branch office of the FAS/Cooperator Programs Division. The Commodity Branch will review each application against the criteria listed in sections 1484.21 and 1484.22 of the Cooperator program regulations. The purpose of this review is to identify meritorious proposals and to recommend an appropriate funding level for each application based upon these criteria.

(2) Phase 2—Competitive Review

Meritorious applications then will be passed on to the Office of the Deputy Administrator, Office of Trade Programs, for the purpose of allocating available funds among the applicants. Applicants will compete for funds on the basis of the following allocation criteria (the number in parentheses represents a percentage weight factor):

(a) Contribution Level (40)

- The applicant's 6-year average share (2007–2012) of all contributions (contributions may include cash and goods and services provided by U.S. entities in support of foreign market development activities) compared to;
- The applicant's 6-year average share (2007–2012) of all Cooperator marketing plan expenditures.

(b) Past Export Performance (20)

- The 6-year average share (2006–2011) of the value of exports promoted by the applicant compared to;
- The applicant's 6-year average share (2006–2011) of all Cooperator marketing plan expenditures plus a 6-year average share (2006–2011) of MAP expenditures, if any.

(c) Past Demand Expansion Performance (20)

- The 6-year average share (2006–2011) of the total value of world trade of the commodities promoted by the applicant compared to;
- The applicant's 6-year average share (2006–2011) of all Cooperator marketing plan expenditures plus a 6-year average share (2006–2011) of MAP expenditures, if any.

(d) Future Demand Expansion Goals (10)

- The projected total dollar value of world trade of the commodities being promoted by the applicant for the year 2017 compared to;
- The applicant's requested funding level.

(e) Accuracy of Past Demand Expansion Projections (10)

- The actual dollar value share of world trade of the commodities being promoted by the applicant for the year 2010 compared to;
- The applicant's past projected share of world trade of the commodities being

promoted by the applicant for the year 2010, as specified in the 2007 Cooperator program application.

The Commodity Branches' recommended funding levels for each applicant are converted to percentages of the total Cooperator program funds available and then multiplied by each weight factor to determine the amount of funds allocated to each applicant.

2. *Anticipated Announcement Date:* Announcements of funding decisions for the Cooperator program are anticipated during October 2011.

VI. Award Administration Information

1. *Award Notices:* The FAS will notify each applicant in writing of the final disposition of its application. The FAS will send an approval letter and project agreement to each approved applicant. The approval letter and project agreement will specify the terms and conditions applicable to the project, including the levels of Cooperator program funding, and cost-share contribution requirements.

2. *Administrative and National Policy Requirements:* Interested parties should review the Cooperator program regulations, which are available at the following URL address: *http://www.fas.usda.gov/mos/programs/fmdprogram.asp.* Hard copies may be obtained by contacting the Program Operations Division.

3. *Reporting:* The FAS requires various reports and evaluations from Cooperators. Reporting requirements are detailed in the Cooperator program regulations in sections 1484.53, 1484.70, and 1484.72.

VII. Agency Contact(s)

For additional information and assistance, contact the Program Operations Division, Office of Trade Programs, Foreign Agricultural Service, U. S. Department of Agriculture.

Courier address: Portals Office Building, Suite 400, 1250 Maryland Avenue, SW., Washington, DC 20024, or *by phone:* (202) 720–4327, or *by fax:* (202) 720–9361, or *by e-mail: podadmin@fas.usda.gov.*

Signed at Washington, DC, on the 25th of March, 2011.

John D. Brewer,

Administrator, Foreign Agricultural Service, and Vice President, Commodity Credit Corporation.

[FR Doc. 2011–9214 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Humboldt-Toiyabe National Forest; Nevada; Environmental Impact Statement for Geothermal Leasing on the Humboldt-Toiyabe National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice of Intent to prepare an environmental impact statement.

SUMMARY: The Humboldt-Toiyabe National Forest (HTNF) will prepare an environmental impact statement (EIS) to evaluate certain National Forest System (NFS) lands for geothermal leasing availability. The project area includes NFS lands on the HTNF in Douglas, Lyon, Mineral, Lander, Nye and White Pine County, NV.

DATES: Comments concerning the scope of the analysis must be received by May 16, 2011. The draft environmental impact statement is expected in October 2011 and the final environmental impact statement is expected in March 2012.

ADDRESSES: Send written comments to Keith Whaley, Project Manager, Humboldt-Toiyabe National Forest, Bridgeport Ranger District, HC 62 Box 1000, Bridgeport, CA 93517. Comments may also be sent via e-mail to *comments-intermtn-humboldt-toiyabe@fs.fed.us* or via facsimile to (760) 932–5899. Comments can be hand-delivered to: Bridgeport Ranger Station, Highway 395 South, Bridgeport, CA, Attn. Keith Whaley. Comments received in response to this Notice of Intent (NOI), including names and addresses of those who comment, will be considered part of the public record for this project and will be available for public inspection and will be released, if requested, under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Keith Whaley, Project Manager, Bridgeport Ranger District, HC 62 Box 1000, Bridgeport, CA 93517; *Telephone:* (760) 932–5821; *E-mail: kwhaley@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose of the proposed action is to determine if certain lands within the HTNF may be made available for geothermal leasing, and if so, to identify reasonable and necessary conditions to protect surface resources. The need for the proposed action is to allow the FS to satisfy their respective statutory and policy mandates in responding to requests for the environmentally responsible development of energy resources; to address provisions of the Energy Policy Act of 2005 (Sections 211 and 222[d][1]); respond to other policy directives calling for clean and renewable energy; and to meet the increasing energy demands of the nation while reducing reliance on foreign energy imports, reducing greenhouse gas emissions, and improving national security.

Proposed Action

The HTNF would make approximately 662,700 acres of NFS lands administratively available for geothermal leasing. The lands to be made available encompass the Nevada portion of the Bridgeport Ranger District (approximately 659,000 acres), one area on the Austin Ranger District (approximately 3,200 acres), one area (approximately 160 acres) on the Tonopah District and one area on the Ely Ranger District (approximately 3,574 acres). Leasing would include stipulations from Chapter 2 of the Geothermal Leasing Programmatic Environmental Impact Statement (BLM, October 2008) and other stipulations determined to be reasonable and necessary to protect surface resources.

The Decision resulting from this analysis would not affect any prior decisions on: (1) Geothermal leases in effect (2) Regional Forester Consent Decisions for specific geothermal leases or (3) lands made available under previous Forest-Level Availability Determination Decisions at the time said Decision is made. In addition, this analysis does not make any leasing determination decisions on any lands being analyzed under a separate environmental analysis at the time of this EIS.

Possible Alternatives

The No-Action Alternative: The USFS would not make an availability determination on these lands identified under this analysis. Processing of geothermal lease applications and nominations would continue, however, they would be evaluated on a case-by-case basis under separate NEPA analyses.

The No Leasing Alternative: The No Leasing Alternative would not allow leasing of geothermal resources on the subject NFS lands. Under this alternative, lands within the project area analyzed would not be available for leasing.

Lead and Cooperating Agencies

The Bureau of Land Management Nevada State office, located at 1340 Financial Blvd, Reno, NV 89502, is a cooperating agency for this NEPA analysis.

Responsible Official

Jeanne M. Higgins, Forest Supervisor, Humboldt-Toiyabe National Forest, 1200 Franklin Way, Sparks, Nevada 89431.

Nature of Decision To Be Made

Based on the environmental analysis and disclosure in the EIS, the Forest Supervisor will decide whether or not to make available for geothermal leasing the lands analyzed in this EIS.

Preliminary Issues

Preliminary issues identified based on our experience with similar projects includes, but is not limited to, cultural resources, wildlife, vegetation, air, water, Native American concerns, visuals, land use, hazardous materials, inventoried roadless areas, social, and economic conditions. Other issues may be identified during the scoping period.

Scoping Process

This NOI initiates the scoping process, which guides the development of the environmental impact statement. The scoping period for this EIS will run 30 days from the published date of this NOI.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however.

Dated: 17, 2011.

Jeanne M. Higgins,

Forest Supervisor.

[FR Doc. 2011–9160 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Lynn Canal/Icy Straits Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Lynn Canal/Icy Straits Resource Advisory Committee will meet in Juneau, Alaska, April 25, 2011. The purpose of this meeting is to orient the new appointees as to the Secure Rural Schools and Community Self-Determination Act of 2008, provide operational guidelines, discuss and adopt specific bylaws for the RAC, and elect a RAC Chairperson.

DATES: The meeting will be held April 25, 2011 from 8:30–3:30.

ADDRESSES: The meeting will be held at the Juneau Ranger District/Admiralty National Monument Office, 8510 Mendenhall Loop Road, Juneau, Alaska. Send written comments to Lynn Canal/Icy Straits Resource Advisory Committee, c/o Admiralty National Monument Ranger, 8510 Mendenhall Loop Road, Juneau, Alaska 99801, or electronically to Debra Robinson, RAC Coordinator at *drobinson03@fs.fed.us.*

FOR FURTHER INFORMATION CONTACT: Debra Robinson, RAC Coordinator Juneau Ranger District/Admiralty National Monument, Tongass National Forest, (907) 789–0209.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Committee discussion is limited to Forest Service staff and Committee members. However, public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: April 5, 2011.

Chad Vanormer,

Admiralty National Monument Ranger.

[FR Doc. 2011–9043 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Glenn/Colusa Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Glenn/Colusa Resource Advisory Committee will meet in Willows, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L 110–343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with title II of the Act. The meeting is open to the public. The purpose of the meeting is to review and discuss existing projects, and review new proposals for additional projects.

DATES: The meeting will be held May 16, 2011 at 1:30 p.m.

ADDRESSES: The meeting will be held at Mendocino National Forest, Grindstone Ranger District Office, Black Butte and Snow Mountain Conference Rooms, located at 825 N. Humboldt, Willows, CA 95988. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Grindstone Ranger District, Stonyford Work Center, 5171 Stonyford-Elk Creek Rd., Stonyford, CA 95979. Please call ahead to 530–963–3128 to facilitate entry into the building to view comments.

FOR FURTHER INFORMATION CONTACT: Laurie L. Pearson, Visitor Information Assistant, and Glenn/Colusa R.A.C. Coordinator, Grindstone Ranger District, 530–963–3128, *LLPearson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday. Requests for reasonable accomodation for access to the facility or procedings may be made by contacting the person listed **FOR FURTHER INFORMATION**.

SUPPLEMENTARY INFORMATION: The following business will be conducted: 1. Introductions, 2. Approval of Minutes, 3. RAC Admin. Updates, 4. Public Comment, 5. New Project Proposals, 6. Presenters, 7. Project Reviews FY 08/09/10, 8. Schedule Monitoring Field Trip, 9. General Discussion, 10. Meeting Schedule, 11. Adjourn. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by May 3, 2011 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent

to Stonyford Work Center, Attn: Laurie L. Pearson, Glenn/Colusa R.A.C. Coordinator, PO Box 160, Stonyford, CA 95979, or by e-mail to *LLPearson@fs.fed.us,* or via facsimile to 530–963–3173.

Dated: April 11, 2011.

Eduardo Olmedo,

DFO.

[FR Doc. 2011–9159 Filed 4–14–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Technical Advisory Committee will meet on May 12, 2011, 10 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues, NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

Agenda

Open Session

1. Opening Remarks by the Chairman and Introduction.
2. Remarks form Bureau of Industry and Security Senior Management.
3. Report of the Composite Working Group (CWG) and Export Control Classification Number Review Subgroup.
4. Update on Regime-Based Activities.
5. Comments from the Public and New Business.

Closed Session

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yspringer@bis.doc.gov* no later than May 5, 2011.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on September 27, 2010, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended, that the portion of the meeting dealing with matters the premature disclosure of which would likely frustrate the implementation of a proposed agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 § § 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: April 11, 2011.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2011–9183 Filed 4–14–11; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–602, A–588–602, A–583–605, A–549–807, A–570–814]

Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, Japan, Taiwan, Thailand, and the People's Republic of China: Continuation of Antidumping Duty Orders

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On October 1, 2010, the Department of Commerce (the Department) initiated the third sunset reviews of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, Japan, Taiwan, Thailand, and the People's Republic of China (PRC), pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). *See Initiation of Five-Year ("Sunset") Review,* 75 FR 60731 (October 1, 2010) (*Notice of Initiation*). As a result of the determinations by the Department and the International Trade Commission (ITC) that revocation of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, Japan, Taiwan, Thailand, and the PRC would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of these antidumping duty orders.

DATES: *Effective Date:* April 15, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine Cartsos or Minoo Hatten, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–1757 or (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2010, the Department initiated and the ITC instituted sunset reviews of the antidumping duty orders[1] on carbon steel butt-weld pipe fittings from Brazil, Japan, Taiwan, Thailand, and the PRC pursuant to section 751(c) of the Act. *See Notice of Initiation.*

As a result of these sunset reviews, the Department determined that revocation of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, Japan, Taiwan, Thailand, and the PRC would likely lead to continuation or recurrence of dumping and notified the ITC of the magnitude of the margins likely to prevail should the orders be revoked. *See Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, Japan, Taiwan, Thailand, and the People's Republic of China: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders,* 76 FR 7151 (February 9, 2011).[2]

On April 8, 2011, the ITC published its determination in the **Federal Register**, pursuant to section 751(c) of the Act, that revocation of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, Japan, Taiwan, Thailand, and the PRC would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. *See Carbon*

[1] *Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings from Brazil,* 51 FR 45152 (December 17, 1986); *Antidumping Duty Order: Certain Carbon Steel Butt-Weld Pipe Fittings from Japan,* 52 FR 4167 (February 10, 1987); *Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings From Taiwan,* 51 FR 45152 (December 17, 1986*); Antidumping Duty Order; Certain Carbon Steel Butt-Weld Pipe Fittings From Thailand,* 57 FR 29702 (July 6, 1992); *Antidumping Duty Order and Amendment to the Final Determination of Sales at Less Than Fair Value; Certain Carbon Steel Butt-Weld Pipe Fittings From the People's Republic of China,* 57 FR 29702 (July 6, 1992).

[2] The **Federal Register** published a correction of its error *in Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, Japan, Taiwan, Thailand, and the People's Republic of China: Final Results of the Expedited Sunset Reviews of the Antidumping Duty Orders,* 76 FR 8345 (February 14, 2011).

Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand, 76 FR 19788 (April 8, 2011), and USITC Publication 4222 (March 2011) entitled *Carbon Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand (Inv. Nos. 731–TA–308–310 and 520–521 (Third Review).*

Scope of the Orders

Brazil

The merchandise covered by the order consists of certain carbon steel butt-weld type fittings, other than couplings, under 14 inches in diameter, whether finished or unfinished, that have been formed in the shape of elbows, tees, reducers, caps, etc., and, if forged, have been advanced after forging. These advancements may include any one or more of the following: coining, heat treatment, shot blasting, grinding, die stamping or painting. Such merchandise was classifiable under Tariff Schedules of the United States Annotated (TSUSA) item number 610.8800. These imports are currently classified under subheading 7307.93.30 of the Harmonized Tariff Schedule of the United States (HTSUS). The HTSUS subheading is provided for convenience and customs purposes. The written product description remains dispositive.

Japan

The merchandise covered by the order consists of certain carbon steel butt-weld type fittings, other than couplings, under 14 inches in inside diameter, whether finished or unfinished, that have been formed in the shape of elbows, tees, reducers, caps, *etc.,* and if forged, have been advanced after forging. These advancements may include any one or more of the following: coining, heat treatment, shot blasting, grinding, die stamping or painting. Such merchandise was classifiable under TSUSA item number 610.8800. These imports are currently classifiable under the HTSUS item number 7307.93.30. Induction pipe bends classifiable under item 7307.93.30 which have at one or both ends tangents that equal or exceed 12 inches in length are excluded from the scope. The HTSUS subheading is provided for convenience and customs purposes. The written product description remains dispositive.

Taiwan

The merchandise covered by the order consists of certain carbon steel butt-weld type fittings, other than couplings, under 14 inches in inside diameter, whether finished or unfinished, that have been formed in the shape of elbows, tees, reducers, and caps, and if forged, have been advanced after forging. These advancements may include one or more of the following: coining, heat treatment, shot blasting, grinding, die stamping or painting. The Department clarified that the so-called sprink-let is within the scope of the order (57 FR 19602). Such merchandise was classifiable under TSUSA item number 610.8800. These imports are currently classifiable under the HTSUS item number 7307.93.3000. The HTSUS subheading is provided for convenience and for customs purposes. The written product description remains dispositive.

Thailand and PRC

The merchandise covered by the orders consists of certain carbon steel butt-weld pipe fittings, having an inside diameter of less than 14 inches, imported in either finished or unfinished form. These formed or forged pipe fittings are used to join sections in piping systems where conditions require permanent, welded connections, as distinguished from fittings based on other fastening methods (e.g., threaded, grooved, or bolted fittings). Carbon steel butt-weld pipe fittings are currently classified under subheading 7307.93.30 of the HTSUS. The HTSUS subheading is provided for convenience and customs purposes. The written product description remains dispositive.

Continuation of Orders

As a result of the determinations by the Department and the ITC that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping duty orders on carbon steel butt-weld pipe fittings from Brazil, Japan, Taiwan, Thailand, and the PRC.

U.S. Customs and Border Protection will continue to collect antidumping cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of the continuation of the orders will be the date of publication of this notice of continuation in the **Federal Register**. Pursuant to sections 751(c)(2) and 751(c)(6)(A) of the Act, the Department intends to initiate the next five-year reviews of these orders not later than 30 days prior to the fifth anniversary of the effective date of continuation.

These five-year sunset reviews and this notice are in accordance with section 751(c) of the Act and is published pursuant to section 777(i) of the Act and 19 CFR 351.218(f)(4).

Dated: April 8, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–9228 Filed 4–14–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–816]

Corrosion-Resistant Carbon Steel Flat Products From the Republic of Korea: Extension of Time Limits for the Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Victoria Cho, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230; telephone: (202) 482–5075.

Background

On September 29, 2010, the U.S. Department of Commerce ("Department") published a notice of initiation of the administrative review of the antidumping duty order on corrosion-resistant carbon steel flat products from the Republic of Korea, covering the period August 1, 2009, to July 31, 2010. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 75 FR 60076 (September 29, 2010). The preliminary results of this review are currently due no later than May 3, 2011.

Extension of Time Limit of Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended ("the Act"), requires that the Department make a preliminary determination within 245 days after the last day of the anniversary month of an order for which a review is requested. Section 751(a)(3)(A) of the Act further states that if it is not practicable to complete the review within the time period specified, the administering authority may extend the 245-day period to issue its preliminary results to up to 365 days.

We determine that completion of the preliminary results of this review within the 245-day period is not practicable.

Additional time is needed to gather and analyze a significant amount of information pertaining to sales practices, manufacturing costs and corporate relationships pertaining to each company participating in the review as well as the company requesting revocation. Given the number and complexity of issues in this case, in accordance with section 751(a)(3)(A) of the Act, we are fully extending by 120 days the time period for issuing the preliminary results of review. Therefore, the preliminary results are now due no later than August 31, 2011. The final results continue to be due 120 days after publication of the preliminary results.

This notice is published pursuant to sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: April 11, 2011.

Gary Taverman,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–9231 Filed 4–14–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–916]

Laminated Woven Sacks From the People's Republic of China: Final Results of Second Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 27, 2010, the Department of Commerce ("Department") published in the **Federal Register** the preliminary results of the second administrative review of the antidumping duty order on laminated woven sacks from the People's Republic of China ("PRC"). *See Laminated Woven Sacks From the People's Republic of China: Preliminary Results of the Second Administrative Review,* 75 FR 81218 (December 27, 2010) ("*Preliminary Results*"). We gave interested parties an opportunity to comment on the *Preliminary Results.* Based upon our analysis of the comments and information received, no changes have been made for the final results. We continue to find that the PRC-wide entity has sold subject merchandise at less than normal value during the period of review ("POR"), August 1, 2009, through July 31, 2010.

DATES: *Effective Date:* April 15, 2011.

FOR FURTHER INFORMATION CONTACT: Jamie Blair-Walker, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; *telephone:* (202) 482–2615.

SUPPLEMENTARY INFORMATION:

Background

On September 29, 2010, the Department initiated this review with respect to one company. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 75 FR 60076 (September 29, 2010). The review was initiated with respect to Zibo Aifudi Plastic Packaging Co., Ltd. ("Aifudi") upon the self-request of Aifudi and the request of Petitioners.[1] On November 3, 2010, Aifudi submitted a letter notifying the Department of its intent to withdraw and refusal to further participate in the ongoing administrative review.[2] Petitioners did not withdraw their request for an administrative review of Aifudi. Therefore, the Department did not rescind the review with respect to Aifudi.

In the *Preliminary Results,* we set the deadline for interested parties to submit case briefs and rebuttal briefs to January 26, 2011, and January 31, 2011, respectively. Due to the early closure of the Department resulting from inclement weather on January 26, 2011, AMS[3] filed a case brief on the morning of the next business day, January 27, 2011. Subsequently, the Department extended the deadline for rebuttal briefs by one day, to February 1, 2011. Petitioners filed a rebuttal brief on February 1, 2011. The Department did not hold a public hearing pursuant to 19 CFR 351.310(d), as no interested parties requested a hearing.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to these reviews are addressed in the "Laminated Woven Sacks from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Second Antidumping Duty Administrative Review" ("Decision Memo"), which is dated concurrently with this notice. A list of the issues which parties raised and to which we respond in the Decision Memo is attached to this notice as an Appendix. The Decision Memo is a public document and is on file in the Central Records Unit, Main Commerce Building, Room 7046, and is accessible on the Department's Web site at *http://www.trade.gov/ia.* The paper copy and electronic version of the memorandum are identical in content.

Scope of the Order

The merchandise covered by the order is laminated woven sacks. Laminated woven sacks are bags or sacks consisting of one or more plies of fabric consisting of woven polypropylene strip and/or woven polyethylene strip, regardless of the width of the strip; with or without an extrusion coating of polypropylene and/or polyethylene on one or both sides of the fabric; laminated by any method either to an exterior ply of plastic film such as biaxially-oriented polypropylene ("BOPP") or to an exterior ply of paper that is suitable for high quality print graphics;[4] printed with three colors or more in register; with or without lining; whether or not closed on one end; whether or not in roll form (including sheets, lay-flat tubing, and sleeves); with or without handles; with or without special closing features; not exceeding one kilogram in weight. Laminated woven sacks are typically used for retail packaging of consumer goods such as pet foods and bird seed.

Effective July 1, 2007, laminated woven sacks are classifiable under Harmonized Tariff Schedule of the United States ("HTSUS") subheadings 6305.33.0050 and 6305.33.0080. Laminated woven sacks were previously classifiable under HTSUS subheading 6305.33.0020. If entered with plastic coating on both sides of the fabric consisting of woven polypropylene strip and/or woven polyethylene strip, laminated woven sacks may be classifiable under HTSUS subheadings 3923.21.0080, 3923.21.0095, and 3923.29.0000. If entered not closed on one end or in roll form (including sheets, lay-flat tubing, and sleeves), laminated woven sacks may be classifiable under other HTSUS subheadings including 3917.39.0050, 3921.90.1100, 3921.90.1500, and 5903.90.2500. If the polypropylene

[1] Petitioners are the Laminated Woven Sacks Committee and its individual members, Coating Excellence International, LLC and Polytex Fibers Corporation.

[2] *See* Letter from Aifudi entitled Laminated Woven Sacks from China; Withdrawal from Proceeding, dated November 3, 2010.

[3] AMS Associates, Inc., operating as Shapiro Packaging ("AMS"), importer of products produced by Aifudi.

[4] "Paper suitable for high quality print graphics," as used herein, means paper having an ISO brightness of 82 or higher and a Sheffield Smoothness of 250 or less. Coated free sheet is an example of a paper suitable for high quality print graphics.

strips and/or polyethylene strips making up the fabric measure more than 5 millimeters in width, laminated woven sacks may be classifiable under other HTSUS subheadings including 4601.99.0500, 4601.99.9000, and 4602.90.0000. Although HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Changes Since the Preliminary Results

In the *Preliminary Results,* we determined that the use of adverse facts available ("AFA") is appropriate as the basis for the weighted-average dumping margin assigned to the PRC-wide entity, which includes Aifudi. There have been no changes since the *Preliminary Results.* Therefore, for the final results, we have adopted our positions in the *Preliminary Results.* Thus, the Department continues to find that the application of total AFA is warranted for the PRC-wide entity pursuant to sections 776(a)(2)(A) and (C) and 776(b) of the Tariff Act of 1930, as amended ("the Act").

Use of Adverse Facts Available

In accordance with section 776(b) of the Act, we determine that the use of AFA as the basis for the weighted-average dumping margin is appropriate for the PRC-wide entity. As explained in the *Preliminary Results,* Aifudi withdrew its participation from this administrative review, did not submit any information on the record regarding its separate rate status, and did not respond to requests for information from the Department. As such, Aifudi has not rebutted the presumption of PRC government control and does not qualify for a separate rate. Therefore, the Department continues to find that Aifudi should be treated as part of the PRC-wide entity.

Because we have determined that Aifudi is part of the PRC-wide entity, the PRC-wide entity is under review. Pursuant to section 776(a)(2)(A) and (C) of the Act, we find that Aifudi failed to respond to the Department's questionnaires, withheld information requested by the Department, and impeded the conduct of this review. Accordingly, the Department continues to find that it is appropriate to base the dumping margin of the PRC-wide entity on the facts otherwise available on the record. Further, because Aifudi's failure to provide the requested information constitutes circumstances under which it is reasonable to conclude that less than full cooperation has been shown, pursuant to section 776(b) of the Act, the Department has determined that, when selecting from among the facts otherwise available, an adverse inference is warranted with respect to the PRC-wide entity.

As AFA, we have applied the highest dumping margin on the record of any segment of this proceeding, which is 91.73 percent.[5] Furthermore, as required by section 776(c) of the Act, we corroborated this margin with respect to the PRC-wide entity, to the extent practicable. For a detailed explanation of how we corroborated this margin, *see Preliminary Results.*[6]

Final Results of Review

The weighted-average dumping margins for the POR are as follows:

Exporter	Weighted average percent margin
PRC-Wide Entity[7]	91.73

Assessment

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection ("CBP") shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For assessment purposes, we calculated importer (or customer)-specific assessment rates for merchandise subject to this review. Where appropriate, we calculated an *ad valorem* rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total entered values associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting *ad valorem* rate against the entered customs values for the subject merchandise. Where appropriate, we calculated a per-unit rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total sales quantity associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting per-unit rate against the entered quantity of the subject merchandise. Where an importer (or customer)-specific assessment rate is *de minimis* (*i.e.,* less than 0.50 percent), the Department will instruct CBP to assess that importer (or customer's) entries of subject merchandise without regard to antidumping duties, in accordance with 19 CFR 351.106(c)(2). The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For Aifudi, the cash deposit rate will be the rate as listed above in the "Final Results of Review" section of this notice; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 91.73 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial

[5] *See Laminated Woven Sacks from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 35646 (June 24, 2008).

[6] *See Preliminary Results,* 75 FR at 81220–21.

[7] The PRC-Wide entity includes Zibo Aifudi Plastic Packaging Co., Ltd.

protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: April 8, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

Appendix I—Issues and Decision Memorandum

Comment 1: Decision Regarding Country of Origin

1a. Procedures in Determining Country of Origin

1b. Authority to Issue Instructions to CBP

Comment 2: Whether to Reject AMS' Case Brief

[FR Doc. 2011–9230 Filed 4–14–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board; Notice of Public Meeting

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the NOAA Science Advisory Board. The members will discuss and provide advice on issues outlined in the agenda below.

DATES: The meeting is scheduled for: Monday, May 16, from 3–5 p.m. Eastern Daylight Time.

ADDRESSES: Conference call. Public access is available at: NOAA, SSMC 3, Room 12836, 1315 East-West Highway, Silver Spring, MD.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, Science Advisory Board, NOAA, Rm. 11230, 1315 East-West Highway, Silver Spring, Maryland 20910. (Phone: 301–734–1156, Fax: 301–713–1459, E-mail: *Cynthia.Decker@noaa.gov*)

SUPPLEMENTARY INFORMATION: The Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

Matters To Be Considered: The agenda for the meeting is as follows:

Date and Time: Monday, May 16 from 3–5 p.m. Eastern Daylight Time.

Status: The meeting will be open to public participation at NOAA, SSMC 3, Room 12836, 1315 East-West Highway, Silver Spring, MD. with a 5-minute public comment period from 4:50–4:55 p.m. The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of one minute. Written comments should be received in the SAB Executive Director's Office by May 11, 2011 to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after May 11, 2011, will be distributed to the SAB, but may not be reviewed prior to the meeting date.

Agenda

1. Recommendations on Coastal and Marine Spatial Planning from the Ecosystem Sciences and Management Working Group.

2. Discussion of a Revised Concept of Operations Document for SAB Working Groups and Task Forces.

Dated: April 11, 2011.

Mark E. Brown,

Chief Financial Officer/Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2011–9201 Filed 4–14–11; 8:45 am]

BILLING CODE 3510–KD–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the procurement list.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services from the Procurement List previously furnished by such agencies.

DATES: *Effective Date:* May 16, 2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, *Telephone:* (703) 603–7740, *Fax:* (703) 603–0655, or *e-mail CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 1/14/2011 (76 FR 2673–2674); 1/28/2011 (76 FR 5142–5143); 2/4/2011 (76 FR 6451–6452); and 2/11/2011 (76 FR 7824–7825), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN: 8465–00–NIB–0211—Pouch, Four 3-

round magazines, M26 12-guage shotgun MASS, Camouflage
NSN: 8465–00–NIB–0212—Pouch, Four 5-round magazines, M26 12-guage shotgun MASS, Camouflage
NSN: 8465–00–NIB–0213—Soft carrying case, Shotgun, 3-round magazine, M26 12-guage shotgun MASS, Camouflage
NSN: 8465–00–NIB–0214—Soft carrying case, Shotgun, 5-round magazine, M26 12-guage shotgun MASS, Camouflage
NPA: L.C. Industries for the Blind, Inc., Durham, NC
Contracting Activity: ARMY CONTRACTING COMMAND, PICATINNY ARSENAL, NJ
COVERAGE: C–List for 100% of the requirement of the Picatinny Arsenal as aggregated by the Department of the Army, Tank and Armament Command.

Services

Service Type/Location: Custodial Service, Donald J. Pease Federal Building, 143 West Liberty Street, Medina, OH
NPA: VGS, Inc., Cleveland, OH
Contracting Activity: GSA, PUBLIC BUILDINGS SERVICE, PROPERTY MANAGEMENT DIVISION, INDEPENDENCE, OH
Service Type/Location: Operations Support Service, Federal Energy Regulatory Commission (FERC), 888 First Street, NE., Washington, DC
NPAs: ServiceSource, Inc., Alexandria, VA (Prime Contractor), Sheltered Occupational Center of Northern Virginia, Inc., Arlington, VA (Subcontractor), Able Forces, Inc., Front Royal, VA (Subcontractor)
Contracting Activity: DEPARTMENT OF ENERGY, FEDERAL ENERGY REGULATORY COMMISSION, WASHINGTON, DC
Service Type/Location: Full Food Service, U.S. Military Academy Preparatory School, West Point, NY
NPA: New Dynamics Corporation, Middletown, NY
Contracting Activity: DEPT OF THE ARMY, XR W6BA ACA WEST POINT, WEST POINT NY

Deletions

On 2/4/2011 (76 FR 6451–6452) and 2/18/2011 (76 FR 9555), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

Cloth, Abrasive

NSN: 5350–00–229–3081
NPA: Louisiana Association for the Blind, Shreveport, LA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX

Portfolio

NSN: 7510–01–502–2918—16″ x 12″ x 4″
NPA: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY

Food Service Cleaner

NSN: 7930–01–512–7758
NPA: The Lighthouse for the Blind, St. Louis, MO
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FORT WORTH, TX

Services

Service Type/Locations: Janitorial/Custodial, Federal Service Center, 5600 Rickenbacker Road, Bell, CA
Social Security Administration Building, 230–244 Breed Street, Los Angeles, CA
NPA: Braswell Rehabilitation Institute for Development of Growth & Educational Services, Inc., Pomona, CA
Contracting Activity: GSA, PUBLIC BUILDINGS SERVICE, OFFICE OF PROPERTY MANAGEMENT, SAN FRANCISCO, CA

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2011–9206 Filed 4–14–11; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and a service previously furnished by such agencies.

Comments Must Be Received on or Before: 5/16/2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Kit, Wiring, ATON Buoy

NSN: 6150–01–040–6848.
NPA: Greenville Rehabilitation Center, Greenville, SC.
Contracting Activity: DEPT OF HOMELAND SECURITY, U.S. COAST GUARD, SFLC PROCUREMENT BRANCH 3, BALTIMORE, MD.
Coverage: C–List for 100% of the requirement of the U.S. Coast Guard, as aggregated by the U.S. Coast Guard.

Neckdam, Chemical, Protective, JPACE, CPC, JC3, Green

NSN: 8415–01–588–2047.
NPA: Peckham Vocational Industries, Inc., Lansing, MI.
Contracting Activity: DEPT OF THE ARMY, W6QK RDECOM CONTR CTR NATICK, MA.
Coverage: C–List for 100% of the requirement of the U.S Army, as aggregated by the Department of the Army Research, Development, & Engineering Command, Natick, MA.

Self-stick, Repositionable Flags

NSN: 7510–01–315–2019—1x1.75, Red.
NSN: 7510–01–315–2020—1x1.75, Green.
NSN: 7510–01–315–2021—1x1.75, Blue.
NSN: 7510–01–315–2022—1x1.75, White.
NSN: 7510–01–315–2023—1x1.75, Orange.
NSN: 7510–01–315–2024—1x1.75, Yellow.
NSN: 7510–01–315–8654—1x1.75, Purple.
NSN: 7510–01–399–1152—1x1.75, Bright Green.
NSN: 7510–01–399–1153—1x1.75, Bright Pink.
NPA: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY.
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY
Coverage: A–List for the Total Government Requirement as aggregated by the General Services Administration.

Army Retiring Soldier Kit

NSN: 9915–00–NSH–0002.
NPA: South Texas Housing and Community Development Corp., Inc., San Antonio, TX.
Contracting Activity: DEPT OF THE ARMY, MISSION & INSTALLATION. CONTRACTING COMMAND CENTER, FORT SAM HOUSTON, TX.
Coverage: C–List for 100% of the requirement of the Department of the Army, as aggregated by the Mission and Installation Contracting Command Center, Fort Sam Houston, TX.

Services

Service Type/Location: Mail Service, CDC Transshipping Facility, 3719 North Peachtree Rd., Atlanta, GA.
NPA: Tommy Nobis Enterprises, Inc., Marietta, GA.
Contracting Activity: DEPT OF HEALTH AND HUMAN SERVICES/CENTERS FOR DISEASE CONTROL, ATLANTA, GA.
Service Type/Location: Janitorial Service, Schofield Barracks Combat Arms Training and Maintenance Facility, Building SB 2225, Schofield Barracks, HI.
NPA: Opportunities and Resources, Inc., Wahiawa, HI.
Contracting Activity: DEPT OF THE NAVY, NAVFAC ENGINEERING COMMAND HAWAII, PEARL HARBOR, HI.
Service Type/Location: Facility Maintenance, US Military Academy Preparatory School, West Point, NY.
NPA: New Dynamics Corp., Middletown, NY.
Contracting Activity: DEPT OF THE ARMY, XR W6BA ACA WEST POINT, WEST POINT NY.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. If approved, the action may result in authorizing small entities to furnish the products and service to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for deletion from the Procurement List.

End of Certification

The following products and service are proposed for deletion from the Procurement List:

Products

Scarf, Branch of Service

NSN: 8455–00–405–2294.
NPA: Lions Industries for the Blind, Inc., Kinston, NC.
Contracting Activity: DEFENSE LOGISTICS AGENCY TROOP SUPPORT, PHILADELPHIA, PA.

Calendar Pad, Type 1, 2010

NSN: 7510–01–545–3774.
NPA: The Easter Seal Society of Western Pennsylvania, Pittsburgh, PA.
Contracting Activity: GENERAL SERVICES ADMINISTRATION, NEW YORK, NY.

Slacks, Woman's, Navy—Tropical Blue

NSN: 8410–01–377–9373.
NPAs: Knox County Association for Retarded Citizens, Inc., Vincennes, IN. VGS, Inc., Cleveland, OH.
Contracting Activity: DEFENSE LOGISTICS AGENCY TROOP SUPPORT, PHILADELPHIA, PA.

Services

Service Type/Location: Administrative/General Support Services, GSA: Various Field Offices, GSA Richmond Field Office, Richmond, VA.
NPA: Goodwill Services, Inc, Richmond, VA.
Contracting Activity: GSA/PUBLIC BUILDINGS SERVICE, R03, RICHMOND, VA.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2011–9207 Filed 4–14–11; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER Citation of Previous Announcement:

Vol. 76, No. 68, Friday, April 8, 2011, page 19752.

ANNOUNCED TIME AND DATE OF MEETING: Wednesday, April 13, 2011, 10 a.m.–11 a.m.

MATTER TO BE CONSIDERED: Decisional Matter: Toddler Beds—Final Rule Meeting Canceled.

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Todd A. Stevenson, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20814 (301) 504–7923.

Dated: April 12, 2011.

Todd A. Stevenson,

Secretary.

[FR Doc. 2011–9284 Filed 4–13–11; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Comment request.

SUMMARY: The Department of Education (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection

requirements and provide the requested data in the desired format. The Director, Information Collection Clearance Division, Information Management and Privacy Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before June 14, 2011.

ADDRESSES: Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov* or mailed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Please note that written comments received in response to this notice will be considered public records.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that Federal agencies provide interested parties an early opportunity to comment on information collection requests. The Director, Information Collection Clearance Division, Information Management and Privacy Services, Office of Management, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might

the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: April 12, 2011.

James Hyler,

Acting Director, Information Collection Clearance Division, Information Management and Privacy Services, Office of Management.

Federal Student Aid

Type of Review: New.

Title of Collection: Employment Certification for Public Service Loan Forgiveness.

OMB Control Number: 1845–NEW.

Agency Form Number(s): N/A.

Frequency of Responses: Annually.

Affected Public: Business and other for-profit; Individuals or households.

Total Estimated Number of Annual Responses: 2,073,643.

Total Estimated Number of Annual Burden Hours: 1,036,822.

Abstract: This form serves as the means by which eligible borrowers in the William D. Ford Federal Direct Loan Program indicate eligible employment for the purpose of final forgiveness under the Public Service Loan Forgiveness Program. The Department and its Direct Loan Program servicers will use the information collected on the Employment Certification for Public Service Loan Forgiveness form to determine whether a borrower has worked for a qualified employer during the certification period and whether payments made against a borrower's outstanding Direct Loan balance were qualifying payments for the purpose of the Public Service Loan Forgiveness Program.

Copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the "Browse Pending Collections" link and by clicking on link number 4563. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. Please specify the complete title of the information collection and OMB Control Number when making your request.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2011–9220 Filed 4–14–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Reopening of Scoping Period for the Northern Pass Transmission Line Project Environmental Impact Statement

AGENCY: Department of Energy.

ACTION: Reopening of scoping period.

SUMMARY: The U.S. Department of Energy (DOE) is reopening the public scoping period for the Northern Pass Transmission Line Project Environmental Impact Statement (EIS) (DOE/EIS–0463). The scoping period now ends on June 14, 2011.

DOE announced on February 11, 2011 (76 FR 7828), its intention to prepare an EIS to assess the potential environmental impacts from its proposal to grant a Presidential Permit to Northern Pass Transmission, LLC, to construct, operate, maintain, and connect a new electric transmission line across the U.S.-Canada border in northern New Hampshire. The EIS will address potential environmental impacts from the proposed action and the range of reasonable alternatives. The U.S. Forest Service, White Mountain National Forest, and the Army Corps of Engineers, New England District, are cooperating agencies.

DOE held seven public scoping meetings from March 14 to 20 in Pembroke, Franklin, Lincoln, Whitefield, Plymouth, Colebrook, and Haverhill, New Hampshire. The public scoping period closed on April 12, 2011. DOE is reopening the public scoping period in response to public requests and to ensure that the public has ample opportunity to provide comments.

DATES: The reopened public scoping period starts with the publication of this Notice in the **Federal Register** and will continue until June 14, 2011. Comments e-mailed or postmarked after this date will be considered to the extent practicable.

ADDRESSES: Comments on the scope of the EIS and requests to be added to the document mailing list should be addressed to: Brian Mills, Office of Electricity Delivery and Energy Reliability (OE–20), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; by electronic mail to *Brian.Mills@hq.doe.gov;* or by facsimile to 202–586–8008. For general information on the DOE NEPA process contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; by electronic mail at *askNEPA@hq.doe.gov;* or by facsimile at 202–586–7031.

FOR FURTHER INFORMATION CONTACT: For information on DOE's proposed action, contact Brian Mills by one of the methods listed in **ADDRESSES** above, or at 202–586–8267. For general information on the DOE NEPA process, contact Ms. Carol M. Borgstrom by one of the methods listed in **ADDRESSES** above, or at 202–586–4600, or leave a message at 800–472–2756. For information on the Forest Service's role as a cooperating agency, contact Tiffany Benna by electronic mail at *tbenna@fs.fed.us;* by phone at 603–536–6241; by facsimile at 603–536–3685; or by mail at 71 White Mountain Drive, Campton, NH 03223. For information on the Army Corps of Engineers' permit

process, contact Erika Mark at 978–318–8250; by electronic mail at *Erika.L.Mark@usace.army.mil;* or by mail at 696 Virginia Road, Concord, MA 01742. Information on the EIS also is available at DOE's website for the proposed action: *http://www.northernpasseis.us.*

Issued in Washington, DC, on April 12, 2011.

Anthony J. Como,

Director, Permitting and Siting Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2011–9161 Filed 4–14–11; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2011–0313; FRL–8869–4]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (*i.e.* a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish in the **Federal Register** a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish in the **Federal Register** periodic status reports on the new chemicals under review and the receipt of notices of commencement (NOC) to begin the manufacture of those chemicals. This document covers the period from October 11, 2010 to December 3, 2010, and provides the required notice and status report for the PMNs and TMEs, both pending or expired, and the NOCs to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

DATES: Comments identified by the specific PMN or TME number, must be received on or before May 16, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2011–0313, and the specific PMN number or TME number for the chemical related to your comment, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Bernice Mudd, Information Management Division, 7407M, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8951; fax number: (202) 564–8955; e-mail address: *mudd.bernice@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the particular PMN or TME addressed in this document. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information

claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Why is EPA taking this Action?

EPA classifies chemical substances as either "existing" chemicals or "new" chemicals. Any substance that is not on EPA's TSCA Chemical Substances Inventory, commonly referred to as the TSCA Inventory, is classified as a "new chemical," while those that are on the TSCA Inventory are classified as an "existing chemical." For more information about the TSCA Inventory go to: *http://www.epa.gov/opptintr/newchems/pubs/inventory.htm.* Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required by section 5 of TSCA to provide EPA with a premanufacture notice, or PMN, before initiating the activity. Section 5(h)(1) authorizes EPA to allow persons, upon application, to manufacture (includes import) or process a new chemical substance, or a chemical substance subject to a significant new use rule (SNUR) issued under TSCA section 5(a), for "test marketing" purposes, which is referred to as a test marketing exemption, or TME. For more information about the requirements applicable to a new chemical go to: *http://www.epa.gov/oppt/newchems/.*

Under TSCA sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish in the **Federal Register** a notice of receipt of a PMN or an application for a TME and to publish in the **Federal Register** periodic status reports on the new chemicals under review and the receipt of the NOCs to begin the manufacture of those chemicals. This document, covers the period from to October 11, 2010 to December 3, 2010, and provides the required notice and status report for the PMNs and TMEs, both pending or expired, and the NOCs to manufacture a new chemical that the Agency has received under TSCA section 5 during this time period.

III. Receipt and Status Reports

In Table I. of this Unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the PMNs received by EPA during this period: The EPA case number assigned to the PMN, the date the PMN was received by EPA, the projected end date for EPA's review of the PMN, the submitting manufacturer; the potential uses identified by the manufacturer/importer in the PMN, and the chemical identity.

TABLE I—75 PMNS RECEIVED FROM: 10/11/10 TO 12/03/10

Case No.	Received date	Projected notice end date	Manufacturer/ Importer	Use	Chemical
P–11–0016 ...	10/08/10	01/05/11	CBI	(G) Coating component	(G) Adipic acid, polymer with benzenepolycarboxylic acids, polyakylene glycol, alkanediols, 1,1′-methylenebis [isocyanatobenzene] and a substituted-, trialkoxysilane
P–11–0017 ...	10/12/10	01/09/11	CBI	(G) Automotive coatings	(G) Aromatic diacid, polymer with polyol, alkyl triol, alkyl alkanoate
P–11–0018 ...	10/12/10	01/09/11	CBI	(G) Resin component	(S) 1h-pyrrole-1-hexanoic acid, 2,5-dihydro-2,5-dioxo-*
P–11–0019 ...	10/13/10	01/10/11	CBI	(G) Reactant	(G) Mercapto silane ester of silica
P–11–0020 ...	10/12/10	01/09/11	CBI	(G) Petroleum additive	(G) Acylated alkenyl succinimide
P–11–0021 ...	10/12/10	01/09/11	Akzo Nobel Coatings Inc.	(S) Designated use of this polymer is for refinishing vehicles. Through the hydroxyl groups on the polymer, the coating is crosslinked with a polyisocyanate material will be atomized by spray application.	(G) The PMN substance (polymer is designated for use in coatings intended for us in refinishing vehicles. Through the hydroxyl group on the polymer, the coatings is crosslinked with polyisocyanate
P–11–0022 ...	10/12/10	01/09/11	Akzo Nobel Coatings Inc.	(S) Designated use of this polymer is for refinishing vehicles. Through the hydroxyl groups on the polymer, the coating is crosslinked with a polyisocyanate.	(G) Methacrylic acid polymer with isobornyl methacrylate sobornyl acrylate 2 hydrox
P–11–0023 ...	10/13/10	01/10/11	Omnova Solutions Inc.	(S) Intermediate in the production of functionalized polymers; surfactant, flow, leveling, and wetting additive for solvent borne coatings.	(G) Methacrylic acid polymer with isobornyl methacrylate sobornyl acrylate 2 hydrox
P–11–0024 ...	10/13/10	01/10/11	Omnova Solutions Inc.	(S) Intermediate in the production of functionalized polymers; surfactant, flow, leveling, and wetting additive for solvent borne coatings.	(G) Methacrylic acid polymer with isobornyl methacrylate sobornyl acrylate 2 hydrox

TABLE I—75 PMNS RECEIVED FROM: 10/11/10 TO 12/03/10—Continued

Case No.	Received date	Projected notice end date	Manufacturer/ Importer	Use	Chemical
P–11–0025 ...	10/13/10	01/10/11	Omnova Solutions Inc.	(S) Intermediate in the production of functionalized polymers; surfactant, flow, leveling, and wetting agent borne coatings.	(G) Methacrylic acid polymer with isobornyl methacrylate sobornyl acrylate 2 hydrox
P–11–0026 ...	10/13/10	01/10/11	Omnova Solutions Inc.	(S) Intermediate in the production of functionalized polymers; surfactant, flow, leveling, and wetting agent borne coatings.	(G) Methacrylic acid polymer with isobornyl methacrylate sobornyl acrylate 2 hydrox
P–11–0027 ...	10/18/10	01/15/11	CBI	(G) Material for electronic parts	(G) (Methoxymethyl) hydrocarbomonocycle
P–11–0028 ...	10/15/10	01/12/11	CBI	(S) Coatings for leather; water borne industrial coatings like wood.	(G) Hexamethylenediisocyanate hompolymer, alkoxy-terminated
P–11–0029 ...	10/19/10	01/16/11	Zeon Chemicals L.P.	(S) Dry etching agent for production of semiconductors; chemical vapor deposition (cvd) for production of semiconductors.	(S) Cyclopentene, 1,3,3,4,4,5,5-heptafluoro-*
P–11–0030 ...	10/19/10	01/16/11	CBI	(S) Flame-retardant coating for textiles.	(G) Waterborne polyurethane
P–11–0031 ...	10/19/10	01/16/11	CBI	(G) The substance is used to produce a component of polyurethane foam to insulate residential, commercial and industrial buildings. This application is contained and non-dispersive.	(G) Phenol, polymer with formaldehyde, reaction products with diethanolamine and alkylamine
P–11–0032 ...	10/19/10	01/16/11	Cognis Corporation	(S) Defoamer for industrial and institutional cleaning applications.	(S) Poly(oxy-1,2-ethanediyl), .alpha.-(2-ethylhexyl)-.omega.-[(2-hydroxydecyl)oxy]-*
P–11–0033 ...	10/18/10	01/15/11	CBI	(S) Hardener for epoxy resin laminating systems.	(S) Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol, reactions products with 1-piperazineethanamine*
P–11–0034 ...	10/18/10	01/15/11	CBI	(S) Hardener for epoxy resin laminating systems.	(S) Formaldehyde, polymer with .alpha.-(2-aminomethylethyl)-.omega.-(2-aminomethylethoxy]poly[oxy(methyl-1,2-ethandiyl)] and 4-(1,1-dimethylethyl)phenol.*
P–11–0035 ...	10/20/10	01/17/11	Huntsman Corporation	(S) Enhanced oil recovery	(G) Alkyl alkoxy sulfate sodium salt
P–11–0036 ...	10/20/10	01/17/11	Huntsman Corporation	(S) Enhanced oil recovery	(G) Alkyl alkoxy sulfate sodium salt
P–11–0037 ...	10/20/10	01/17/11	Huntsman Corporation	(S) Enhanced oil recovery	(G) Alkyl alkoxy sulfate sodium salt
P–11–0038 ...	10/21/10	01/18/11	Instrumental Polymer Technologies, LLC.	(S) Base polymer for coatings	(S) Carbonic acid, dimethyl ester, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol, cyclohexyl ester*
P–11–0039 ...	10/21/10	01/18/11	CBI	(G) Coating	(G) Silsesquioxanes, polyacrylate
P–11–0040 ...	10/22/10	01/19/11	CBI	(G) Component of lubricant.	(G) Lubricant ingredient
P–11–0041 ...	10/21/10	01/18/11	Dow Chemical Company.	(S) Production engineered lubricants for closed system use; greases; friction modifier for metalworking lubricants.	(G) Industrial lubricants
P–11–0042 ...	10/25/10	01/22/11	CBI	(S) Hardener for epoxy resin laminating systems.	(S) 1,2-ethanediamine, N_1,N_2-bis(2-aminoethyl)-, reaction products with bu glycidyl ether*
P–11–0043 ...	10/26/10	01/23/11	Gelest, Inc.	(S) Conversion to 1,1,3,3-tetramethyldisiloxane—see gls138; reducing agent for organic substrates, *e.g.* pharmaceutical synthesis.	(S) Disiloxane, 1-butyl-1,1,3,3-tetramethyl-*
P–11–0044 ...	10/26/10	01/23/11	Gelest, Inc.	(S) End-capper for silicones; research.	(S) Disiloxane, 1,3-dibutyl-1,1,3,3-tetramethyl-*
P–11–0045 ...	10/26/10	01/23/11	Gelest, Inc.	(S) Oxygen permeable component of contact lens formulation; research.	(S) Pentasiloxane, 1-butyl-1,1,3,3,5,5,7,7,9,9-decamethyl-*
P–11–0046 ...	10/26/10	01/23/11	Gelest, Inc.	(S) Conversion to hydrophobic substrates; research.	(S) Siloxanes and silicones, di-me, bu group- and hydrogen-terminated *
P–11–0047 ...	10/22/10	01/19/11	Akzo Nobel Surface Chemistry LLC.	(G) Friction modifier	(G) *N,N*-di(hydrogenated tallakyls)-1,3-propanediamine

TABLE I—75 PMNS RECEIVED FROM: 10/11/10 TO 12/03/10—Continued

Case No.	Received date	Projected notice end date	Manufacturer/ Importer	Use	Chemical
P–11–0048 ...	10/27/10	01/24/11	CBI	(G) Open, non-dispersive textile finish.	(G) Modified fluorinated urethane
P–11–0049 ...	10/27/10	01/24/11	Thor Specialties, Inc.	(G) Flame retardant for incorporation into polymer resins (open non-dispersive use).	(G) Organic-*N,P*-compound
P–11–0050 ...	10/27/10	01/24/11	Thor Specialties, Inc.	(G) Flame retardant for incorporation into polymer resins (open non-dispersive use).	(G) Organic-*N,P*-compound
P–11–0051 ...	10/28/10	01/25/11	CBI	(S) Flow modifier for aqueous cleaning solutions; flow modifier for aqueous dispersions	(G) Amino methacrylate copolymer
P–11–0052 ...	11/01/10	01/29/11	Piedmont Chemical Industries I, LLC.	(S) Uv curable inks	(S) Fatty acids, C_{18}-unsaturated, dimers, hydrogenated, esters with pentaerythritol acrylate *
P–11–0053 ...	11/03/10	01/31/11	CBI	(G) Automotive coating	(G) Substituted alkanoic acid, polymer with alkanediol and cyclic ether, alkanoate
P–11–0054 ...	11/03/10	01/31/11	Mane, USA	(G) Perfumery ingredient	(S) 2*H*-pyran-4-ol, 2-(1-ethylpropyl) tetrahydro-4-methyl
P–11–0055 ...	11/02/10	01/30/11	Forbo Adhesives, LLC	(G) Hot melt polyurethane purge	(G) Polyester urethane polymer
P–11–0056 ...	11/03/10	01/31/11	CBI	(S) Acylic resin used in uv curable inks and coatings.	(G) Aliphatic urethane acrylate polymer
P–11–0057 ...	11/03/10	01/31/11	CBI	(S) Acrylic resin used in uv curable inks and coatings.	(G) Aliphatic urethane acrylate polymer
P–11–0058 ...	11/02/10	01/30/11	CBI	(G) Catalyst ingredient	(G) Aromatic diol, diaryl carboxylate
P–11–0059 ...	11/04/10	02/01/11	CBI	(G) Ingredient in paint. Degree of containment: highly dispersive use.	(G) Trialkylsilyl acrylate copolymer
P–11–0060 ...	11/04/10	02/01/11	CBI	(G) Adhesive system component	(G) Methylenebis [isocyanatobenzene], polymer with alkanedioic acid, alkylene glycols, alkoxylated alkanepolyol and substituted trialkoxysilane
P–11–0061 ...	11/05/10	02/02/11	Huntsman Textile Effects.	(S) Exhaust dyeing cotton fabrics	(G) Reaction product of substituted naphthalenesulfonic acid diazotized and couple with substituted triazine and substituted naphthalenesulfonic acid alkyl amino phenyl compound
P–11–0062 ...	11/05/10	02/02/11	CBI	(G) Gear oil additive	(G) Carbomonocyclic alkene polymer with alkyl alkenoate, polyalkylidene alkenoate and dialkylaminoalkyl alkenamide
P–11–0063 ...	11/08/10	02/05/11	CBI	(S) Coating material for use in textile and/or paper.	(G) Perfluoroalkyl acrylate copolymer
P–11–0064 ...	11/08/10	02/05/11	Isola Group	(G) Homide 108 is one of the monomers in the resin polymerization.	(G) *N*-(2,6-xylyl) maleimide
P–11–0065 ...	11/09/10	02/06/11	CBI	(G) Intermediate	(G) Alkyl methacrylate
P–11–0066 ...	11/09/10	02/06/11	CBI	(G) Additive in transmission fluids ...	(G) Acrylic polymer
P–11–0067 ...	11/09/10	02/06/11	CBI	(G) Additive in transmission fluids ...	(G) Acrylic polymer
P–11–0068 ...	11/12/10	02/09/11	CBI	(G) Polymeric dye carrier	(G) Polyester polyamide
P–11–0069 ...	11/12/10	02/09/11	CBI	(S) Crosslinker for polymers	(G) Dispersible isocyanate crosslinker
P–11–0070 ...	11/05/10	02/02/11	Starfire Systems, Inc.	(S) Precurser for producing silicon oxycarbide ceramics.	(G) Alkyl siloxane polymer
P–11–0071 ...	11/05/10	02/02/11	Starfire Systems, Inc.	(S) High temperature resistant adhesive; ceramic matrix composites; polymer matrix composits.	(G) Alkyl siloxane polymer
P–11–0072 ...	11/15/10	02/12/11	Cognis Corporation	(G) The formulated pmn substance will be imported for use as a lubricant oil for gear boxes.	(S) Decanedioic acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol, isooctadecanoate *
P–11–0073 ...	11/12/10	02/09/11	Huntsman Corporation	(S) Intermediate for enhanced oil recovery surfactants.	(G) Alkylxylene
P–11–0074 ...	11/19/10	02/16/11	CBI	(S) A component in ultraviolet light/electron beam curable formulations.	(G) Glyceryl polypropylene glycol ether polymer with isophorone diisocyanate, methacrylate blocked
P–11–0075 ...	11/19/10	02/16/11	CBI	(G) For use in the manufacture of paper.	(G) Polyphenolic condensation polymer

TABLE I—75 PMNS RECEIVED FROM: 10/11/10 TO 12/03/10—Continued

Case No.	Received date	Projected notice end date	Manufacturer/ Importer	Use	Chemical
P–11–0076 ...	11/22/10	02/19/11	CBI	(S) Pigment dispersant for use in water-based coating.	(G) Polyurethane derivative
P–11–0077 ...	11/23/10	02/20/11	CBI	(G) Printing additive	(G) Benzenedicarboxylic acid, polymer with 1,4-butanediol, (2e)-2-butenedioic acid, decanedioic acid, ethenylbenzene, 2-ethylhexyl 2-propenoate, hexanedioic acid, 1,6-hexane derivatives and 2-propenoic acid, tert-bu peroxide-initiated
P–11–0078 ...	11/24/10	02/21/11	Shin-etsu Silicones of America Inc.	(S) Treatment from textile; fabric softener.	(S) Siloxanes and silicones, dimethyl, hydroxy terminated, reaction products with *N*-[3-(dimethoxymethylsilyl)propyl]-1,2-ethanediamine *
P–11–0079 ...	11/30/10	02/27/11	H.B. Fuller	(G) Industrial adhesive	(G) Polyester, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane
P–11–0080 ...	11/30/10	02/27/11	CBI	(G) Component of a floor coating	(G) Urethane acrylate
P–11–0081 ...	11/30/10	02/27/11	K+S North America	(S) Intermediate to be used in the production of 1h-pyrazole, 3,4-dimethyl-, phosphate, a fertilizer additive.	(S) 3,4-dimethyl-1H-pyrazole *
P–11–0082 ...	11/30/10	02/27/11	CBI	(G) Personal care, industrial & household hygiene, floucculants, specialty coatings.	(G) Styrene-acrylate copolymer
P–11–0083 ...	12/02/10	03/01/11	Huntsman Textile Effects.	(S) Exhaust dyeing cotton fabrics	(G) Reaction product of substituted naphthalenesulfonic acid and substituted benzenesulfonic acid diazotized and coupled with alkyl benzene substituted triazine amino phenyl compound
P–11–0084 ...	12/01/10	02/28/11	CBI	(G) Encapsulated for electronic parts.	(G) Epoxylated nitrile rubber
P–11–0085 ...	12/03/10	03/02/11	CBI	(G) Chemical reagent for industrial syntheses.	(G) Polyfluoroalkylpropionic acid ethyl ester
P–11–0086 ...	12/03/10	03/02/11	CBI	(G) Chemical reagent for industrial syntheses.	(G) Polyfluoroalkyl phosphoric acid
P–11–0087 ...	12/03/10	03/02/11	CBI	(G) Chemical processing aid	(G) Polyfluoroalkyl phosphoric acid salt, aqueous solution
P–11–0088 ...	12/03/10	03/02/11	CBI	(G) Chemical processing aid	(G) Polyfluoroalkyl phosphoric acid salt, aqueous solution
P–11–0089 ...	12/03/10	03/02/11	CBI	(G) Chemical processing aid	(G) Polyfluoroalkyl phosphoric acid salt, aqueous solution
P–11–0090 ...	12/03/10	03/02/11	CBI	(G) Chemical intermediate	(G) Heteroaromatic compound

In Table II. of this Unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the TMEs received by EPA during this period: The EPA case number assigned to the TME, the date the TME was received by EPA, the projected end date for EPA's review of the TME, the submitting manufacturer/ importer, the potential uses identified by the manufacturer/importer in the TME, and the chemical identity.

TABLE II—05 TMES RECEIVED FROM: 10/18/10 TO 12/03/10

Case No.	Received date	Projected notice end date	Manufacturer/importer	Use	Chemical
T–11–0002 ...	12/13/10	01/26/11	Cytec Industries Inc. ...	(S) Dispersing additive for organic and inorganic pigments and extenders.	(G) Substituted alkanoic acid, polymer with alkanoic acid alkyl esters, with substituted polyglycol-initiated.

TABLE II—05 TMES RECEIVED FROM: 10/18/10 TO 12/03/10—Continued

Case No.	Received date	Projected notice end date	Manufacturer/importer	Use	Chemical
T–11–0003 ...	12/13/10	01/26/11	Cytec Industries Inc. ...	(G) Coatings resin	(G) Substituted alkyl homopolymer, substituted alkylacrylate and heteromonocyclic homopolymer monoester with substituted alkylacrylate.
T–11–0004 ...	12/13/10	01/26/11	CBI	(G) Inhibitor for oil field applications	(G) Tertiary ammonium compound.
T–11–0005 ...	12/14/10	01/27/11	Cytec Industries Inc. ...	(G) Binder resin	(G) Modified epoxy resin.
T–11–0006 ...	01/11/11	02/24/11	CBI	(G) Inhibitor for oil field applications	(G) Tertiary ammonium compound.

In Table III. of this Unit, EPA provides the following information (to the extent that such information is not claimed as CBI) on the NOCs received by EPA during this period: The EPA case number assigned to the NOC, the date the NOC was received by EPA, the projected end date for EPA's review of the NOC, and the chemical identity.

TABLE III—37 NOCS RECEIVED FROM: 10/11/10 TO 12/3/10

Case No.	Received date	Commencement notice end date	Chemical
J–09–0004	10/21/10	06/30/10	(G) Contained use of a genetically modified microorganism trichoderma reesei.
J–10–0002	10/20/10	10/18/10	(G) Carbohydrase.
J–10–0003	10/20/10	10/15/10	(G) T. Reesei 3408.
P–05–0145	11/01/10	10/21/05	(G) Polyether polyol.
P–05–0297	01/07/11	12/02/10	(G) Aqueous polyurethane dispersion.
P–05–0400	12/20/10	01/10/06	(S) 1-butanone, 3-(dodecylthio)-1-(2,6,6-trimethyl-3-cyclohexen-1-yl)-*.
P–05–0526	11/10/10	10/24/10	(G) Polyurethane resin.
P–05–0840	01/24/11	12/22/10	(G) Polycarbonate polyurethane.
P–05–0842	01/24/11	12/22/10	(G) Polycarbonate polyurethane.
P–05–0843	01/24/11	12/22/10	(G) Polycarbonate polyurethane.
P–06–0450	12/13/10	11/18/10	(S) Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propenyl)-.omega.-hydroxy-, c12–15-alkyl ethers*.
P–06–0451	12/13/10	11/12/10	(S) Poly(oxy-1,2-ethanediyl), .alpha.-(2-methyl-2-propenyl)-.omega.-hydroxy-, c10–16-alkyl ethers*.
P–06–0618	11/01/10	10/20/10	(G) Salts of modified tall-oil fatty acid amidoamines.
P–06–0619	11/01/10	10/20/10	(G) Salts of modified tall-oil fatty acids.
P–07–0353	10/07/10	08/28/10	(G) Alkyl acid fluoride.
P–07–0719	11/30/10	11/03/10	(S) Benzeneacetonitrile, .alpha.-butylidene-, (.alpha. z)-*.
P–08–0273	12/21/10	12/10/10	(G) Alkyl silyl phosphonate.
P–08–0299	12/20/10	12/15/10	(S) Propanol, 1(or 2)-(methyl-2-[(1,7,7-trimethylbicyclo[2.2.1]hept-2-yl)oxy]ethoxy]-*.
P–08–0376	10/12/10	10/06/10	(G) Arylalkylamine, *N*-[4-[2-(substitutedaryl)diazenyl]aryl]-*N*-alkyl.
P–08–0401	01/04/11	12/16/10	(G) Polyether modified fatty acid dimer.
P–08–0422	01/04/11	12/16/10	(G) Potassium polystyrene maleate.
P–08–0486	10/05/10	09/17/10	(G) Polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)], 3-hydroxy-2-(hydroxymethyl)-2-methylpropanoic acid and alkyldiisocyanate, ammonium salt.
P–08–0502	01/12/11	12/16/10	(G) Cyclic guanidine.
P–08–0537	11/23/10	11/01/10	(G) Comple keto-amine.
P–08–0550	11/29/10	11/20/10	(S) 1-propene, 1,3,3,3-tetrafluoro-, (1e)-*.
P–08–0643	12/30/10	12/17/10	(G) Fluorinated acrylic copolymer.
P–09–0083	10/04/10	09/03/10	(G) Cationic polyamide.
P–09–0131	11/23/10	11/11/10	(G) Aromatic carboxylic acid.
P–09–0146	10/01/10	09/28/10	(S) Formaldehyde, polymers with acetone-phenol reaction products and phenol, sodium salts*.
P–09–0363	11/12/10	10/28/10	(G) Polyalkenyl derives. of aliphatic dicarboxylic anhydride, imides with melamine.
P–09–0364	11/12/10	10/28/10	(G) Alkenoic acid, polymer with alkyl alkenoates, sodium salt.
P–09–0382	11/30/10	11/09/10	(S) Iron, citrate phosphate potassium complexes*.
P–09–0416	11/30/10	11/26/10	(G) 3'*H*-cyclopropacarbopolycycle-3'-butanoic acid, 3'-phenyl-, methyl ester; 3'*H*-cyclopropacarbopolycycle-3'-butanoic acid, 3'-phenyl-, methyl ester.
P–09–0430	10/04/10	09/14/10	(G) Polymeric monoazo compound.
P–09–0431	10/04/10	09/14/10	(G) Polymeric monoazo compound.
P–09–0432	10/04/10	09/14/10	(G) Polymeric monoazo triphenylmethane.
P–09–0433	10/04/10	09/14/10	(G) Polymeric triphenylmethane.

If you are interested in information that is not included in these tables, you may contact the person listed under **FOR FURTHER INFORMATION CONTACT** to access additional non-CBI information that may be available.

List of Subjects

Environmental protection, Chemicals, Hazardous substances, Imports, Notice of commencement, Premanufacturer, Reporting and recordkeeping requirements, Test marketing exemptions.

Dated: April 4, 2011.

Darryl S. Ballard,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2011–8574 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8996–4]

Environmental Impacts Statements;

Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–1399 or *http://www.epa.gov/compliance/nepa/*

Weekly receipt of Environmental Impact Statements

Filed 04/04/2011 Through 04/08/2011

Pursuant to 40 CFR 1506.9.

Notice

In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has included its comment letters on EISs on its Web site at: *http://www.epa.gov/compliance/nepa/eisdata.html.* Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20110108, Draft EIS, USFS, OR, Kapka Butte Sno-Park Project, Proposal to Build a New Sno-Park to Provide more High-Elevation Parking for Winter Recreationist, Bend-Ft. Rock Ranger District, Deschutes National Forest, Deschutes County, OR, *Comment Period Ends:* 05/30/2011, *Contact:* Beth Peer 541–383–4769.

EIS No. 20110109, Draft EIS, USFS, OR, Snow Basin Vegetation Management Project, Proposal to Implementing Commercial Harvest of Timber, Post Harvest Non-Commercial Thinning, Whitman Ranger District, Wallowa-Whitman Forest, Baker County, OR, *Comment Period Ends:* 05/30/2011, *Contact:* Dea Nelson 541–523–1316.

EIS No. 20110110, Draft EIS, RUS, GA, Biomass Power Plant Project, Application for Financial Assistance to Construction 100 Megawatt (MW) Biomass Plant and Related Facilities, Warren County, GA, *Comment Period Ends:* 05/31/2011, *Contact:* Stephanie A. Strength 970–403–3559.

EIS No. 20110111, Draft EIS, FERC, WA, Wells Hydroelectric Project, Application to Relicense, Public Utility District No. 1 Columbia River near Pateros and Brewster in Douglas, Okanogan, and Chelan Counties, WA, *Comment Period Ends:* 05/30/2011, *Contact:* Mary O'Driscoll 1–866–208–3372.

EIS No. 20110112, Draft EIS, BLM, NM, HB In-Situ-Solution Mining Project, Proposal to Extract the Potash Remaining in Inactive Underground Mine, Eddy County, NM, *Comment Period Ends:* 06/13/2011, *Contact:* David Alderman 575–234–6232.

EIS No. 20110113, Final EIS, FHWA, MI, M–15 Reconstruction, I–75 to I–69, Funding and NPDES and U.S. Army COE Section 404 Permits Issuance, Oakland and Genesee Counties, MI, *Review Period Ends:* 05/16/2011, *Contact:* David T.Williams 517–702–1820.

EIS No. 20110114, Draft EIS, FERC, WA, Boundary Hydroelectric Project, Application for Hydroelectric License, FERC Project No. 2144–038 and Sullivan Creek Project, Application for Surrender of Hydropower FERC Project No. 2225–015, Pend Oreille County, WA, *Comment Period Ends:* 05/30/2011, *Contact:* Mary O'Driscoll 1–866–208–3372.

EIS No. 20110115, Final EIS, BLM, NV, Genesis Project, Proposes Expansion of Existing Mine Pits and Development of the Bluestar Ridge Open Pit Mine, Newmont Mining Corporation, Eureka County, NV, *Review Period Ends:* 05/09/2011, *Contact:* Kirk Laird 775–753–0272.

EIS No. 20110116, Draft EIS, NOAA, 00, Amendment 10 to the Fishery Management Plan for Spiny Lobster, Establish Annual Catch Limits and Accountability Measures for Caribbean Spiny Lobster, Gulf of Mexico and South Atlantic Regions, *Comment Period Ends:* 06/01/2011, *Contact:* Roy E. Crabtree, PhD 727–824–5701.

EIS No. 20110117, Final EIS, BLM, CA, First Solar Desert Sunlight Solar Farm (DSSF) Project, Proposing To Develop a 550–Megawatt Photovoltaic Solar Project, Also Proposes to Facilitate the Construction and Operation of the Red Bluff Substation, California Desert Conservation Area (CDCA) Plan, Riverside County, CA, *Review Period Ends:* 05/09/2011, *Contact:* Allison Shaffer 760–833–7104.

EIS No. 20110118, Final EIS, DOI, WA, Cle Elum Dam Fish Passage Facilities and Fish Reintroduction Project, To Restore Connectivity, Biodiversity, and Natural Production of Anadromous Salmonids, Kittitas County, WA, *Review Period Ends:* 05/08/2011, *Contact:* Jim Taylor 208–378–5081.

EIS No. 20110119, Final EIS, USFS, CA, Kings River Experimental Watershed Forest Health and Research Project, Implementation, Sierra National Forest, High Sierra Ranger District, Fresno County, CA, *Review Period Ends:* 05/09/2011, *Contact:* Judi Tapia 559–297–0706 Ext. 4938.

Amended Notices

EIS No. 20100118, Draft EIS, USACE, KY, Withdrawn—East Kentucky Power Cooperative, Proposed Baseload Power Plant, to Constructing and Operating a 278 Megawatt Circulating Fluidized Bed Electric Generating Unit (CFD), and Associated Infrastructure at the Existing J.K. Smith Power Station, Application for US Army COE Section 10 and 404 Permits, Clark County, KY, *Comment Period Ends:* 05/24/2010, *Contact:* Michael Hasty 502–315–6676. Revision to FR Notice Published: Officially Withdrawn by the Preparing Agency by letter dated 04/05/2011.

Dated: April 12, 2011.

Aimee S. Hessert,

Deputy Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2011–9185 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9296–2]

Science Advisory Board Staff Office; Notification of Two Public Teleconferences of the Clean Air Scientific Advisory Committee (CASAC) Air Monitoring and Methods Subcommittee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) Science

Advisory Board (SAB) Staff Office announces two public teleconference calls of the Clean Air Scientific Advisory Committee (CASAC) Air Monitoring and Methods Subcommittee (AMMS) to provide advice on EPA's draft plans for Photochemical Assessment Monitoring Stations (PAMS) Network Re-engineering.

DATES: Two public teleconference calls will be held on Monday, May 16, 2011 from 12:30 p.m. to 4:30 p.m. and on Tuesday, May 17, 2011 from 12:30 p.m. to 4:30 p.m. (Eastern Time).

ADDRESSES: The public teleconferences will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and public teleconference may contact Mr. Edward Hanlon, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–2134; by fax at (202) 565–2098 or via e-mail at *hanlon.edward@epa.gov.* General information concerning the EPA CASAC can be found at the EPA CASAC Web site at *http://www.epa.gov/casac.* Any inquiry regarding EPA's PAMS Network Re-engineering Project should be directed to Mr. Kevin Cavender, EPA Office of Air Quality Planning and Standards (OAQPS), at *cavender.kevin@epa.gov* or 919–541–2364.

SUPPLEMENTARY INFORMATION:

Background: The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409D(d)(2), to provide advice, information, and recommendations to the Administrator on the scientific and technical aspects of issues related to the criteria for air quality standards, research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. Pursuant to FACA and EPA policy, notice is hereby given that the CASAC AMMS will hold two public teleconference calls to provide advice on EPA's draft plans for PAMS Network Re-engineering. EPA's Office of Air and Radiation (OAR) designed the PAMS network in the 1990s to provide comprehensive monitoring data in areas not in attainment for ozone. The PAMs network monitors for ozone and its precursors, such as oxides of nitrogen and volatile organic compounds and tracks progress for ozone control strategies. Since the promulgation of the PAMS network, there have been changes to the ozone National Ambient Air Quality Standards (NAAQS) including a shift from a 1-hour averaging time to an 8-hour averaging time, as well as changes in the ozone standard. EPA is planning an in-depth review of the PAMS requirements in the context of the revised NAAQS, improvements in monitoring technology, and changes in emissions of ozone precursors that have all occurred over the past 10–15 years. OAR requested CASAC advice on potential revisions to the scientific and technical aspects of EPA's PAMS program, including changes to required measurements and associated network design requirements, technology, sampling frequency, and overall program objectives in the context of the most recently revised ozone NAAQS.

Availability of Meeting Materials: The agenda and materials in support of these teleconference calls will be placed on the EPA CASAC Web site at *http://www.epa.gov/casac* in advance of the teleconference calls.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for CASAC to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the Designated Federal Officer for the relevant advisory committee directly.

Oral Statements: In general, individuals or groups requesting an oral presentation at this public teleconference will be limited to three minutes per speaker. Interested parties should contact Mr. Edward Hanlon, DFO, in writing (preferably via e-mail), at the contact information noted above, by May 9, 2011 to be placed on the list of public speakers for the teleconference. *Written Statements:* Written statements should be received in the SAB Staff Office by May 9, 2011 so that the information may be made available to the Panel for their consideration. Written statements should be supplied to the DFO in electronic format via e-mail (acceptable file formats: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format). It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Edward Hanlon at the phone number or e-mail address noted above, preferably at least ten days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: March 28, 2011.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2011–9198 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9296–3]

Science Advisory Board Staff Office, Notification of a Public Teleconference of the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces a public teleconference of the Clean Air Scientific Advisory Committee (CASAC) Lead Review Panel to provide consultative advice on EPA's draft *Integrated Review Plan for the National Ambient Air Quality Standards for Lead* (draft IRP).

DATES: The public teleconference will be held on Thursday, May 5, 2011 from 1 p.m. to 5 p.m. (Eastern Time).

Location: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain information concerning the public

meeting may contact Mr. Aaron Yeow, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by telephone/voice mail at (202) 564–2050 or at *yeow.aaron@epa.gov*. General information about the CASAC, as well as any updates concerning the meeting announced in this notice, may be found on the EPA Web site at *http://www.epa.gov/casac*.

SUPPLEMENTARY INFORMATION: *Background:* The CASAC was established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409D(d)(2), to provide advice, information, and recommendations to the Administrator on the scientific and technical aspects of issues related to the criteria for air quality standards, research related to air quality, sources of air pollution, and the strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality. The CASAC is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2. Pursuant to FACA and EPA policy, notice is hereby given that the CASAC Lead Review Panel will hold a public meeting to provide consultative advice on EPA's draft *Integrated Review Plan for the National Ambient Air Quality Standards for Lead.* The CASAC Lead Review Panel and the CASAC will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the National Ambient Air Quality Standards (NAAQS) for the six "criteria" air pollutants, including lead. EPA is currently reviewing the primary (health-based) and secondary (welfare-based) NAAQS for lead. Accordingly, the SAB Staff Office solicited nominations for the CASAC Lead Review Panel on October 28, 2009 (74 FR 55548–55549). Membership of the Panel is listed at *http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees Subcommittees/CASAC%20Lead%20Review%20Panel%20%282010–2013%29*.

EPA's Integrated Review Plan (IRP) will serve as the framework for its review of the lead NAAQS. The draft IRP presents the current plan and specifies the schedule for the entire review, the process for conducting the review, and the key policy-relevant science issues that will guide the review. The draft document also describes the different phases of the review, including the science assessment, risk/exposure assessment, and policy assessment/rulemaking, for which EPA will prepare documents which will be submitted for later CASAC review and public comment. The purpose of this teleconference is for the CASAC Panel to provide consultative advice on the draft *Integrated Review Plan for the National Ambient Air Quality Standards for Lead.*

Availability of Meeting Materials: Agendas and materials in support of this meeting will be placed on the EPA Web site at *http://www.epa.gov/casac* in advance of the meeting. For technical questions and information concerning the review materials please contact Dr. Deirdre Murphy of EPA's Office of Air and Radiation at (919) 541–0729, or *murphy.deirdre@epa.gov*.

Procedures for Providing Public Input: Public comment for consideration by EPA's federal advisory committees and panels has a different purpose from public comment provided to EPA program offices. Therefore, the process for submitting comments to a federal advisory committee is different from the process used to submit comments to an EPA program office.

Federal advisory committees and panels, including scientific advisory committees, provide independent advice to EPA. Members of the public can submit comments for a federal advisory committee to consider as it develops advice for EPA. Input from the public to the CASAC will have the most impact if it provides specific scientific or technical information or analysis for CASAC panels to consider or if it relates to the clarity or accuracy of the technical information. Members of the public wishing to provide comment should contact the Designated Federal Officer directly. *Oral Statements:* In general, individuals or groups requesting an oral presentation at a teleconference will be limited to three minutes. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Interested parties should contact Mr. Aaron Yeow, DFO, in writing (preferably via e-mail) at the contact information noted above by April 28, 2011 for the teleconference, to be placed on the list of public speakers. *Written Statements:* Written statements should be supplied to the DFO via email at the contact information noted above by April 28, 2011 for the teleconference so that the information may be made available to the Panel members for their consideration. Written statements should be supplied in one of the following electronic formats: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format. It is the SAB Staff Office general policy to post written comments on the Web page for the advisory meeting or teleconference. Submitters are requested to provide an unsigned version of each document because the SAB Staff Office does not publish documents with signatures on its Web sites. Members of the public should be aware that their personal contact information, if included in any written comments, may be posted to the SAB Web site. Copyrighted material will not be posted without explicit permission of the copyright holder.

Accessibility: For information on access or services for individuals with disabilities, please contact Mr. Aaron Yeow at (202) 564–2050 or *yeow.aaron@epa.gov*. To request accommodation of a disability, please contact Mr. Yeow preferably at least ten days prior to each meeting to give EPA as much time as possible to process your request.

Dated: March 31, 2011.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2011–9211 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–1046; FRL–8869–9]

Proposed Pesticide Program's Pilot Fragrance Notification Program; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA's Office of Pesticide Programs (OPP) is publishing for comment a proposed Pilot Fragrance Notification Program (PFNP) for registrants seeking to add new or modify existing fragrances in new or currently registered pesticide products. The Agency intends to implement the proposed PFNP for two years as a process improvement effort to streamline the current 90–day process used to amend registrations to a 30–day notification process when fragrance ingredients are added, removed, or modified.

DATES: Comments must be received on or before May 16, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–1046, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–1046. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: SanYvette Williams, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7702; fax number: (703) 305–7484; e-mail address: *williams.sanyvette@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are a registrant wishing to add or modify fragrances in registered products or fragrance suppliers. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What action is the agency taking?

The Agency is taking this action as a follow up to the 2007 Fragrance Notification Pilot Program and it is very similar in conduct. The proposed PFNP incorporates the ability to self certify and rely on the Fragrance Ingredient List (FIL). The FIL is comprised of more than 1,500 fragrance component ingredients contained in pesticide products previously reviewed and registered by the Agency and have undergone an evaluation to determine their suitability for safe use as components of fragrances used in nonfood use pesticide product formulations. Only fragrances in which all of the components in the fragrance are on the FIL are eligible to participate in the proposed PFNP.

The objectives of the current pilot are to improve public transparency, reduce the amount of paperwork required of registrants and decrease tracking. The number of fragrance documents needing to be tracked would be decreased because they would be submitted twice a year versus with every application. These efficiencies will allow resources to be focused on other regulatory work without compromise to public health or the environment.

This is a voluntary program where interested entities have an opportunity to participate. The Agency is publishing this for comment by registrants as part of process improvement. Comments on the proposed process for this pilot are welcomed.

List of Subjects

Environmental protection.

Dated: April 8, 2011.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2011–9190 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9296–4]

Science Advisory Board Staff Office; Request for Nominations of Candidates to the EPA's Advisory Council on Clean Air Compliance Analysis (Council) EPA's Clean Air Scientific Advisory Committee (CASAC) and EPA's Science Advisory Board (SAB)

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations of scientific experts from a diverse range of disciplinary areas to be considered for appointment to the Advisory Council on Clean Air Compliance Analysis (Council), Clean Air Scientific Advisory Committee (CASAC), the Science Advisory Board (SAB), or SAB Committees described in this notice. Appointments are anticipated to be filled by the start of Fiscal Year 2012. Sources in addition to this **Federal Register** Notice may also be utilized in the solicitation of nominees.

DATES: Nominations should be submitted in time to arrive no later than May 16, 2011.

FOR FURTHER INFORMATION CONTACT: Nominators unable to submit nominations electronically as described below may submit a paper copy by the Designated Federal Officers for the committees, as identified below. General inquiries regarding the work of the Council, CASAC and SAB or SAB Standing Committees may also be directed to them.

Background: Established by statute, the Council (42 U.S.C 7612), the CASAC (42 U.S.C. 7409), and SAB (42 U.S.C. 4365) are EPA's chartered Federal Advisory Committees that provide independent scientific and technical peer review, consultation, advice and recommendations directly to the EPA Administrator the scientific bases for EPA's actions and programs. As Federal Advisory Committees, the Council, CASAC, and SAB conduct business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. Generally, Council, CASAC and SAB meetings are announced in the **Federal Register**, conducted in public view, and provide opportunities for public input during deliberations. Additional information about these Federal Advisory Committees may be found at *http://www.epa.gov/advisorycouncilcaa, http://www.epa.gov/casac* and *http://www.epa.gov/sab,* respectively.

Members of the Council, CASAC, and the SAB, constitute a distinguished body of non-EPA scientists, engineers, economists, and social scientists that are nationally and internationally recognized experts in their respective fields. Members are appointed by the EPA Administrator for a period of three years. This notice specifically requests nominations for the Council, CASAC, the SAB, and SAB Committees from academia, industry, state, and tribal governments, research institutes, and non-governmental organizations throughout the United States.

Expertise Sought: The Council was established in 1990 pursuant to the Clean Air Act (CAA) Amendments of 1990 to provide advice and recommendations to the EPA Administrator on technical and economic aspects of the impacts of the Clean Air Act (CAA) on the public health, economy, and environment of the United States. The SAB Staff office is seeking nominations for individuals to serve on the Council with demonstrated expertise in air pollution issues. A nominee's expertise may include the following disciplines: *Environmental economics; economic modeling; air quality modeling; atmospheric science and engineering; epidemiology; statistics, and human health risk assessment.* For further information on the Council, please contact Ms. Stephanie Sanzone, DFO, by telephone at 202–564–2067 or by e-mail at *sanzone.stephanie@epa.gov.*

Established in 1977 under the Clean Air Act (CAA) Amendments, the chartered CASAC reviews and offers scientific advice to the EPA Administrator on technical aspects of national ambient air quality standards for criteria pollutants. As required under the CAA section 109(d), CASAC will be composed of seven members, with at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies. The SAB Staff Office is seeking nominations of experts to serve on the CASAC with demonstrated experience in: *Public health; environmental medicine; environmental health sciences; and risk assessment.* For further information about CASAC, please contact Dr. Holly Stallworth, DFO, by telephone at 202–564–2073 or by e-mail at *stallworth.holly@epa.gov.*

The chartered SAB was established in 1978 by the Environmental Research, Development and Demonstration Act to provide independent advice to the Administrator on general scientific and technical matters underlying the Agency' policies and actions. All the work of the SAB is under the direction of the Board. The chartered Board provides strategic advice to the EPA Administrator on a variety of EPA science and research programs and reviews and approves all SAB subcommittee and panel reports. The SAB Staff Office is seeking nominations of experts to serve on the chartered SAB in the following disciplines: *Social, behavioral and decision sciences; ecological sciences and risk assessment; environmental modeling; environmental economics; environmental engineering; environmental medicine; pediatrics; public health; and human health risk assessment.* For further information about the SAB, please contact Dr. Angela Nugent, DFO, by telephone at 202–564–2218 or by e-mail at *nugent.angela@epa.gov.*

The SAB Drinking Water Committee (DWC) provides advice on the technical aspects of EPA's national drinking water standards program. The SAB Staff Office is seeking nominations of experts to serve on the DWC in the following disciplines: *Microbiology; epidemiology; public health; and environmental engineering.* For further information about the DWC, please contact Mr. Aaron Yeow, DFO, by telephone at 202–564–2050 or by e-mail at *yeow.aaron@epa.gov.*

The SAB Environmental Economics Advisory Committee (EEAC) provides advice on methods and analyses related to economics, costs, and benefits of EPA environmental programs. The SAB Staff office is seeking nominations of experts in environmental *economics* to serve on the EEAC. For further information about the EEAC, please contact Dr. Holly Stallworth, DFO, by telephone at 202–564–2073 or by e-mail at *stallworth.holly@epa.gov.*

The SAB Exposure and Human Health Committee (EHHC) provides advice on the development and use of guidelines for human health effects, exposure assessment, and human health risk assessment of chemical contaminants. The SAB Staff Office is seeking nominations of experts to serve on the EHHC in the following disciplines: *Toxicology; biostatistics; and risk assessment.* For further information about the EHHC please contact Dr. Suhair Shallal, DFO, by telephone at

202–564–2057 or by e-mail at *shallal.suhair@epa.gov.*

The SAB Ecological Processes and Effects Committee (EPEC) provides advice on technical issues related to the science and research to protect and restore the health of ecosystems. The SAB Staff Office is seeking nominations of experts to serve on EPEC with demonstrated expertise in the following disciplines: *Aquatic ecology; ecotoxicology; and ecological risk assessment.* For further information about the EPEC please contact Dr. Thomas Armitage, DFO, by telephone at 202–564–2155 or by e-mail at *armitage.thomas@epa.gov.*

The Radiation Advisory Committee (RAC) provides advice on radiation protection, radiation science, and radiation risk assessment. The SAB Staff Office is seeking nominations of experts to serve on RAC with demonstrated expertise in the following disciplines: *Radiation biology; radiation biophysics; radiation dosimetry; radiation risk assessment; and cancer epidemiology.* For further information about the RAC please contact Dr. K. Jack Kooyoomjian, DFO, by telephone at 202–564–2064 or by e-mail at k*ooyoomjian.jack@epa.gov.*

Selection criteria include:

—Demonstrated scientific credentials and expertise in their own fields.

—Willingness to commit time on the committee and demonstrated ability to work constructively and effectively on committees.

—Background and experiences that would help members contribute to the diversity of perspectives on the committee), *e.g.,* geographic, economic, social, cultural, educational backgrounds, and professional affiliations.

—Consideration of the collective breadth and depth of scientific expertise; a balance of scientific perspectives; and continuity of knowledge and understanding of EPA missions and environmental programs in the context of the committee as a whole.

How To Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to these chartered advisory committees. Individuals may self-nominate. Nominations should be submitted in electronic format (preferred) following the instructions for "Nominating Experts to a Chartered Advisory Committee" provided on the SAB Web site. The form can be accessed through the "Nomination of Experts" link on the blue navigational bar on the SAB Web site at *http://www.epa.gov/sab.* To be considered, all nominations should include the information requested. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

Nominators are asked to identify the specific committee(s) for which nominees would like to be considered. The Web site requests contact information about: The person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's curriculum vita; and a biographical sketch of the nominee indicating current position, educational background; research activities; and recent service on other national advisory committees or national professional organizations. Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB Web site, should contact the Designated Federal Officer for the committee, as identified above. Non-electronic submissions must follow the same format and contain the same information as the electronic form. The SAB Staff Office will acknowledge receipt of nominations.

Candidates invited to serve will be asked to submit the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110–48). This confidential form allows EPA to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded through the "Ethics Requirements for Advisors" link on the blue navigational bar on the SAB Web site at *http://www.epa.gov/sab.* This form should not be submitted as part of a nomination.

To help the Agency in evaluating the effectiveness of its outreach efforts, please tell us how you learned of this opportunity.

Dated: April 6, 2011.

Anthony Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2011–9212 Filed 4–14–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[AU Docket No. 10–248; DA 11–420]

Auction of 700 MHz Band Licenses Scheduled for July 19, 2011; Notice and Filing Requirements, Minimum Opening Bids, Upfront Payments, and Other Procedures for Auction 92

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the procedures and minimum opening bids for the upcoming auction of 16 licenses in the 698–806 MHz band (700 MHz band), designated as Auction 92, and is intended to familiarize prospective bidders with these procedures, minimum opening bid amounts, and deadlines for the auction.

DATES: Applications to participate in Auction 92 and required upfront payments must be filed prior to 6:00 p.m. Eastern Time (ET) on May 11, 2011. Bidding for construction permits in Auction 92 is scheduled to begin on July 19, 2011.

FOR FURTHER INFORMATION CONTACT: *Wireless Telecommunications Bureau, Auctions and Spectrum Access Division:* For legal questions: Lynne Milne at (202) 418–0660. *Mobility Division:* For service rules and licensing issues: Michael Connelly (legal) or Keith Harper (technical) at (202) 418–0620. To request materials in accessible formats (Braille, large print, electronic files or audio format) for people with disabilities, send an e-mail to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 or (202) 418–0432 (TTY).

SUPPLEMENTARY INFORMATION: This is a summary of the *Auction 92 Procedures Public Notice* which was released on March 16, 2011. The complete text of the *Auction 92 Procedures Public Notice,* including attachments, as well as related Commission documents, are available for public inspection and copying from 8 a.m. to 4:30 p.m. ET Monday through Thursday and from 8 a.m. to 11:30 a.m. ET on Friday in the FCC Reference Information Center, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The *Auction 92 Procedures Public Notice* and related Commission documents may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–488–5300, facsimile 202–488–5563, or

Web site: *http://www.BCPIWEB.com,* using document number DA 11–420 for the *Auction 92 Procedures Public Notice.* The *Auction 92 Procedures Public Notice* and related documents are also available on the Internet at the Commission's Web site: *http://wireless.fcc.gov/auctions/92/.*

I. General Information

A. Introduction

On December 15, 2010, the Wireless Telecommunications Bureau (Bureau) released a public notice seeking comment on competitive bidding procedures to be used in Auction 92. A summary of this public notice was published in the **Federal Register** on January 7, 2011, 76 FR 1158. One party submitted comments in response to the *Auction 92 Comment Public Notice,* and three parties submitted filings by the reply comment deadline.

i. Licenses To Be Offered in Auction 92

The 16 licenses in Auction 92 were offered in Auction 73 and remained unsold or were licenses on which a winning bidder defaulted. A complete list of licenses offered in Auction 92 is available in Attachment A to the *Auction 92 Procedures Public Notice.*

B. Rules and Disclaimers

i. Relevant Authority

Prospective applicants must familiarize themselves thoroughly with the Commission's general competitive bidding rules, rules relating to the 700 MHz band and emerging technologies, and rules relating to applications, environmental requirements, practice and procedure. Prospective applicants must also be thoroughly familiar with the procedures, terms and conditions contained in the *Auctions 92 Procedures Public Notice* and in the Commission's decisions in proceedings regarding competitive bidding procedures, application requirements, and obligations of Commission licensees. The terms contained in the Commission's rules, relevant orders, and public notices are not negotiable. The Commission may amend or supplement information contained in public notices at any time, and will issue public notices to convey any new or supplemental information. It is the responsibility of all applications to remain current with all Commission rules and with all public notices pertaining to this auction.

ii. Prohibited Communications and Compliance With Antitrust Laws

To ensure the competitiveness of the auction process, 47 CFR 1.2105(c) prohibits auction applicants for licenses in any of the same geographic license areas from communicating with each other about bids, bidding strategies, or settlements unless such applicants have identified each other on their short-form applications (FCC Form 175) as parties with whom they have entered into agreements pursuant to 47 CFR 1.2105(a)(2)(viii).

a. Entities Subject to Section 1.2105

5. 47 CFR 1.2105(c)'s prohibition on certain communications will apply to any applicants that submit short-form applications seeking to participate in a Commission auction for licenses in the same or overlapping markets. Thus, unless they have identified each other on their short-form applications as parties with whom they have entered into agreements under 47 CFR 1.2105(a)(2)(viii), applicants for any of the same or overlapping markets must affirmatively avoid all communications with or disclosures to each other that affect or have the potential to affect bids or bidding strategy. In some instances, this prohibition extends to communications regarding the post-auction market structure. This prohibition applies to all applicants regardless of whether such applicants become qualified bidders or actually bid. In Auction 92, this rule would apply to applicants designating on the short-form application any of the same licenses. The rule would also prohibit, for example, an applicant bidding for a CMA license and another applicant bidding for an EA license that covers any of the same geographic area from communicating, absent a disclosed agreement.

6. Applicants are also reminded that, for purposes of this prohibition on certain communications, 47 CFR 1.2105(c)(7)(i) defines applicant as including all officers and directors of the entity submitting a short-form application to participate in the auction, all controlling interests of that entity, as well as all holders of partnership and other ownership interests and any stock interest amounting to 10 percent or more of the entity, or outstanding stock, or outstanding voting stock of the entity submitting a short-form application. For example, where an individual served as an officer for two or more applicants, the Bureau has found that the bids and bidding strategies of one applicant are necessarily conveyed to the other applicant, and, absent a disclosed bidding agreement, an apparent violation of 47 CFR 1.2105(c) occurs.

7. Information concerning Auction 92 applicants' license selections will not be available to the public. Therefore, the Commission will inform each applicant by letter of the identity of each of the other applicants that has applied for licenses covering any of the same geographic areas as the licenses that it has selected in its short-form application.

8. Individuals and entities subject to 47 CFR 1.2105(c) should take special care in circumstances where their employees may receive information directly or indirectly from a competing applicant relating to any competing applicant's bids or bidding strategies. An exception to the prohibition on certain communications allows non-controlling interest holders to obtain interests in more than one competing applicant without violating 47 CFR 1.2105(c), provided specified conditions are met (including a certification that no prohibited communications have occurred or will occur), but that exception does not extend to controlling interest holders.

9. Auction 92 applicants selecting licenses for any of the same geographic license areas are encouraged not to use the same individual as an authorized bidder. A violation of 47 CFR 1.2105(c) could occur if an individual acts as the authorized bidder for two or more competing applicants, and conveys information concerning the substance of bids or bidding strategies between such applicants. Also, if the authorized bidders are different individuals employed by the same organization (*e.g.,* law firm or engineering firm or consulting firm), a violation similarly could occur. In such a case, at a minimum, applicants should certify on their applications that precautionary steps have been taken to prevent communication between authorized bidders and that applicants and their bidding agents will comply with 47 CFR 1.2105(c).

b. Prohibition Applies Until Down Payment Deadline

10. 47 CFR 1.2105(c)'s prohibition on certain communications begins at the short-form application filing deadline and ends at the down payment deadline after the auction, which will be announced in a future public notice.

c. Prohibited Communications

11. Applicants should note that they must not communicate directly or indirectly about bids or bidding strategy to other applicants in this auction. 47 CFR 1.2105(c) prohibits not only a communication about an applicant's own bids or bidding strategy, but also a communication of another applicant's bids or bidding strategy. While 47 CFR 1.2105(c) does not prohibit non-auction-

related business negotiations among auction applicants, applicants must remain vigilant so as not to communicate directly or indirectly information that affects, or could affect, bids or bidding strategy, or the negotiation of settlement agreements.

12. Applicants are cautioned that the Commission remains vigilant about prohibited communications taking place in other situations. For example, the Commission has warned that prohibited communications concerning bids and bidding strategies may include communications regarding capital calls or requests for additional funds in support of bids or bidding strategies to the extent such communications convey information concerning bids and bidding strategies directly or indirectly. Moreover, the Commission has found a violation of 47 CFR 1.2105(c) where a bidder used the Commission's bidding system to disclose its bidding strategy in a manner that explicitly invited other auction participants to cooperate and collaborate in specific markets, and has placed auction participants on notice that the use of its bidding system to disclose market information to competitors will not be tolerated and will subject bidders to sanctions. Accordingly, applicants should use caution in their dealings with other parties, such as members of the press, financial analysts, or others who might become conduits for the communication of prohibited bidding information. For example, where limited information disclosure procedures are in place, as is the case for Auction 92, a qualified bidder's statement to the press that it has lost bidding eligibility and stopped bidding in the auction could give rise to a finding of a 47 CFR 1.2105(c) violation. Similarly, an applicant's public statement of intent not to participate in Auction 92 bidding could also violate the rule.

13. Applicants are also hereby placed on notice that disclosure of information relating to bidder interests and bidder identities that has not yet been made public by the Commission at the time of disclosure may violate the provisions of 47 CFR 1.2105(c) that prohibit certain communications. This is so even though similar types of information were revealed prior to and during other Commission auctions subject to different information procedures. Thus, communication by an applicant of its license selections to another applicant for one or more of the same licenses, or communication of the fact that an applicant does nor does not hold provisionally winning bids on particular licenses, may well violate 47 CFR 1.2105(c).

14. In addition, when completing short-form applications, applicants should avoid any statements or disclosures that may violate 47 CFR 1.2105(c), particularly in light of the limited information procedures in effect for Auction 92. Specifically, applicants should avoid including any information in their short-form applications that might convey information regarding their license selection, such as using applicant names that refer to licenses being offered, referring to certain licenses or markets in describing bidding agreements, or including any information in attachments that may otherwise disclose applicants' license selections.

d. Disclosure of Bidding Agreements and Arrangements

15. The Commission's rules do not prohibit applicants from entering into otherwise lawful bidding agreements before filing their short-form applications, as long as they disclose the existence of the agreement(s) in their short-form applications. If parties agree in principle on all material terms prior to the short-form application filing deadline, each party to the agreement must identify the other party or parties to the agreement on its short-form application under 47 CFR 1.2105(c), even if the agreement has not been reduced to writing. If the parties have not agreed in principle by the short-form filing deadline, they should not include the names of parties to discussions on their applications, and they may not continue negotiation, discussion, or communication with any other applicants for licenses covering any of the same or overlapping geographic areas after the short-form application filing deadline.

e. Section 1.2105(c) Certification

16. By electronically submitting a short-form application, each applicant in Auction 92 certifies its compliance with 47 CFR 1.2105(c). However, the Bureau cautions that merely filing a certifying statement as part of an application will not outweigh specific evidence that a prohibited communication has occurred, nor will it preclude the initiation of an investigation when warranted. The Commission has stated that it intends to scrutinize carefully any instances in which bidding patterns suggest that collusion may be occurring. Any applicant found to have violated 47 CFR 1.2105(c) may be subject to sanctions.

f. Duty To Report Prohibited Communications: Reporting Procedure

17. 47 CFR 1.2105(c)(6) provides that any applicant that makes or receives a communication that appears to violate 47 CFR 1.2105(c) must report such communication in writing to the Commission immediately, and in no case later than five business days after the communication occurs. The Commission has clarified that each applicant's obligation to report any such communication continues beyond the five-day period after the communication is made, even if the report is not made within the five day period.

18. 47 CFR 1.65 requires an applicant to maintain the accuracy and completeness of information furnished in its pending application and to notify the Commission of any substantial change that may be of decisional significance to that application. Thus, 47 CFR 1.65 requires an auction applicant to notify the Commission of any substantial change to the information or certifications included in its pending short-form application. An applicant is therefore required by 47 CFR 1.65 to report to the Commission any communication the applicant has made to or received from another applicant after the short-form application filing deadline that affects or has the potential to affect bids or bidding strategy, unless such communication is made to or received from a party to an agreement identified under 47 CFR 1.2105(a)(2)(viii).

19. 47 CFR 1.65(a) and 1.2105(c) requires applicants in competitive bidding proceedings to furnish additional or corrected information within five days of a significant occurrence, or to amend their short-form applications no more than five days after the applicant becomes aware of the need for amendment. These rules are intended to facilitate the auction process by making the information available promptly to all participants and to enable the Bureau to act expeditiously on those changes when such action is necessary.

20. A party reporting any communication pursuant to 47 CFR 1.65, 1.2105(a)(2), or 1.2105(c)(6) must take care to ensure that any report of a prohibited communication does not itself give rise to a violation of 47 CFR 1.2105(c). For example, a party's report of a prohibited communication could violate the rule by communicating prohibited information to other applicants through the use of Commission filing procedures that would allow such materials to be made available for public inspection.

21. 47 CFR 1.2105(c) requires parties to file only a single report concerning such communications and to file that report with Commission personnel expressly charged with administering the Commission's auctions. This rule is designed to minimize the risk of inadvertent dissemination of information in such reports. Pursuant to the amended rule, any reports required by 47 CFR 1.2105(c) must be filed consistent with the instructions set forth in the *Auction 92 Procedures Public Notice.* For Auction 92, such reports must be filed with the Chief of the Auctions and Spectrum Access Division, Wireless Telecommunications Bureau, by the most expeditious means available. Specifically, any such report must be submitted by e-mail to *auction92@fcc.gov* or delivered to the following address: Margaret W. Wiener, Chief, Auctions and Spectrum Access Division, Wireless Telecommunications Bureau, Federal Communications Commission, 445 12th Street SW., Room 6423, Washington, DC 20554.

22. A party seeking to report such a prohibited communication should consider submitting its report with a request that the report or portions of the submission be withheld from public inspection pursuant to 47 CFR 0.459. If requesting that a report be withheld from public inspection, the cover page of the filing must prominently display that the report seeks confidential treatment, and cover all of the material to which the request applies. Such parties also are encouraged to coordinate with the Auctions and Spectrum Access Division staff if they have any questions about the procedures for submitting such reports. The *Auction 92 Procedures Public Notice* provides additional guidance on procedures for submitting application-related information.

g. Winning Bidders Must Disclose Terms of Agreements

23. Applicants that are winning bidders will be required to disclose in their long-form applications the specific terms, conditions, and parties involved in any bidding consortia, joint venture, partnership, or agreement, understanding, or other arrangement entered into relating to the competitive bidding process, including any agreement relating to the post-auction market structure. Applicants must be aware that failure to comply with the Commission's rules can result in enforcement action.

h. Antitrust Laws

24. Applicants are also reminded that, regardless of compliance with the Commission's rules, they remain subject to the antitrust laws, which are designed to prevent anticompetitive behavior in the marketplace. Compliance with the disclosure requirements of 47 CFR 1.2105(c) will not insulate a party from enforcement of the antitrust laws. For instance, a violation of the antitrust laws could arise out of actions taking place well before any party submitted a short-form application. The Commission has cited a number of examples of potentially anticompetitive actions that would be prohibited under antitrust laws: For example, actual or potential competitors may not agree to divide territories in order to minimize competition, regardless of whether they split a market in which they both do business, or whether they merely reserve one market for one and another market for the other. Similarly, the Bureau previously reminded potential applicants and others that even where the applicant discloses parties with whom it has reached an agreement on the short-form application, thereby permitting discussions with those parties, the applicant is nevertheless subject to existing antitrust laws.

25. To the extent the Commission becomes aware of specific allegations that suggest that violations of the federal antitrust laws may have occurred, the Commission may refer such allegations to the United States Department of Justice for investigation. If an applicant is found to have violated the antitrust laws or the Commission's rules in connection with its participation in the competitive bidding process, it may be subject to forfeiture of its upfront payment, down payment, or full bid amount and may be prohibited from participating in future auctions, among other sanctions.

iii. Protection of Incumbent Operations

26. 700 MHz Band licensees must operate in accordance with Commission rules to reduce the potential for interference to public reception of the signals of digital television (DTV) broadcast stations transmitting on DTV Channel 51. These limitations may restrict the ability of such geographic area licensees to use certain portions of the electromagnetic spectrum or provide service to some parts of their geographic license areas.

a. International Coordination

27. Potential bidders seeking licenses for geographic areas that are near the Canadian or Mexican borders are subject to international agreements with Canada and Mexico. Pursuant to these agreements, the U.S. must protect the signals of Canadian and Mexican television broadcast stations located in the border area. Unless otherwise modified by international treaty, licensees must not cause interference to, and must accept harmful interference from, television broadcast operations in Mexico and Canada. Further, until such time as existing agreements are replaced or modified to reflect the new uses, licensees in the band will be subject to existing agreements.

b. Quiet Zones

28. 700 MHz band licensees must protect the radio quiet zones specified at 47 CFR 1.924. Licensees are cautioned that they must receive the appropriate approvals directly from the relevant quiet zone entity prior to operating within the areas described in 47 CFR 1.924.

iv. Spectrum Holdings Subject to Competition Analysis

29. To avoid anti-competitive spectrum aggregation, the Commission in 2008 announced its intention to apply prospectively a competitive analysis to spectrum acquired through auctions, just as the Commission has done previously to spectrum acquired through transactions. Accordingly, the Bureau will apply a competitive analysis to spectrum acquired through this auction when evaluating the winning bidder's long-form application. The Commission's competitive analysis includes an examination of the appropriate market definitions including a determination of the product market, geographic markets, market participants, and the input market for spectrum available for the provision of mobile telephony/broadband services.

v. Due Diligence

30. Each applicant must take seriously its duties and responsibilities and carefully determine before filing an application that the applicant has the legal, technical and financial resources to participate in Auction 92, as well as construct and operate a 700 MHz facility if the auction applicant becomes a licensee as a result of its participation in this auction.

31. The Bureau cautions potential applicants formulating their bidding strategies to investigate and consider the extent to which these frequencies are occupied, and how such occupancy may affect their business plans. For example, there are incumbent operations already licensed and operating in these bands that must be protected. These limitations may restrict the ability of licensees to use certain portions of the electromagnetic spectrum or provide

service to certain areas in their geographic license areas. Applicants should become familiar with the status of any such operations and applicable Commission rules, orders and any pending proceedings related to the service, in order to make reasoned, appropriate decisions about their participation in this auction and their bidding strategy.

32. Potential applicants are reminded that they are solely responsible for investigating and evaluating all technical and marketplace factors that may have a bearing on the value of the licenses being offered in this auction. Bidders are responsible for assuring themselves that, if they win a license, they will be able to build and operate facilities in accordance with the Commission's rules. The Commission makes no representations or warranties about the use of this spectrum for particular services. Applicants should be aware that an FCC auction represents an opportunity to become a licensee subject to certain conditions and regulations. An FCC auction does not constitute an endorsement by the FCC of any particular service, technology, or product, nor does an FCC license constitute a guarantee of business success.

33. Applicants should perform their individual due diligence before proceeding, as they would with any new business venture. In particular, potential applicants are strongly encouraged to conduct their own research prior to the beginning of bidding in Auction 92 in order to determine the existence of any pending legislative, administrative, or judicial proceedings that might affect their decisions regarding participation in the auction. Participants in Auction 92 are strongly encouraged to continue such research throughout the auction. In addition, potential bidders should perform technical analyses sufficient to assure themselves that, should they be a winning bidder in competitive bidding for a specific license, they will be able to build and operate facilities that will fully comply with the Commission's technical and legal requirements as well as other applicable Federal, state, and local laws.

34. Applicants should also be aware that certain pending and future proceedings, including rulemaking proceedings or petitions for rulemaking, applications (including those for modification), requests for special temporary authority, waiver requests, petitions to deny, petitions for reconsideration, informal oppositions, and applications for review, before the Commission may relate to particular applicants or incumbent licensees or the licenses available in Auction 92. In addition, pending and future judicial proceedings may also relate to particular applicants or incumbent licensees, or to the licenses available in Auction 92. Prospective applicants are responsible for assessing the likelihood of the various possible outcomes and for considering their potential impact on spectrum licenses available in this auction.

35. Applicants should perform due diligence to identify and consider all proceedings that may affect the spectrum licenses being auctioned and that could have an impact on the availability of spectrum for Auction 92. In addition, although the Commission may continue to act on various pending applications, informal objections, petitions, and other requests for Commission relief, some of these matters may not be resolved by the beginning of bidding in the auction. Applicants are solely responsible for identifying associated risks and for investigating and evaluating the degree to which such matters may affect their ability to bid on, otherwise acquire, or make use of licenses being offered in this auction.

36. Applicants may research the Bureau's licensing database on the Internet in order to determine which frequencies are already licensed to incumbent licensees. Applicants may obtain information about licenses available in Auction 92 through the Bureau's online licensing databases at *http://wireless.fcc.gov/uls.* Additional guidance on searching these databases is provided in the *Auction 92 Procedures Public Notice.*

37. The Commission makes no representations or guarantees regarding the accuracy or completeness of information in its databases or any third party databases, including, for example, court docketing systems. To the extent the Commission's databases may not include all information deemed necessary or desirable by an applicant, applicants may obtain or verify such information from independent sources or assume the risk of any incompleteness or inaccuracy in said databases. Furthermore, the Commission makes no representations or guarantees regarding the accuracy or completeness of information that has been provided by incumbent licensees and incorporated into its databases.

38. Potential applicants are strongly encouraged to physically inspect any prospective sites located in, or near, the geographic area for which they plan to bid, and also to familiarize themselves with the relevant environmental review obligations.

vi. Use of Integrated Spectrum Auction System

39. The Commission will make available a browser-based bidding system to allow bidders to participate in Auction 92 over the Internet using the Commission's Integrated Spectrum Auction System (ISAS or FCC Auction System). The Commission makes no warranty whatsoever with respect to the FCC Auction System. In no event shall the Commission, or any of its officers, employees, or agents, be liable for any damages whatsoever (including, but not limited to, loss of business profits, business interruption, loss of business information, or any other loss) arising out of or relating to the existence, furnishing, functioning, or use of the FCC Auction System that is accessible to qualified bidders in connection with this auction. Moreover, no obligation or liability will arise out of the Commission's technical, programming, or other advice or service provided in connection with the FCC Auction System.

vii. Environmental Review Requirements

40. Licensees must comply with the Commission's rules regarding implementation of the National Environmental Policy Act and other federal environmental statutes. The construction of a wireless antenna facility is a federal action and the licensee must comply with the Commission's environmental rules for each such facility. Further information about such environmental review requirements is provided in the *Auction 92 Procedures Public Notice.*

C. Auction Specifics

i. Auction Start Date

41. Bidding in Auction 92 will begin on Tuesday, July 19, 2011. The initial schedule for bidding will be announced by public notice at least one week before the start of the auction. Unless otherwise announced, bidding on all licenses will be conducted on each business day until bidding has stopped on all licenses.

ii. Bidding Methodology

42. As discussed in more detail in the *Auction 92 Procedures Public Notice,* the bidding methodology for Auction 92 will be simultaneous multiple round (SMR) bidding. The Commission will conduct this auction over the Internet using the FCC Auction System, and telephonic bidding will be available as well. Qualified bidders are permitted to bid electronically via the Internet or by

telephone. All telephone calls are recorded.

iii. Pre-Auction Dates and Deadlines

43. The following dates and deadlines apply:

Auction Tutorial Available (via Internet)	May 2, 2011.
Short-Form Application (FCC Form 175) Filing Window Opens May 2, 2011;	12 noon ET.
Short-Form Application (FCC Form 175) Filing Window Deadline	May 11, 2011; prior to 6:00 p.m. ET.
Upfront Payments (via wire transfer)	June 17, 2011; 6:00 p.m. ET.
Mock Auction	July 15, 2011.
Auction Begins	July 19, 2011.

iv. Requirements for Participation

44. Those wishing to participate in this auction must: (1) submit a short-form application (FCC Form 175) electronically prior to 6:00 p.m. ET, May 11, 2011, following the electronic filing procedures set forth in Attachment C to the *Auction 92 Procedures Public Notice;* (2) submit a sufficient upfront payment and an FCC Remittance Advice Form (FCC Form 159) by 6:00 p.m. ET, June 17, 2011, following the procedures and instructions set forth in Attachment D to the *Auction 92 Procedures Public Notice;* and (3) comply with all provisions outlined in the *Auction 92 Procedures Public Notice* and applicable Commission rules.

II. Short-Form Application (FCC Form 175) Requirements

A. General Information Regarding Short-Form Applications

45. An application to participate in an FCC auction, referred to as a short-form application or FCC Form 175, provides information used in determining whether the applicant is legally, technically, and financially qualified to participate in Commission auctions for licenses or permits. The short-form application is the first part of the Commission's two-phased auction application process. In the first phase of this process, parties desiring to participate in the auction must file streamlined, short-form applications in which they certify under penalty of perjury as to their qualifications. Eligibility to participate in bidding is based on the applicants' short-form applications and certifications as well as their upfront payments. In the second phase of the process, winning bidders must file a more comprehensive long-form application (FCC Form 601) and have a complete and accurate ownership disclosure information report (FCC Form 602) on file with the Commission.

46. Entities and individuals seeking licenses available in Auction 92 must file a short-form application electronically via the FCC Auction System prior to 6 p.m. ET on May 11, 2011, following the procedures prescribed in Attachment C to the *Auction 92 Procedures Public Notice.* If an applicant claims eligibility for a bidding credit, the information provided in its FCC Form 175 will be used in determining whether the applicant is eligible for the claimed bidding credit. Applicants filing a short-form application are subject to the Commission's rule prohibiting certain communications beginning on the deadline for filing.

47. Applicants bear full responsibility for submitting accurate, complete and timely short-form applications. All applicants must certify on their short-form applications under penalty of perjury that they are legally, technically, financially and otherwise qualified to hold a license. Applicants should read carefully the instructions set forth in Attachment C to the *Auction 92 Procedures Public Notice* and should consult the Commission's rules to ensure that, in addition to the materials described in that public notice, all the information that is required under the Commission's rules is included within their short-form applications.

48. An individual or entity may not submit more than one short-form application for a single auction. If a party submits multiple short-form applications, only one application may be accepted for filing.

49. Applicants also should note that submission of a short-form application (and any amendments thereto) constitutes a representation by the certifying official that he or she is an authorized representative of the applicant, that he or she has read the form's instructions and certifications, and that the contents of the application, its certifications, and any attachments are true and correct. Applicants are not permitted to make major modifications to their applications; such impermissible changes include a change of the certifying official to the application. Submission of a false certification to the Commission may result in penalties, including monetary forfeitures, license forfeitures, ineligibility to participate in future auctions, and/or criminal prosecution.

B. License Selection

50. An applicant must select the licenses on which it wants to bid from the Eligible Licenses list on its short-form application. Applicants interested in participating in Auction 92 must have selected license(s) available in this auction by the short-form application filing deadline. Applicants must review and verify their license selections before the deadline for submitting short-form applications. Applicants will not be able to change their license selections after the short-form application filing deadline. The FCC Auction System will not accept bids from an applicant on licenses that the applicant has not selected on its short-form application.

C. Disclosure of Bidding Arrangements

51. Applicants will be required to identify in their short-form application all parties with whom they have entered into any agreements, arrangements, or understandings of any kind relating to the licenses being auctioned, including any agreements relating to post-auction market structure.

52. After the filing of short-form applications, the Commission's rules do not prohibit a party holding a non-controlling, attributable interest in one applicant from acquiring an ownership interest in or entering into a joint bidding arrangement with other applicants, provided that: (1) The attributable interest holder certifies that it has not and will not communicate with any party concerning the bids or bidding strategies of more than one of the applicants in which it holds an attributable interest, or with which it has entered into a joint bidding arrangement; and (2) the arrangements do not result in a change in control of any of the applicants.

D. Ownership Disclosure Requirements

53. All applicants must comply with the uniform Part 1 ownership disclosure standards and provide information

required by 47 CFR 1.2105 and 1.2112. Specifically, in completing the short-form application, applicants will be required to fully disclose information on the real party- or parties-in-interest and ownership structure of the applicant, including both direct and indirect ownership interests of 10 percent or more. The ownership disclosure standards for the short-form application are prescribed in 47 CFR 1.2105 and 1.2112. Each applicant is responsible for information submitted in its short-form application being complete and accurate.

54. In certain circumstances, an applicant's most current ownership information on file with the Commission, if in an electronic format compatible with the short-form application (such as information submitted in an on-line FCC Form 602 or in an FCC Form 175 filed for a previous auction using ISAS) will automatically be entered into the applicant's short-form application. Each applicant is responsible for ensuring that the information submitted in their short-form application for Auction 92 is complete and accurate. Accordingly, applicants should carefully review any information automatically entered to confirm that it is complete and accurate as of the deadline for filing the short-form application. Applicants can update directly in the short-form application any information that was entered automatically and needs to be changed.

E. Designated Entity Provisions

55. Eligible applicants in Auction 92 may claim small business bidding credits. In addition to the information provided below, applicants should review carefully the Commission's decisions regarding the designated entity provisions.

i. Bidding Credits for Small Businesses

56. A bidding credit represents an amount by which a bidder's winning bid will be discounted. For Auction 92, bidding credits will be available to small businesses and very small businesses, and consortia thereof.

a. Bidding Credit Eligibility Criteria

57. The level of bidding credit is determined as follows: (1) A bidder with attributed average annual gross revenues that exceed $15 million and do not exceed $40 million for the preceding three years (small business) will receive a 15 percent discount on its winning bid; and (2) a bidder with attributed average annual gross revenues that do not exceed $15 million for the preceding three years (very small business) will receive a 25 percent discount on its winning bid.

58. Bidding credits are not cumulative. A qualifying applicant may claim either a 15 percent or 25 percent bidding credit on its winning bid.

b. Revenue Disclosure on Short-Form Application

59. An entity applying as a small or very small business must provide gross revenues for the preceding three years of each of the following: (1) The applicant, (2) its affiliates, (3) its controlling interests, (4) the affiliates of its controlling interests, and (5) the entities with which it has an attributable material relationship. Certification that the average annual gross revenues of such entities and individuals for the preceding three years do not exceed the applicable limit is not sufficient. Additionally, if an applicant is applying as a consortium of small businesses or very small businesses, this information must be provided for each consortium member.

ii. Attributable Interests

a. Controlling Interests

60. Controlling interests of an applicant include individuals and entities with either *de facto* or *de jure* control of the applicant. Typically, ownership of greater than 50 percent of an entity's voting stock evidences *de jure* control. *De facto* control is determined on a case-by-case basis. The following are some common indicia of *de facto* control: (1) The entity constitutes or appoints more than 50 percent of the board of directors or management committee; (2) the entity has authority to appoint, promote, demote, and fire senior executives that control the day-to-day activities of the licensee; and (3) the entity plays an integral role in management decisions.

61. Applicants should refer to 47 CFR 1.2110(c)(2) and Attachment C of the *Auction 92 Procedures Public Notice* to understand how certain interests are calculated in determining control. For example, pursuant to 47 CFR 1.2110(c)(2)(ii)(F), officers and directors of an applicant are considered to have controlling interest in the applicant.

b. Affiliates

62. Affiliates of an applicant or controlling interest include an individual or entity that: (1) Directly or indirectly controls or has the power to control the applicant; (2) is directly or indirectly controlled by the applicant; (3) is directly or indirectly controlled by a third party that also controls or has the power to control the applicant; or (4) has an "identity of interest" with the applicant. The Commission's definition of an affiliate of the applicant encompasses both controlling interests of the applicant and affiliates of controlling interests of the applicant. For more information regarding affiliates, applicants should refer to 47 CFR 1.2110(c)(5) and Attachment C to the *Auction 92 Procedures Public Notice.*

c. Material Relationships

63. The Commission requires the consideration of certain leasing and resale (including wholesale) relationships—referred to as attributable material relationships—in determining designated entity eligibility for bidding credits. An applicant or licensee has an attributable material relationship when it has one or more agreements with any individual entity for the lease or resale (including under a wholesale agreement) of, on a cumulative basis, more than 25 percent of the spectrum capacity of any individual license held by the applicant or licensee. The attributable material relationship will cause the gross revenues of that entity and its attributable interest holders to be attributed to the applicant or licensee for the purposes of determining the applicant's or licensee's (i) eligibility for designated entity benefits and (ii) liability for unjust enrichment on a license-by-license basis.

64. The Commission grandfathered material relationships in existence before the release of the *Designated Entity Second Report and Order,* meaning that those preexisting relationships alone would not cause the Commission to examine a designated entity's ongoing eligibility for existing benefits or its liability for unjust enrichment. The Commission did not, however, grandfather preexisting material relationships for determinations of an applicant's or licensee's designated entity eligibility for future auctions or in the context of future assignments, transfers of control, spectrum leases, or other reportable eligibility events. Rather, in such circumstances, the Commission reexamines the applicant's or licensee's designated entity eligibility, taking into account all existing material relationships, including those previously grandfathered.

d. Gross Revenue Exceptions

65. The Commission has clarified that, in calculating an applicant's gross revenues under the controlling interest standard, it will not attribute to the applicant the personal net worth, including personal income, of its officers and directors. However, to the

extent that an officer or director of the applicant is a controlling interest holder of other entities, the gross revenues of those entities will be attributed to the applicant. Moreover, if an officer or director operates a separate business, the gross revenues derived from that separate business would be attributed to the applicant, although income from such separate business which is only personal income would not be attributed.

66. The Commission has also exempted from attribution to the applicant the gross revenues of the affiliates of a rural telephone cooperative's officers and directors, if certain conditions specified in 47 CFR 1.2110(b)(3)(iii) are met. An applicant claiming this exemption must provide, in an attachment, an affirmative statement that the applicant, affiliate and/or controlling interest is an eligible rural telephone cooperative within the meaning of 47 CFR 1.2110(b)(3)(iii), and the applicant must supply any additional information as may be required to demonstrate eligibility for the exemption from the attribution rule. Applicants seeking to claim this exemption must meet all of the conditions. Additional guidance on claiming this exemption may be found in Attachment C to the *Auction 92 Procedures Public Notice.*

e. Bidding Consortia

67. A consortium of small businesses or very small businesses is a conglomerate organization composed of two or more entities, each of which individually satisfies the definition of a small business or very small business. Thus, each member of a consortium of small businesses or very small businesses that applies to participate in Auction 92 must individually meet the criteria for small businesses or very small businesses. Each consortium member must disclose its gross revenues along with those of its affiliates, its controlling interests, the affiliates of its controlling interests, and any entities having an attributable material relationship with the member. Although the gross revenues of the consortium members will not be aggregated for purposes of determining the consortium's eligibility as a small business or very small business, this information must be provided to ensure that each individual consortium member qualifies for any bidding credit awarded to the consortium.

F. Tribal Lands Bidding Credit

68. Applicants do not provide information regarding tribal lands bidding credits on their short-form applications. Instead, winning bidders may apply for the tribal lands bidding credit after the auction when they file their more detailed, long-form applications.

G. Provisions Regarding Former and Current Defaulters

69. Current defaulters or delinquents are not eligible to participate in Auction 92, but former defaulters can participate so long as they are otherwise qualified and make upfront payments that are fifty percent more than the normal upfront payment amounts. An applicant is considered a current defaulter or a current delinquent when it, any of its affiliates, any of its controlling interests, or any of the affiliates of its controlling interests, is in default on any payment for any Commission license (including a down payment) or is delinquent on any non-tax debt owed to any Federal agency as of the filing deadline for short-form applications. An applicant is considered a former defaulter or a former delinquent when it, any of its affiliates, any of its controlling interests, or any of the affiliates of its controlling interests, have defaulted on any Commission license or been delinquent on any non-tax debt owed to any Federal agency, but have since remedied all such defaults and cured all of the outstanding non-tax delinquencies.

70. On the short-form application, an applicant must certify under penalty of perjury that it, its affiliates, its controlling interests, and the affiliates of its controlling interests, as defined by 47 CFR 1.2110, are not in default on any payment for a Commission license (including down payments) and that it is not delinquent on any non-tax debt owed to any Federal agency. Each applicant must also state under penalty of perjury whether it, its affiliates, its controlling interests, and the affiliates of its controlling interests, have ever been in default on any Commission license or have ever been delinquent on any non-tax debt owed to any Federal agency. Prospective applicants are reminded that submission of a false certification to the Commission is a serious matter that may result in severe penalties, including monetary forfeitures, license revocations, exclusion from participation in future auctions, and/or criminal prosecution. These statements and certifications are prerequisites to submitting an application to participate in an FCC auction.

71. Applicants are encouraged to review the Bureau's previous guidance on default and delinquency disclosure requirements in the context of the short-form application process. For example, to the extent that Commission rules permit late payment of regulatory or application fees accompanied by late fees, such debts will become delinquent for purposes of 47 CFR 1.2105(a) and 1.2106(a) only after the expiration of a final payment deadline. Therefore, with respect to regulatory or application fees, the provisions of 47 CFR 1.2105(a) and 1.2106(a) regarding default and delinquency in connection with competitive bidding are limited to circumstances in which the relevant party has not complied with a final Commission payment deadline. Parties are also encouraged to consult with the Bureau's Auctions and Spectrum Access Division staff if they have any questions about default and delinquency disclosure requirements.

72. The Commission considers outstanding debts owed to the United States Government, in any amount, to be a serious matter. The Commission adopted rules, including a provision referred to as the red light rule, that implement the Commission's obligations under the Debt Collection Improvement Act of 1996, which governs the collection of claims owed to the United States. Under the red light rule, the Commission will not process applications and other requests for benefits filed by parties that have outstanding debts owed to the Commission. In the same rulemaking order, the Commission explicitly declared, however, that the Commission's competitive bidding rules are not affected by the red light rule. As a consequence, the Commission's adoption of the red light rule does not alter the applicability of any of the Commission's competitive bidding rules, including the provisions and certifications of 47 CFR 1.2105 and 1.2106, with regard to current and former defaults or delinquencies.

73. Applicants are reminded, however, that the Commission's Red Light Display System, which provides information regarding debts currently owed to the Commission, may not be determinative of an auction applicant's ability to comply with the default and delinquency disclosure requirements of 47 CFR 1.2105. Thus, while the red light rule ultimately may prevent the processing of long-form applications by auction winners, an auction applicant's lack of current red light status is not necessarily determinative of its eligibility to participate in an auction or of its upfront payment obligation.

74. Moreover, prospective applicants in Auction 92 should note that any long-form applications filed after the close of bidding will be reviewed for compliance with the Commission's red light rule, and such review may result in the

dismissal of a winning bidder's long-form application. Applicants that have their long-form application dismissed will be deemed to have default and will be subject to default payments under 47 CFR 1.2104(f) and 1.2109(c).

H. Optional Applicant Status Identification

75. Applicants owned by members of minority groups and/or women, as defined in 47 CFR 1.2110(c)(3), and rural telephone companies, as defined in 47 CFR 1.2110(c)(4), may identify themselves regarding this status in filling out their short-form applications. This applicant status information is collected for statistical purposes only and assists the Commission in monitoring the participation of designated entities in its auctions.

I. Minor Modifications to Short-Form Applications

76. After the deadline for filing initial applications, an Auction 92 applicant is permitted to make only minor changes to its application. Permissible minor changes include, among other things, deletion and addition of authorized bidders (to a maximum of three) and revision of addresses and telephone numbers of the applicant and its contact person. An applicant is not permitted to make a major modification to its application (*e.g.,* change of license selection, change control of the applicant, change the certifying official, or claim eligibility for a higher percentage of bidding credit) after the initial application filing deadline. Thus, any change in control of an applicant, resulting from a merger, for example, will be considered a major modification to the applicant's application, which will consequently be dismissed. Even if an applicant's short-form application is dismissed, the applicant would remain subject to the prohibition of certain communications pursuant to 47 CFR 1.2105(c) until the down payment deadline, which will be established after the auction closes.

77. If an applicant wishes to make permissible minor changes to its short-form application, such changes should be made electronically to its short-form application using the FCC Auction System whenever possible. Applicants are reminded to click on the SUBMIT button in the FCC Auction System for the change to be submitted and considered by the Commission. After the revised application has been submitted, a confirmation page will be displayed that states the submission time, submission date and a unique file number. The Bureau advises applicant to print and retain a copy of this confirmation page.

78. An applicant cannot use the FCC Auction System outside of the initial and resubmission filing windows to make changes to its short-form application other than administrative changes (*e.g.* changing certain contact information or the name of an authorized bidder). If these or other permissible minor changes need to be made outside of these windows, the applicant must submit a letter briefly summarizing the changes and subsequently update its short-form application in ISAS once the system is available. Moreover, after the filing window has closed, ISAS will not permit applicants to make certain changes, such as the applicant's legal classification and bidding credit.

79. Any letter describing changes to an applicant's short-form application should be submitted by e-mail to *auction92@fcc.gov.* The e-mail summarizing the changes must include a subject or caption referring to Auction 92 and the name of the applicant, for example, RE: Changes to Auction 92 Short-Form Application of ABC Corp. The Bureau requests that parties format any attachments to e-mail as Adobe® Acrobat® (pdf) or Microsoft® Word documents. Questions about short-form application amendments should be directed to the Auctions and Spectrum Access Division at (202) 418–0660.

80. Any application amendment and related statements of fact must be certified by (1) the applicant, if the applicant is an individual; (2) one of the partners if the applicant is a partnership; (3) an officer, director, or duly authorized employee, if the applicant is a corporation; (4) a member who is an officer, if the applicant is an unincorporated association; (5) the trustee, if the applicant is an amateur radio service club; or (6) a duly elected or appointed official who is authorized to make such certifications under the laws of the applicable jurisdiction, if the applicant is a governmental entity.

81. Applicants must not submit application-specific material through the Commission's Electronic Comment Filing System (ECFS), which was used for submitting comments regarding Auction 92. Parties submitting information related to their applications should use caution to ensure that their submissions do not contain confidential information or communicate information that would violate 47 CFR 1.2105(c) or the limited information procedures adopted for Auction 92. A party seeking to submit information that might reflect non-public information, such as an applicant's license selections, upfront payment amount, or bidding eligibility, should consider submitting any such information along with a request that the filing or portions of the filing be withheld from public inspection until the end of the prohibition of certain communications pursuant to 47 CFR 1.2105(c).

J. Maintaining Current Information in Short-Form Applications

82. 47 CFR 1.65 and 1.2105(b) require an applicant to maintain the accuracy and completeness of information furnished in its pending application and in competitive bidding proceedings to furnish additional or corrected information to the Commission within five days of a significant occurrence, or to amend a short form application no more than five days after the applicant becomes aware of the need for the amendment. Changes that cause a loss of or reduction in the percentage of bidding credit specified on the originally submitted application must be reported immediately, and no later than five business days after the change occurs. If an amendment reporting substantial changes is a major amendment, as defined by 47 CFR 1.2105, the major amendment will not be accepted and may result in the dismissal of the application. As explained previously, after the application filing deadline, applicants may make only minor changes to their applications. Applicants must click on the SUBMIT button in the FCC Auction System for the changes to be submitted and considered by the Commission. In addition, an applicant cannot update its short-form application using the FCC Auction System after the initial and resubmission filing windows close. If 47 CFR 1.65 submissions are needed after these windows close, applicants must submit a letter, briefly summarizing the changes, by e-mail to *auction92@fcc.gov.* The e-mail summarizing the changes must include a subject or caption referring to Auction 92 and the name of the applicant. The Bureau requests that parties format any attachments to e-mail as Adobe® Acrobat® (pdf) or Microsoft® Word documents. Applicants must not submit application-specific material through ECFS. A party seeking to submit information that might reflect non-public information, such as an applicant's license selections, upfront payment amount, or bidding eligibility, should consider submitting any such information along with a request that the filing or portions of the filing be withheld from public inspection until the end of the prohibition of certain

communications pursuant to 47 CFR 1.2105(c).

III. Pre-Auction Procedures

A. Online Auction Tutorial—Available May 2, 2011

83. No later than Monday, May 2, 2011, the Commission will post an educational auction tutorial on the Auction 92 web page for prospective bidders to familiarize themselves with the auction process. This online tutorial will provide information about pre-auction procedures, completing short-form applications, auction conduct, the FCC Auction Bidding System, auction rules, and 700 MHz Band service rules. The tutorial will also provide an avenue to ask FCC staff questions about the auction, auction procedures, filing requirements, and other matters related to this auction.

84. The auction tutorial will be accessible through a web browser from the FCC's Auction 92 web page at *http://wireless.fcc.gov/auctions/92/* through an Auction Tutorial link. Once posted, this tutorial will remain available for reference in connection with the procedures outlined in the *Auction 92 Procedures Public Notice* and accessible anytime.

B. Short-Form Applications—Due Prior to 6 p.m. ET on May 11, 2011

85. In order to be eligible to bid in this auction, applicants must first follow the procedures set forth in Attachment C to the *Auction 92 Procedures Public Notice* to submit a short-form application (FCC Form 175) electronically via the FCC Auction System. This short-form application must be submitted through the FCC Auction System prior to 6 p.m. ET on May 11, 2011. Late applications will not be accepted. There is no application fee required when filing an FCC Form 175, but an applicant must submit a timely upfront payment to be eligible to bid.

86. Applications may generally be filed at any time beginning at noon ET on May 2, 2011, until the filing window closes at 6 p.m. ET on May 11, 2011. Applicants are strongly encouraged to file early and are responsible for allowing adequate time for filing their applications. Applicants may update or amend their applications multiple times until the filing deadline on May 11, 2011.

87. An applicant must always click on the SUBMIT button on the Certify & Submit screen to successfully submit its FCC Form 175 and any modifications; otherwise the application or changes to the application will not be received or reviewed. Additional information about accessing, completing, and viewing the FCC Form 175 is included in Attachment C of the *Auction 92 Procedures Public Notice.*

C. Application Processing and Minor Corrections

88. After the deadline for filing FCC Form 175 applications, the Commission will process all timely submitted applications to determine which are complete, and subsequently will issue a public notice identifying (1) those applications that are complete; (2) those applications that are rejected; and (3) those applications that are incomplete because of minor defects that may be corrected. The public notice will include the deadline for resubmitting corrected applications.

89. After the application filing deadline on May 11, 2011, applicants continue to be able to make only minor corrections to their applications. Applicants will not be permitted to make major modifications to their applications (*e.g.,* change license selection, change control of the applicant, change the certifying official, or claim eligibility for a higher percentage of bidding credit).

90. Commission staff will communicate only with an applicant's contact person or certifying official, as designated on the applicant's short-form application, unless the applicant's certifying official or contact person notifies the Commission in writing that applicant's counsel or other representative is authorized to speak on its behalf. Authorizations may be sent by e-mail to *auction92@fcc.gov.*

D. Upfront Payments—Due June 17, 2011

91. In order to be eligible to bid in this auction, applicants must submit an upfront payment accompanied by an FCC Remittance Advice Form (FCC Form 159). After completing its short-form application, an applicant will have access to an electronic version of the FCC Form 159 that can be printed and sent by fax to U.S. Bank in St. Louis, Missouri. All upfront payments must be made as instructed in the *Auction 92 Procedures Public Notice* and must be received in the proper account at U.S. Bank before 6 p.m. ET on June 17, 2011.

i. Making Upfront Payments by Wire Transfer

92. Wire transfer payments must be received before 6 p.m. ET on June 17, 2011. No other payment method is acceptable. The Commission will not accept checks, credit cards, or automated clearing house (ACH) payments to satisfy this upfront payment requirement. To avoid untimely payments, applicants should discuss arrangements (including bank closing schedules) with their bankers several days before they plan to make the wire transfer, and allow sufficient time for the transfer to be initiated and completed before the deadline. Information required for this wire transfer is specified in the *Auction 92 Procedures Public Notice.*

93. At least one hour before placing the order for the wire transfer (but on the same business day), applicants must fax a completed FCC Form 159 (Revised 2/03) to U.S. Bank at (314) 418–4232. On the fax cover sheet, applicants should write Wire Transfer—Auction Payment for Auction 92. In order to meet the Commission's upfront payment deadline, an applicant's payment must be credited to the Commission's account for Auction 92 before the deadline.

94. Each applicant is responsible for ensuring timely submission of its upfront payment and for timely filing of an accurate and complete FCC Remittance Advice Form (FCC Form 159). An applicant should coordinate with its financial institution well ahead of the due date regarding its wire transfer and allow sufficient time for the wire transfer to be initiated and completed prior to the deadline. The Commission repeatedly has cautioned auction participants about the importance of planning ahead to prepare for unforeseen last-minute difficulties in making payments by wire transfer. Each applicant also is responsible for obtaining confirmation from its financial institution that its wire transfer to U.S. Bank was successful and from Commission staff that the Commission has timely received the applicant's upfront payment and deposited it into the proper account. For confirmation that the Commission has timely received the applicant's upfront payment and deposited it into the proper account, an applicant may contact Gail Glasser of the Office of Managing Director's Auctions Accounting Group at (202) 418–0578, or alternatively, Theresa Meeks at (202) 418–2945.

95. Please note the following information regarding upfront payments: (1) All payments must be made in U.S. dollars; (2) all payments must be made by wire transfer; (3) upfront payments for Auction 92 go to a lockbox number different from the lockboxes used in previous FCC auctions, and (4) failure to deliver a sufficient upfront payment as instructed by the June 17, 2011, deadline will result in dismissal of the short-form

application and disqualification from participation in the auction.

ii. FCC Form 159

96. A completed FCC Remittance Advice Form (FCC Form 159, Revised 2/03) must be faxed to U.S. Bank to accompany each upfront payment. Proper completion of FCC Form 159 is critical to ensuring correct crediting of upfront payments. Detailed instructions for completion of FCC Form 159 are included in Attachment D to the *Auction 92 Procedures Public Notice.* An electronic pre-filled version of the FCC Form 159 is available after submitting the FCC Form 175. Payers using the pre-filled FCC Form 159 are responsible for ensuring that all of the information on the form, including payment amounts, is accurate. The FCC Form 159 can be completed electronically, but must be filed with U.S. Bank by fax.

iii. Upfront Payments and Bidding Eligibility

97. Applicants that are former defaulters, as described above, must pay upfront payments 50 percent greater than non-former defaulters. For purposes of this calculation, the applicant includes the applicant itself, its affiliates, its controlling interests, and affiliates of its controlling interests, as defined by 47 CFR 1.2110.

98. Applicants must make upfront payments sufficient to obtain bidding eligibility on the licenses on which they will bid. The amount of the upfront payment determines a bidder's initial bidding eligibility, the maximum number of bidding units on which a bidder may place bids. In order to bid on a particular license, a qualified bidder must have selected the license on its FCC Form 175 and must have a current eligibility level that meets or exceeds the number of bidding units assigned to that license. At a minimum, therefore, an applicant's total upfront payment must be enough to establish eligibility to bid on at least one of the licenses selected on its FCC Form 175, or else the applicant will not be eligible to participate in the auction. A bidder's total upfront payment does not affect the total dollar amount the bidder may bid on any given license. An applicant does not have to make an upfront payment to cover all licenses the applicant selected on its FCC Form 175, but only enough to cover the maximum number of bidding units that are associated with licenses on which the bidder wishes to place bids and hold provisionally winning bids in any given round. Provisionally winning bids are bids that would become final winning bids if the auction were to close after the given round.

99. Each license in Auction 92 is assigned a specific number of bidding units equal to the upfront payment listed for the license, on a bidding unit for dollar basis. The bidding unit level for each license will remain constant throughout the auction.

100. The upfront payment amount submitted by each applicant determines a bidder's initial bidding eligibility. The upfront payments and bidding units for each license in Auction 92 are set forth in Attachment A of the *Auction 92 Procedures Public Notice.*

101. In calculating its upfront payment amount, an applicant should determine the maximum number of bidding units on which it may wish to be active (bid on or hold provisionally winning bids on) in any single round, and submit an upfront payment amount covering that number of bidding units. In order to make this calculation, an applicant should add together the bidding units for all licenses on which it seeks to be active in any given round. Applicants should check their calculations carefully, as there is no provision for increasing a bidder's eligibility after the upfront payment deadline.

102. If an applicant is a former defaulter, it must calculate its upfront payment for all of its identified licenses by multiplying the number of bidding units on which it wishes to be active by 1.5. In order to calculate the number of bidding units to assign to former defaulters, the Commission will divide the upfront payment received by 1.5 and round the result up to the nearest bidding unit. If a former defaulter fails to submit a sufficient upfront payment to establish eligibility to bid on at least one of the licenses selected on its FCC Form 175, the applicant will not be eligible to participate in the auction.

iv. Applicant's Wire Transfer Information for Purposes of Refunds of Upfront Payments

103. To ensure that refunds of upfront payments are processed in an expeditious manner, the Commission is requesting that all pertinent refund information specified in the *Auction 92 Procedures Public Notice* be supplied. Applicants can provide the information electronically during the initial short-form application filing window after the form has been submitted. (Applicants are reminded that information submitted as part of an FCC Form 175 will be available to the public; for that reason, wire transfer information must not be included in an FCC Form 175.) Wire Transfer Instructions can also be manually faxed to the FCC, Financial Operations, Auctions Accounting Group, Attn: Gail Glasser, at (202) 418–2843 (fax). All refunds will be returned to the payer of record as identified on the FCC Form 159 unless the payer submits written authorization instructing otherwise. For additional information, please call Gail Glasser at (202) 418–0578.

E. Auction Registration

104. Approximately ten days before the auction, the Bureau will issue a public notice announcing all qualified bidders for the auction. Qualified bidders are those applicants with submitted FCC Form 175 applications that are deemed timely-filed, accurate, and complete, provided that such applicants have timely submitted an upfront payment that is sufficient to qualify them to bid.

105. All qualified bidders are automatically registered for the auction. Registration materials will be distributed prior to the auction by overnight mail. The mailing will be sent only to the contact person at the contact address listed in the FCC Form 175 and will include the SecurID® tokens that will be required to place bids, the Integrated Spectrum Auction System (ISAS) Bidder's Guide, and the Auction Bidder Line phone number.

106. Qualified bidders that do not receive this registration mailing will not be able to submit bids. Therefore, any qualified bidder that has not received this mailing by noon on Wednesday, July 13, 2011, should call (717) 338–2868. Receipt of this registration mailing is critical to participating in the auction, and each applicant is responsible for ensuring it has received all of the registration material.

107. In the event that SecurID® tokens are lost or damaged, only a person who has been designated as an authorized bidder, the contact person, or the certifying official on the applicant's short-form application may request replacements. Qualified bidders requiring the replacement of these items must call Technical Support at (877) 480–3201, option nine; (202) 414–1250; or (202) 414–1255 (TTY).

F. Remote Electronic Bidding

108. The Commission will conduct this auction over the Internet, and telephonic bidding will be available as well. Only qualified bidders are permitted to bid. Each applicant should indicate its bidding preference—electronic or telephonic—on its FCC Form 175. In either case, each authorized bidder must have its own SecurID® token, which the Commission

will provide at no charge. Each applicant with one authorized bidder will be issued two SecurID® tokens, while applicants with two or three authorized bidders will be issued three tokens. For security purposes, the SecurID® tokens, the telephonic bidding telephone number, and the Integrated Spectrum Auction System (ISAS) Bidder's Guide are only mailed to the contact person at the contact address listed on the FCC Form 175. Each SecurID® token is tailored to a specific auction. SecurID® tokens issued for other auctions or obtained from a source other than the FCC will not work for Auction 92.

109. Please note that the SecurID® tokens can be recycled, and the Bureau encourages bidders to return the tokens to the FCC. The Bureau will provide pre-addressed envelopes that bidders may use to return the tokens once the auction has ended.

G. Mock Auction—July 15, 2011

110. All qualified bidders will be eligible to participate in a mock auction on Friday, July 15, 2011. The mock auction will enable qualified bidders to become familiar with the FCC Auction System prior to the auction. Participation by all bidders is strongly recommended. Details will be announced by public notice.

IV. Auction Event

111. The first round of bidding for Auction 92 will begin on Tuesday, July 19, 2011. The initial bidding schedule will be announced in a public notice listing the qualified bidders, which is to be released approximately 10 days before the start of the auction.

A. Auction Structure

i. Simultaneous Multiple Round Auction

112. All licenses in Auction 92 will be offered in a single auction using the Commission's standard simultaneous multiple-round (SMR) auction format. This type of auction offers every license for bid at the same time and consists of successive bidding rounds in which eligible bidders may place bids on individual licenses. A bidder may bid on, and potentially win, any number of licenses. Unless otherwise announced, bids will be accepted on all licenses in each round of the auction until bidding stops on every license.

ii. Information Available to Bidders Before and During the Auction

113. After consideration of the comments submitted on this issue, the Bureau decided to restrict the information available to bidders in this auction. Pursuant to the anonymous bidding procedures adopted for Auction 92, the Bureau will withhold, until after the close of bidding, public release of (1) bidders' license selections on their short-form applications (FCC Form 175), (2) the amounts of bidders' upfront payments and bidding eligibility, and (3) information that may reveal the identities of bidders placing bids and taking other bidding-related actions.

114. After the conclusion of each round, the Bureau will disclose all relevant information about the bids placed and/or withdrawn except the identities of the bidders performing the actions and the net amounts of the bids placed or withdrawn. As in past auctions conducted with limited information procedures, the Bureau will indicate, for each license, the minimum acceptable bid amount for the next round and whether the license has a provisionally winning bid. After each round, the Bureau will also release, for each license, the number of bidders that placed a bid on the license. Furthermore, the Bureau will indicate whether any proactive waivers were submitted in each round, and the Bureau will release the stage transition percentage—the percentages of licenses (as measured in bidding units) on which there were new bids—for the round. In addition, bidders can log in to the FCC Auction System to see, after each round, whether their own bids are provisionally winning. The Bureau will provide descriptions and/or samples of publicly-available and bidder-specific (non-public) results files prior to the start of the auction.

115. The Bureau, however, retains the discretion not to use limited information procedures if the Bureau, after examining the level of potential competition as expressed in the license selection on the short-form applications filed for Auction 92, determines that the circumstances indicate that limited information procedures would not be an effective tool for deterring anti-competitive behavior. For example, if only two applicants become qualified to participate in the bidding, limited information procedures would be ineffective in preventing bidders from knowing the identity of the competing bidder and, therefore, limited information procedures would not serve to deter attempts at signaling and retaliatory bidding behavior.

116. *Other Issues.* Information disclosure procedures established for this auction will not interfere with the administration of or compliance with the Commission's prohibition of certain communications. 47 CFR 1.2105(c)(1) provides that, after the short-form application filing deadline, all applicants for licenses in any of the same geographic license areas are prohibited from disclosing to each other in any manner the substance of bids or bidding strategies until after the down payment deadline, subject to specified exceptions.

117. In Auction 92, the Commission will not disclose information regarding license selection or the amounts of bidders' upfront payments and bidding eligibility. As in the past, the Commission will disclose the other portions of applicants' short-form applications through its online database, and certain application-based information through public notices.

118. To assist applicants in identifying other parties subject to 47 CFR 1.2105(c), the Bureau will notify separately each applicant in Auction 92 whether applicants with short-form applications to participate in pending auctions, including but not limited to Auction 92, have applied for licenses in any of the same geographic areas as that applicant. Specifically, after the Bureau conducts its initial review of applications to participate in Auction 92, it will send to each applicant in Auction 92 a letter that lists the other applicants that have pending short-form applications for licenses in any of the same geographic areas. The list will identify the other applicants by name but will not list their license selections. As in past auctions, additional information regarding other applicants that is needed to comply with 47 CFR 1.2105(c)—such as the identities of other applicants' controlling interests and entities with a greater than ten percent ownership interest—will be available through the publicly accessible online short-form application database. For purposes of 47 CFR 1.2105(c), the term applicant includes all officers and directors of the applicant and all other controlling interests, as well as all parties with ownership interests greater than ten percent.

119. When completing short-form applications, applicants should avoid any statements or disclosures that may violate the prohibition of certain communications pursuant to 47 CFR 1.2105(c), particularly in light of the Commission's procedures regarding the availability of certain information in Auction 92. While applicants' license selections will not be disclosed until after Auction 92 closes, the Commission will disclose other portions of short-form applications through its online database and public notices. Accordingly, applicants must avoid including any information in their short-form applications that might

convey information regarding license selections. For example, applicants should avoid using applicant names that refer to licenses being offered, referring to certain licenses or markets in describing bidding agreements, or including any information in attachments that may otherwise disclose applicants' license selections.

120. If an applicant is found to have violated the Commission's rules or antitrust laws in connection with its participation in the competitive bidding process, the applicant may be subject to various sanctions, including forfeiture of its upfront payment, down payment, or full bid amount and prohibition from participating in future auctions.

121. Direct or indirect communication to other applicants or the public disclosure of non-public information (*e.g.,* bid withdrawals, proactive waivers submitted, reductions in eligibility) could violate the Commission's anonymous bidding procedures and 47 CFR 1.2105(c). To the extent an applicant believes that such a disclosure is required by law or regulation, including regulations issued by the Securities and Exchange Commission, the Bureau strongly urges that the applicant consult with the Commission staff in the Auctions and Spectrum Access Division before making such disclosure.

iii. Eligibility and Activity Rules

122. The Bureau will use upfront payments to determine initial (maximum) eligibility (as measured in bidding units) for Auction 92. The amount of the upfront payment submitted by a bidder determines initial bidding eligibility, the maximum number of bidding units on which a bidder may be active. Each license is assigned the specific number of bidding units listed in Attachment A of the *Auction 92 Procedures Public Notice.* Bidding units for a given license do not change as prices rise during the auction. A bidder's upfront payment is not attributed to specific licenses. Rather, a bidder may place bids on any of the licenses selected on its FCC Form 175 as long as the total number of bidding units associated with those licenses does not exceed its current eligibility. Eligibility cannot be increased during the auction; it can only remain the same or decrease. Thus, in calculating its upfront payment amount, an applicant must determine the maximum number of bidding units it may wish to bid on or hold provisionally winning bids on in any single round, and submit an upfront payment amount covering that total number of bidding units. At a minimum, an applicant's upfront payment must cover the bidding units for at least one of the licenses it selected on its FCC Form 175. The total upfront payment does not affect the total dollar amount a bidder may bid on any given license.

123. In order to ensure that an auction closes within a reasonable period of time, an activity rule requires bidders to bid actively throughout the auction, rather than wait until late in the auction before participating. Bidders are required to be active on a specific percentage of their current bidding eligibility during each round of the auction.

124. A bidder's activity level in a round is the sum of the bidding units associated with any licenses covered by new and provisionally winning bids. A bidder is considered active on a license in the current round if it is either the provisionally winning bidder at the end of the previous bidding round and does not withdraw the provisionally winning bid in the current round, or if it submits a bid in the current round.

125. The minimum required activity is expressed as a percentage of the bidder's current eligibility, and increases by stage as the auction progresses. Failure to maintain the requisite activity level will result in the use of an activity rule waiver, if any remain, or a reduction in the bidder's eligibility, possibly curtailing or eliminating the bidder's ability to place additional bids in the auction.

iv. Auction Stages

126. For now, the Bureau will conduct the auction in two stages and employ an activity rule. A bidder desiring to maintain its current bidding eligibility would be required to be active on licenses representing at least 80 percent of its current bidding eligibility, during each round of Stage One, and at least 95 percent of its current bidding eligibility in Stage Two.

127. *Stage One:* During the first stage of the auction, a bidder desiring to maintain its current bidding eligibility will be required to be active on licenses representing at least 80 percent of its current bidding eligibility in each bidding round. Failure to maintain the required activity level will result in the use of an activity rule waiver or, if the bidder has no activity rule waivers remaining, a reduction in the bidder's bidding eligibility in the next round. During Stage One, reduced eligibility for the next round will be calculated by multiplying the bidder's current round activity (the sum of bidding units of the bidder's provisionally winning bids and bids during the current round) by five-fourths (5/4).

128. *Stage Two:* During the second stage of the auction, a bidder desiring to maintain its current bidding eligibility is required to be active on 95 percent of its current bidding eligibility. Failure to maintain the required activity level will result in the use of an activity rule waiver or, if the bidder has no activity rule waivers remaining, a reduction in the bidder's bidding eligibility in the next round. During Stage Two, reduced eligibility for the next round will be calculated by multiplying the bidder's current round activity (the sum of bidding units of the bidder's provisionally winning bids and bids during the current round) by twenty-nineteenths (20/19).

129. *CAUTION:* Since activity requirements increase in Stage Two, bidders must carefully check their activity during the first round following a stage transition to ensure that they are meeting the increased activity requirement. This is especially critical for bidders that have provisionally winning bids and do not plan to submit new bids. In past auctions, some bidders have inadvertently lost bidding eligibility or used an activity rule waiver because they did not re-verify their activity status at stage transitions. Bidders may check their activity against the required activity level by logging into the FCC Auction System.

130. The Bureau has the discretion to further alter the activity requirements before and/or during the auction as circumstances warrant, and also has other mechanisms by which it may influence the speed of an auction.

v. Stage Transitions

131. The auction will start in Stage One. The Bureau will regulate the pace of the auction by announcement. The Bureau retains the discretion to change the activity requirements during the auction. For example, the Bureau could transition the auction to Stage Two, to add an additional stage with a higher activity requirement, not to transition to Stage Two, and to transition to Stage Two with an activity requirement that is higher or lower than 95 percent. This determination will be based on a variety of measures of auction activity, including, but not limited to, the number of new bids and the percentages of licenses (as measured in bidding units) on which there are new bids. Potential bidders should note that the stage of the auction does not affect the auction stopping rules. The auction may conclude in Stage One.

vi. Activity Rule Waivers

132. Each bidder in the auction will be provided with three activity rule

waivers. Bidders may use an activity rule waiver in any round during the course of the auction. Use of an activity rule waiver preserves the bidder's eligibility despite the bidder's activity in the current round being below the required minimum activity level. An activity rule waiver applies to an entire round of bidding and not to a particular license. Activity rule waivers can be either proactive or automatic and are principally a mechanism for auction participants to avoid the loss of bidding eligibility in the event that exigent circumstances prevent them from placing a bid in a particular round.

133. The FCC Auction System assumes that bidders with insufficient activity would prefer to apply an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver at the end of any bidding round where a bidder's activity level is below the minimum required unless (1) there are no activity rule waivers available or (2) the bidder overrides the automatic application of a waiver by reducing eligibility. If a bidder has no waivers remaining and does not satisfy the activity requirement, the FCC Auction System will permanently reduce the bidder's eligibility, possibly curtailing or eliminating the bidder's ability to place additional bids in the auction.

134. A bidder with insufficient activity that wants to reduce its bidding eligibility rather than use an activity rule waiver must affirmatively override the automatic waiver mechanism during the bidding round by using the reduce eligibility function in the FCC Auction System. In this case, the bidder's eligibility is permanently reduced to bring the bidder into compliance with the activity rule. Once eligibility has been reduced, a bidder will not be permitted to regain its lost bidding eligibility even if the round has not yet ended.

135. Finally, a bidder may apply an activity rule waiver proactively as a means to keep the auction open without placing a bid. If a bidder proactively applies an activity waiver (using the apply waiver function in the FCC Auction System) during a bidding round in which no bids are placed or withdrawn, the auction will remain open and the bidder's eligibility will be preserved. However, an automatic waiver applied by the FCC Auction System in a round in which there are no new bids, withdrawals, or proactive waivers will not keep the auction open. A bidder cannot submit a proactive waiver after submitting a bid in a round, and submitting a proactive waiver will preclude a bidder from placing any bids in that round. It is important for bidders to understand that applying a waiver is irreversible. Once a bidder submits a proactive waiver, the bidder cannot unsubmit the waiver even if the round has not yet ended.

vii. Auction Stopping Rules

136. For Auction 92, the Bureau will employ a simultaneous stopping rule approach. A simultaneous stopping rule means that all licenses remain available for bidding until bidding closes simultaneously on all licenses. More specifically, bidding will close simultaneously on all licenses after the first round in which no bidder submits any new bids, applies a proactive waiver, or withdraws any provisionally winning bids.

137. As explained in the Auction 92 Procedures Public Notice, the Bureau retains the discretion to exercise alternative stopping rules, with or without prior announcement in the auction. For example, under Option 1, the auction would close for all licenses after the first round in which no bidder applies a waiver, withdraws a provisionally winning bid, or places any new bids on any license on which it is not the provisionally winning bidder. Thus, absent any other bidding activity, a bidder placing a new bid on a license for which it is the provisionally winning bidder would not keep the auction open under this modified stopping rule. Under Option 2, the auction would close for all licenses after the first round in which no bidder applies a waiver, withdraws a provisionally winning bid, or places any new bids on any license that is not FCC held. Thus, absent any other bidding activity, a bidder placing a new bid on a license that does not already have a provisionally winning bid (an FCC-held license) would not keep the auction open under this modified stopping rule. Under Option 3, the auction would close using a modified version of the simultaneous stopping rule that combines Option 1 and Option 2. Under Option 4, the auction would end after a specified number of additional rounds. If the Bureau invokes this special stopping rule, it will accept bids in the specified final round(s) and the auction will close. Under Option 5, the auction would remain open even if no bidder places any new bids, applies a waiver, or withdraws any provisionally winning bids. In this event, the effect will be the same as if a bidder had applied a waiver. Thus, the activity rule will apply as usual, and a bidder with insufficient activity will either lose bidding eligibility or use a waiver.

viii. Auction Delay, Suspension, or Cancellation

138. By public notice or by announcement during the auction, the Bureau may delay, suspend, or cancel the auction in the event of natural disaster, technical obstacle, administrative or weather necessity, evidence of an auction security breach or unlawful bidding activity, or for any other reason that affects the fair and efficient conduct of competitive bidding. In such cases, the Bureau, in its sole discretion, may elect to resume the auction starting from the beginning of the current round, resume the auction starting from some previous round, or cancel the auction in its entirety. Network interruption may cause the Bureau to delay or suspend the auction. The Bureau emphasizes that exercise of this authority is solely within the discretion of the Bureau, and its use is not intended to be a substitute for situations in which bidders may wish to apply their activity rule waivers.

B. Bidding Procedures

i. Round Structure

139. The initial schedule of bidding rounds will be announced in the public notice listing the qualified bidders, which is released approximately 10 days before the start of the auction. Each bidding round is followed by the release of round results. Multiple bidding rounds may be conducted in a given day. Details regarding round results formats and locations will also be included in the qualified bidders public notice.

140. The Bureau has the discretion to change the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. The Bureau may increase or decrease the amount of time for the bidding rounds, the amount of time between rounds, or the number of rounds per day, depending upon bidding activity and other factors.

ii. Reserve Price and Minimum Opening Bids

141. There will be no reserve prices for the licenses to be offered in Auction 92. After consideration of comments submitted, the Bureau adopted the specific minimum opening bid amounts for each license available in Auction 92 listed in Attachment A of the *Auctions 92 Procedures Public Notice.*

iii. Bid Amounts

142. In each round, eligible bidders will be able to place a bid on a given license using one or more pre-defined

bid amounts, if the bidder has sufficient eligibility to place a bid on the particular license. The FCC Auction System interface will list the acceptable bid amounts for each license. In the event of duplicate bid amounts due to rounding, the FCC Auction System will omit the duplicates and will list fewer acceptable bid amounts for the license.

a. Minimum Acceptable Bids

143. The first of the acceptable bid amounts is called the minimum acceptable bid amount. The minimum acceptable bid amount for a license will be equal to its minimum opening bid amount until there is a provisionally winning bid on the license. After there is a provisionally winning bid for a license, the minimum acceptable bid amount for that license will be equal to the amount of the provisionally winning bid plus a percentage of that bid amount calculated using the formula specified in the *Auction 92 Procedures Public Notice.* In general, the percentage will be higher for a license receiving many bids than for a license receiving few bids. In the case of a license for which the provisionally winning bid has been withdrawn, the minimum acceptable bid amount will equal the second highest bid received for the license.

144. The percentage of the provisionally winning bid used to establish the minimum acceptable bid amount (the additional percentage) is calculated at the end of each round, based on an activity index. The activity index is a weighted average of (a) the number of distinct bidders placing a bid on the license, and (b) the activity index from the prior round. Specifically, the activity index is equal to a weighting factor times the number of bidders placing a bid covering the license in the most recent bidding round plus one minus the weighting factor times the activity index from the prior round. The additional percentage is determined as one plus the activity index times a minimum percentage amount, with the result not to exceed a given maximum. The additional percentage is then multiplied by the provisionally winning bid amount to obtain the minimum acceptable bid for the next round. For round 1 calculations, however, the index from the prior round is set at 0, because there is no prior round (i.e. no round 0).

145. The weighting factor is set at 0.5, the minimum percentage (floor) at 0.1 (10%), and the maximum percentage (ceiling) at 0.3 (30%). At these initial settings, the minimum acceptable bid for a license will generally be between ten percent and thirty percent higher than the provisionally winning bid, depending upon the bidding activity for the license. Equations and examples were provided in Attachment B of the *Auction 92 Procedures Public Notice.*

b. Additional Bid Amounts

146. Any additional bid amounts are calculated using the minimum acceptable bid amount and a bid increment percentage, which need not be the same as the percentage used to calculate the minimum acceptable bid amount. The first additional acceptable bid amount equals the minimum acceptable bid amount times one plus the bid increment percentage. The Bureau will begin the auction with eight additional bid amounts per license. The Bureau will use a bid increment percentage of 5 percent. With a bid increment percentage of 5 percent, the calculation is (minimum acceptable bid amount) * (1 + 0.05), or (minimum acceptable bid amount) * 1.05; the second additional acceptable bid amount equals the minimum acceptable bid amount times one plus two times the bid increment percentage, or (minimum acceptable bid amount) * 1.1, etc. The Bureau will start the auction without a limit on the dollar amount by which minimum acceptable bids and additional bid amounts may increase. The Bureau retains the discretion to change the minimum acceptable bid amounts, the additional bid amounts, the number of acceptable bid amounts, and the parameters of the formulas used to calculate minimum acceptable bid amounts and additional bid amounts, and impose a limit on bid amounts if it determines that circumstances so dictate. Further, the Bureau retains the discretion to do so on a license-by-license basis. If the Bureau exercises this discretion, it will alert bidders by announcement in the FCC Auction System during the auction.

iv. Provisionally Winning Bids

147. At the end of each bidding round, a provisionally winning bid will be determined based on the highest bid amount received for each license. A provisionally winning bid will remain the provisionally winning bid until there is a higher bid on the same license at the close of a subsequent round. Provisionally winning bids at the end of the auction become the winning bids. Bidders are reminded that provisionally winning bids count toward activity for purposes of the activity rule.

148. The Bureau will use a random number generator to select a single provisionally winning bid in the event of identical high bid amounts being submitted on a license in a given round (*i.e.,* tied bids). The FCC Auction System will assign a random number to each bid upon submission. The tied bid with the highest random number wins the tiebreaker and becomes the provisionally winning bid. Bidders, regardless of whether they hold a provisionally winning bid, can submit higher bids in subsequent rounds. However, if the auction were to end with no other bids being placed, the winning bidder would be the one that placed the provisionally winning bid.

v. Bidding

149. All bidding will take place remotely either through the FCC Auction System or by telephonic bidding. There will be no on-site bidding during Auction 92. Please note that telephonic bid assistants are required to use a script when entering bids placed by telephone. Telephonic bidders are therefore reminded to allow sufficient time to bid by placing their calls well in advance of the close of a round. The length of a call to place a telephonic bid may vary; please allow a minimum of ten minutes.

150. A bidder's ability to bid on specific licenses is determined by two factors: (1) The licenses selected on the bidder's FCC Form 175 and (2) the bidder's eligibility. The bid submission screens will allow bidders to submit bids on only those licenses the bidder selected on its FCC Form 175.

151. In order to access the bidding function of the FCC Auction System, bidders must be logged in during the bidding round using the passcode generated by the SecurID® token and a personal identification number (PIN) created by the bidder. Bidders are strongly encouraged to print a round summary for each round after they have completed all of their activity for that round.

152. In each round, an eligible bidder will be able to place bids on a given license in any of up to nine pre-defined bid amounts, if the bidder has sufficient eligibility to place a bid on a particular license. For each license, the FCC Auction System will list the acceptable bid amounts in a drop-down box. Bidders use the drop-down box to select from among the acceptable bid amounts. The FCC Auction System also includes an upload function that allows bidders to upload text files containing bid information.

153. Until a bid has been placed on a license, the minimum acceptable bid amount for that license will be equal to its minimum opening bid amount. Once there are bids on a license, minimum acceptable bids for a license for the following round will be determined.

154. During a round, an eligible bidder may submit bids for as many licenses as it wishes (provided that it is eligible to bid), remove bids placed in the current bidding round, withdraw provisionally winning bids from previous rounds, or permanently reduce eligibility. If a bidder submits multiple bids for the exact same license in the same round, the system takes the last bid entered as that bidder's bid for the round. Bidders should note that the bidding units associated with licenses for which the bidder has removed or withdrawn bids do not count towards the bidder's current activity.

155. Finally, bidders are cautioned to select their bid amounts carefully because bidders that withdraw a provisionally winning bid from a previous round, even if the bid was mistakenly or erroneously made, are subject to bid withdrawal payments.

vi. Bid Removal and Bid Withdrawal

156. *Bid Removal.* Before the close of a bidding round, a bidder has the option of removing any bids placed in that round. By using the remove bids function in the FCC Auction System, a bidder may effectively unsubmit any bid placed within that round. A bidder removing a bid placed in the same round is not subject to withdrawal payments. If a bid is placed on a license during a round, it will count towards the activity for that round, but when that bid is then removed during the same round it was placed, the activity associated with it is also removed, i.e., a bid that is removed does not count toward bidding activity.

157. *Bid Withdrawal.* Once a round closes, a bidder may no longer remove a bid. However, in a later round, a bidder may withdraw provisionally winning bids from previous rounds for licenses using the withdraw bids function in the FCC Auction System. A provisionally winning bidder that withdraws its provisionally winning bid from a previous round during the auction is subject to the bid withdrawal payments specified in 47 CFR 1.2104(g). Once a bid withdrawal is submitted during a round, that withdrawal cannot be unsubmitted even if the round has not yet ended.

158. If a provisionally winning bid is withdrawn, the minimum acceptable bid amount will equal the amount of the second highest bid received for the license, which may be less than, or in the case of tied bids, equal to, the amount of the withdrawn bid. The Commission will serve as a placeholder provisionally winning bidder on the license until a new bid is submitted on that license. The Bureau retains the discretion to lower the minimum acceptable bid on such licenses in the next round or in later rounds.

159. *Calculation of Bid Withdrawal Payment.* Generally, the Commission imposes payments on bidders that withdraw provisionally winning bids during the course of an auction. If a bidder withdraws its bid and there is no higher bid in the same or subsequent auction(s), the bidder that withdrew its bid is responsible for the difference between its withdrawn bid and the winning bid in the same or subsequent auction(s). If there are multiple bid withdrawals on a single license and no subsequent higher bid is placed and/or the license is not won in the same auction, the payment for each bid withdrawal will be calculated based on the sequence of bid withdrawals and the amounts withdrawn. No withdrawal payment will be assessed for a withdrawn bid if either the subsequent winning bid or any subsequent intervening withdrawn bid, in either the same or subsequent auction(s), equals or exceeds that withdrawn bid. Thus, a bidder that withdraws a bid will not be responsible for any final withdrawal payment if there is a subsequent higher bid in the same or subsequent auction(s).

160. 47 CFR 1.2104(g)(1) sets forth the payment obligations of a bidder that withdraws a provisionally winning bid on a license during the course of an auction, and provides for the assessment of interim bid withdrawal payments. The Commission will assess an interim withdrawal payment equal to fifteen percent of the amount of the withdrawn bid. The fifteen percent interim payment will be applied toward any final bid withdrawal payment that will be assessed after subsequent auction of the license. Assessing an interim bid withdrawal payment ensures that the Commission receives a minimal withdrawal payment pending assessment of any final withdrawal payment. 47 CFR 1.2104(g) provides specific examples showing application of the bid withdrawal payment rule.

vii. Round Results

161. Limited information about the results of a round will be made public after the conclusion of the round. Specifically, after a round closes, the Bureau will make available for each license, its current provisionally winning bid amount, the minimum acceptable bid amount for the following round, the amounts of all bids placed on the license during the round, and whether the license is FCC held. The system will also provide an entire license history detailing all activity that has taken place on a license with the ability to sort by round number. The reports will be publicly accessible. Moreover, after the auction closes, the Bureau will make available complete reports of all bids placed during each round of the auction, including bidder identities.

viii. Auction Announcements

162. The Commission will use auction announcements to report necessary information such as schedule changes and stage transitions. All auction announcements will be available by clicking a link in the FCC Auction System.

V. Post-Auction Procedures

163. Shortly after bidding has ended, the Commission will issue a public notice declaring the auction closed, identifying the winning bidders, and establishing the deadlines for submitting down payments, long-form applications, final payments, and ownership disclosure information reports.

A. Down Payments and Final Payments

164. Within ten business days after release of the auction closing public notice, each winning bidder must submit sufficient funds (in addition to its upfront payment) to bring its total amount of money on deposit with the Commission for Auction 92 to 20 percent of the net amount of its winning bids (gross bids less any applicable small business bidding credit).

165. Each winning bidder will be required to submit the balance of the net amount of its winning bids within ten business days after the applicable deadline for submitting down payments.

B. Long-Form Application (FCC Form 601)

166. Within ten business days after release of the auction closing notice, winning bidders must electronically submit a properly completed long-form application (FCC Form 601) for the license(s) they won through Auction 92. Winning bidders claiming eligibility for a small business or very small business bidding credit must demonstrate their eligibility for the bidding credit. Further instructions on these and other filing requirements will be provided to winning bidders in the auction closing public notice.

167. Winning bidders organized as bidding consortia must comply with applicable long-form application procedures as described in the *Auction 92 Procedures Public Notice.* Specifically, each member (or group of members) of a winning consortium

seeking separate licenses will be required to file a separate long-form application for its respective license(s). If the license is to be partitioned or disaggregated, the member (or group) filing the long-form application must provide the relevant partitioning or disaggregation agreement in its long-form application. In addition, if two or more consortium members wish to be licensed together, they must first form a legal business entity, and any such entity must meet the applicable designated entity criteria.

C. Ownership Disclosure Information Report (FCC Form 602)

168. Within ten business days after release of the auction closing public notice, each winning bidder must also comply with the ownership reporting requirements in 47 CFR 1.913, 1.919, and 1.2112 by submitting an ownership disclosure information report for wireless telecommunications services (FCC Form 602) with its long-form application.

169. If an applicant already has a complete and accurate FCC Form 602 on file in ULS, it is not necessary to file a new report, but applicants must verify that the information on file with the Commission is complete and accurate. If the applicant does not have an FCC Form 602 on file, or if it is not complete and accurate, the applicant must submit one.

170. When an applicant submits a short-form application, ULS automatically creates an ownership record. This record is not an FCC Form 602, but may be used to pre-fill the FCC Form 602 with the ownership information submitted on the applicant's short-form application. Applicants must review the pre-filled information and confirm that it is complete and accurate as of the filing date of the long-form application before certifying and submitting the FCC Form 602. Further instructions will be provided to winning bidders in the auction closing public notice.

D. Tribal Lands Bidding Credit

171. A winning bidder that intends to use its license(s) to deploy facilities and provide services to federally recognized tribal lands that are unserved by any telecommunications carrier or that have a wireline penetration rate equal to or below 85 percent is eligible to receive a tribal lands bidding credit as set forth in 47 CFR 1.2107 and 1.2110(f). A tribal lands bidding credit is in addition to, and separate from, any other bidding credit for which a winning bidder may qualify.

172. Unlike other bidding credits that are requested prior to the auction, a winning bidder applies for the tribal lands bidding credit after the auction when it files its long-form application (FCC Form 601). When initially filing the long-form application, the winning bidder will be required to advise the Commission whether it intends to seek a tribal lands bidding credit, for each license won in the auction, by checking the designated box(es). After stating its intent to seek a tribal lands bidding credit, the applicant will have 180 days from the close of the long-form application filing window to amend its application to select the specific tribal lands to be served and provide the required tribal government certifications. Licensees receiving a tribal lands bidding credit are subject to performance criteria as set forth in 47 CFR 1.2110(f)(3)(vii).

173. For additional information on the tribal lands bidding credit, including how the amount of the credit is calculated, applicants should review the Commission's rulemaking proceeding regarding tribal lands bidding credits and related public notices. Relevant documents can be viewed on the Commission's Web site by going to *http://wireless.fcc.gov/auctions/* and clicking on the Tribal Lands Credits link.

E. Default and Disqualification

174. Any winning bidder that defaults or is disqualified after the close of the auction (i.e., fails to remit the required down payment within the prescribed period of time, fails to submit a timely long-form application, fails to make full payment, or is otherwise disqualified) will be subject to the payments described in 47 CFR 1.2104(g)(2). The payments include both a deficiency payment, equal to the difference between the amount of the bidder's bid and the amount of the winning bid the next time a license covering the same spectrum is won in an auction, plus an additional payment equal to a percentage of the defaulter's bid or of the subsequent winning bid, whichever is less. The Bureau set the additional default payment for this auction at fifteen percent of the applicable bid.

175. Finally, in the event of a default, the Commission has the discretion to re-auction the license or offer it to the next highest bidder (in descending order) at its final bid amount. In addition, if a default or disqualification involves gross misconduct, misrepresentation, or bad faith by an applicant, the Commission may declare the applicant and its principals ineligible to bid in future auctions, and may take any other action that it deems necessary, including institution of proceedings to revoke any existing authorizations held by the applicant.

F. Refund of Remaining Upfront Payment Balance

176. After the auction, applicants that are not winning bidders or are winning bidders whose upfront payment exceeded the total net amount of their winning bids may be entitled to a refund of some or all of their upfront payment. All refunds will be returned to the payer of record, as identified on the FCC Form 159, unless the payer submits written authorization instructing otherwise. Bidders should not request a refund of their upfront payments before the Commission releases a public notice declaring the auction closed, identifying the winning bidders, and establishing the deadlines for submitting down payments, long-form applications, and final payments. Bidders must comply with the specific instructions provided in the *Auction 92 Procedures Public Notice* for such refunds.

Federal Communications Commission.

Gary D. Michaels,

Deputy Chief, Auctions and Spectrum Access Division, WTB.

[FR Doc. 2011–9200 Filed 4–14–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 1299, Oaktree Federal Savings, New Orleans, LA and 7804, Oaktree Savings Bank, SSB

Notice is hereby given that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Oaktree Federal Savings, New Orleans, Louisiana and for Oaktree Savings Bank, SSB ("Receiver") intends to terminate its receiverships for said institutions. The Resolution Trust Corporation ("RTC") was appointed Receiver for Oaktree Federal Savings and Oaktree Savings Bank, SSB and pursuant to 12 U.S.C. 1441a(m)(1) FDIC succeeded RTC as Receiver. The liquidation of receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based on the foregoing, the Receiver has determined that the continued existence of the receiverships will serve no useful purpose. Consequently, notice is given that the receiverships shall be terminated, to be effective no sooner

than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, *Attention:* Receivership Oversight Department 8.1, 1601 Bryan Street, Dallas, Texas 75201.

No comments concerning the termination of these receiverships will be considered which are not sent within this time frame.

Dated: April 11, 2011.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2011–9127 Filed 4–14–11; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update Listing of Financial Institutions in Liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as "of record" notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *http://www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: April 11, 2011.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC Ref. No.	Bank name	City	State	Date closed
10351	Nevada Commerce Bank	Las Vegas	NV	04/08/2011
10352	Western Springs National Bank and Trust.	Western Springs	IL	04/08/2011

[FR Doc. 2011–9158 Filed 4–14–11; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 2, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. *Phillip Frost,* Miami Beach, Florida; to acquire voting shares of Coconut Grove Bankshares, Inc., and thereby indirectly acquire voting shares of Coconut Grove Bank, both of Miami, Florida.

Board of Governors of the Federal Reserve System, April 12, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–9166 Filed 4–14–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than May 12, 2011.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. *China Investment Corporation and Central Huijin Investment Limited,* both in Beijing, China; to become bank holding companies by indirectly acquiring 80 percent of the voting shares of The Bank of East Asia (U.S.A.) National Association, New York, New York.

2. *Industrial and Commercial Bank of China Limited,* Beijing, China; to become a bank holding company by acquiring 80 percent of the voting shares of The Bank of East Asia (U.S.A.) National Association, New York, New York.

Board of Governors of the Federal Reserve System, April 12, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–9165 Filed 4–14–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Evaluation of the Potential Developmental Effects of Cancer Chemotherapy During Pregnancy: Call for Information and Nomination of Scientific Experts

AGENCY: National Institute of Environmental Health Sciences (NIEHS); National Toxicology Program; National Institutes of Health (NIH), HHS.

ACTION: Call for information and nomination of scientific experts.

SUMMARY: CERHR is evaluating the scientific evidence regarding the potential developmental effects of cancer chemotherapy during pregnancy. CERHR invites the submission of information about ongoing studies or upcoming publications on the pregnancy outcomes and long-term health of offspring exposed to cancer chemotherapy agents during pregnancy and associated topics that might be considered for inclusion in the evaluation. CERHR also invites the nomination of scientific experts to potentially serve as technical advisors in conducting the evaluation or as members of an *ad hoc* expert panel to be convened to peer review the draft Monograph on Cancer Chemotherapy during Pregnancy (see **SUPPLEMENTARY INFORMATION**). The peer review meeting is tentatively scheduled for August 29–30, 2011 at the NIEHS. When set, the date and location of the meeting will be announced in the **Federal Register** and posted on the CERHR Website (*http://cerhr.niehs.nih.gov*). The peer review meeting will be open to the public with time scheduled for oral public comment.

DATES: All information and nominations should be received by May 16, 2011.

ADDRESSES: Information and nominations may be submitted to Dr. Kembra Howdeshell, CERHR, NTP, NIEHS, P.O. Box 12233, MD K2–04, Research Triangle Park, NC 27709 (mail), 919–316–4708 (telephone), or *howdeshellkl@niehs.nih.gov* (email). Courier address: NIEHS, 530 Davis Drive, Room K2161, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

A significant number of pregnant women are diagnosed with cancer each year. The frequency of such diagnoses is difficult to determine, but has been estimated to be between 1 in 1000 to 1 in 6000 pregnancies. Treatment for cancer most often involves some form of chemotherapy. The United States Food and Drug Administration has categorized nearly all chemotherapy agents as Pregnancy Category D, *i.e.,* investigational or post-marketing data show risk to the fetus. The evidence for risk for health effects from exposure to the chemotherapeutic agents usually comes from studies in laboratory animals. The general medical opinion on chemotherapy use during pregnancy is that it should be avoided in the first trimester and that treatment during the second and third trimesters, with the exception of a few chemotherapy agents, presents minimal risk to the fetus.

While some reviews have been published in the medical literature on pregnancy outcomes following chemotherapy during pregnancy, the majority of these reviews focus on specific cancer types or specific chemotherapeutic agents. Thus, CERHR proposes to conduct a comprehensive survey of the literature and systematically evaluate the scientific evidence regarding the developmental toxicity of cancer chemotherapy during pregnancy in humans for the six most frequently diagnosed cancers in pregnant women, *i.e.,* lymphoma, leukemia, and cancers of the breast, ovary, skin, and cervix. This review will evaluate a large literature, including more than 700 papers and approximately 40 chemotherapeutic agents, available on pregnancy outcomes in humans following chemotherapy. The CERHR evaluation will include studies of individual, as well as combinations of, chemotherapy agents and the period of gestation in which they are administered. The document should provide clinicians, patients, and researchers with a comprehensive review of the incidence and types of adverse effects observed in humans exposed *in utero* to cancer chemotherapy. While CERHR recognizes that some chemotherapeutic agents are also used to treat non-cancer health conditions of pregnant women, the focus of the proposed evaluation is on cancer chemotherapy. The NTP Board of Scientific Counselors (BSC) discussed the CERHR evaluation of developmental effects of cancer chemotherapy on June 21, 2010 (75 FR 21003). BSC meeting minutes are available at *http://ntp.niehs.nih.gov/go/9741.*

Request for Information

CERHR invites the public and other interested parties to submit information on cancer chemotherapy during pregnancy, including data on pregnancy outcomes, long-term health reports of human offspring, and laboratory animal toxicology information from completed, ongoing, or planned studies. This information will be considered in evaluating the potential developmental effects of exposure to cancer chemotherapy during pregnancy. Information should be submitted to CERHR (see **ADDRESSES**).

Request for Nomination of Scientific Experts

CERHR invites nominations of qualified scientists (*i.e.,* basic scientists, clinicians, and toxicologists) to serve as technical advisors and/or as members of an *ad hoc* expert panel to peer review the draft NTP Monograph on Cancer Chemotherapy during Pregnancy. Scientists serving as technical advisors or on the peer review panel should represent a wide range of expertise including, but not limited to: developmental biology, developmental toxicology, epidemiology, medicine (*e.g.,* obstetrics, oncology, and pediatrics), neurotoxicology, pharmacokinetics, reproductive toxicology, renal toxicology, and biostatistics. Technical advisors and expert panel members should meet criteria to serve as an expert including, but not limited to, formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, and membership in relevant professional societies. Nomination should include contact information and current curriculum vitae (if possible) and be forwarded to CERHR (see **ADDRESSES**). Final selection of individuals to serve on the peer review panel will be made in accordance with the Federal Advisory Committee Act and Department of Health and Human Services implementing regulations. All technical advisors and panel members serve as individual experts and not as representatives of their employers or other organizations.

Background Information on CERHR

The NTP established CERHR in 1998 (63 FR 68782). CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. CERHR publishes monographs that assess the evidence regarding whether

environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse effects on reproduction and/or development and provide opinion on whether these substances are hazardous for humans. Information about CERHR can be obtained from its homepage (*http://cerhr.niehs.nih.gov*).

Dated: April 7, 2011.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2011–9182 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues will conduct its fifth meeting in May. At this meeting, the Commission will discuss the topic of Federal standards regarding human subjects protection in Federally funded scientific studies.

DATES: The meeting will take place Wednesday, May 18, 2011, from 9 a.m. to approximately 4:45 p.m., and Thursday, May 19, 2011, from 9 a.m. to approximately 1:15 p.m.

ADDRESSES: The Warwick New York Hotel, 65 West 54th Street, New York, NY 10019. Phone 212–247–2700.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue, NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3963. E-mail: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *http://www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the fifth meeting of the Presidential Commission for the Study of Bioethical Issues (PCSBI). The meeting will be held from 9 a.m. to approximately 4:45 p.m. on Wednesday, May 18, 2011, and from 9 a.m. to approximately 1:15 p.m. on Thursday, May 19, 2011, at the Warwick New York Hotel, New York, NY. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *http://www.bioethics.gov.*

Under authority of Executive Order 13521, dated November 24, 2009, the President established PCSBI to serve as a public forum and advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that assure ethically responsible conduct of scientific research, healthcare delivery, and technological innovation. In undertaking these duties, the Commission will examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for useful international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The main agenda item for this fifth meeting is to review Federal as well as transnational standards of human subjects protections in scientific studies supported by the Federal government as requested by President Obama on November 24, 2010.

The draft meeting agenda and other information about PCSBI, including information about access to the webcast, will be available at *http://www.bioethics.gov.*

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. There will be a public comment session in the afternoon on May 18, 2011. Individuals who would like to provide public comment at that time should notify Esther Yoo by telephone at 202–233–3960, or e-mail at *Esther.Yoo@bioethics.gov* before May 9, 2011. To accommodate as many speakers as possible the time for each individual to speak may be limited. If the number of individuals wishing to speak is greater than can reasonably be accommodated during the scheduled meeting, the Commission may randomly select speakers from among those who register to speak.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should also notify Esther Yoo (contact information above) in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Written comments will also be accepted and are especially welcome. Please address written comments by e-mail to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW, Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: April 6, 2011.

Valerie H. Bonham,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2011–9123 Filed 4–14–11; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10369]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Solicitation for Applications: Community-based Care Transitions Program; *Use:* The Community-based Care Transitions Program (CCTP) described in Section 3026 of the Affordable Care Act will run for 5 years with a mandated start date of January 1, 2011. This program provides funding to community-based organizations in partnership with acute care hospitals for the provision of care transition services delivered to high risk

Medicare beneficiaries. The legislation provides $500,000,000 for the program. The goals of the CCTP are to improve transitions of beneficiaries from the inpatient hospital setting to other care settings, to improve quality of care, to reduce readmissions for high risk beneficiaries, and to document measureable savings to the Medicare program. *Form Number:* CMS–10369 (OMB#: 0938–NEW); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 80,000. (For policy questions regarding this collection contact Juliana Tiongson at 410–786–0342. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 14, 2011:*

1. Electronically. You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 6, 2011.

Martique Jones,

Director, Regulations Development Group—Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–9125 Filed 4–12–11; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–216–94 and CMS–10112]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization/Histocompatibility Laboratory Statement of Reimbursable Costs, manual instructions and supporting regulations contained in 42 CFR 413.20 and 413.24; *Use:* This form is required by statue and regulation for participation in the Medicare program. The information is used to determine payment for Medicare. Organ Procurement Organizations and Histocompatibility Laboratories are the users. *Form Number:* CMS–216–94 (OMB# 0938–0102); Frequency: Yearly; *Affected Public:* Business or other for-profit, Not-for-profit institutions; Number *of Respondents:* 115; *Total Annual Responses:* 115; *Total Annual Hours:* 5175. (For policy questions regarding this collection contact Angela Havrilla at 410–786–4516 or Amelia Citerone at 410–786–3901. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Phone Surveys of Products and Services for Medicare Payment Validation and Supporting Regulations in 42 CFR 405.502. *Use:* The phone surveys of products and services for Medicare payment validation and supporting regulations in 42 CFR 405.502 will be used to identify specific products/services provided to Medicare beneficiaries and the costs associated with the provision of those products/services. The information collected will be used to validate the Medicare payment amounts for those products/services and institute revisions of payment amounts where necessary. The respondents will be the companies that have provided the product/service under review to Medicare beneficiaries. *Form Number:* CMS–10112 (OMB# 0938–0939); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profit; *Number of Respondents:* 4,000; *Total Annual Responses:* 4,000; *Total Annual Hours:* 16,000. (For policy questions regarding this collection contact Michael Rich at 410–786–6856. For all other issues call 410–786–1326.)

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 16, 2011.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: April 8, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–9024 Filed 4–14–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–304 and CMS–304a; and CMS–368 and CMS–R–144]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment.

Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program—Labelers Reconciliation of State Invoice (CMS–304) and Prior Quarter Adjustment Statement (CMS–304a); *Use:* Section 1927(b)(2) of the Social Security Act establishes manufacturer requirements for paying quarterly rebates to States as part of the Medicaid Drug Rebate Program. Specifically, in order to receive a rebate on drugs dispensed to Medicaid recipients, States are required to submit quarterly utilization data to drug manufacturers that have national rebate agreements with the Federal Government. Form CMS–304 is used by manufacturers for both unit adjustments and disputes in response to the State's invoice for current quarter utilization. The form CMS–304a is required only in those instances where a manufacturer discovers unit adjustments and/or disputes from a previous quarter's State invoice. Both forms are used to reconcile drug rebate payments made by manufacturers with the State invoices of rebates due; *Form Numbers:* CMS–304 and CMS–304a (OMB#: 0938–0676); *Frequency:* Quarterly; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 1,011; *Total Annual Responses:* 4,044; *Total Annual Hours:* 183,120. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Medicaid Drug Rebate Forms: CMS–R–144 (Quarterly Report Data) and CMS–368 (Administrative Data); *Use:* Section 1927(b)(2) of the Social Security Act establishes State requirements for reporting drug utilization data to CMS and to drug manufacturers participating in the Medicaid Drug Rebate Program. Specifically, in order to receive a rebate on drugs dispensed to Medicaid recipients, States are required to submit quarterly utilization data reports to drug manufacturers that have national rebate agreements with the Federal Government. In addition, a copy of these reports must also be submitted to CMS. Form CMS–R–144 is used by the States to submit this utilization information to both manufacturers and CMS. Form CMS–368 is a report of contact for the State to name the individuals involved in the drug rebate program and is required only in those instances where a change to the original data submittal is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of the rebate program; *Form Numbers:* CMS–R–144 and CMS–368 (OMB#: 0938–0852); *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 14, 2011:*

1. Electronically. You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: April 8, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–9025 Filed 4–14–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10337]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Limited Competition for State Planning and Establishment Grants for the Affordable Care Act's Exchanges; *Use:* On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act. On March 30, 2010, the Health Care and Education Reconciliation Act of 2010 was signed into law. The two laws are collectively referred to as the Affordable Care Act. The Affordable Care Act includes a wide variety of provisions designed to expand coverage, provide more health care choices, enhance the quality of health care for all Americans, hold insurance companies more accountable, and lower health care costs.

The Affordable Care Act provides each State with the option to set up a State-operated Health Benefits

Exchange. An Exchange is an organized marketplace to help consumers and small businesses buy health insurance in a way that permits easy comparison of available plan options based on price, benefits, and quality. By pooling people together, reducing transaction costs, and increasing price and quality transparency, Exchanges create more efficient and competitive health insurance markets for individuals and small employers. The Exchange will carry out a number of functions as required by the Affordable Care Act, including certifying qualified health plans, administering premium tax credits and cost-sharing reductions, responding to consumer requests for assistance, and providing an easy-to-use website and written materials that individuals can use to assess eligibility and enroll in health insurance coverage, and coordinating eligibility for and enrollment in other state health subsidy programs, including Medicaid and CHIP. Section 1311 of the Affordable Care Act provides for grants to States for the planning and establishment of American Health Benefit Exchanges. The Secretary is planning to disburse funds in at least three phases: first, for planning; second, for early information technology development; and third, for implementation. $51 million was made available for States for State Exchange planning. Forty-nine States and the District of Columbia applied and have been awarded grant funds. $5 million was made available for Territories Exchange early implementation. Five Territories were eligible to receive a Notice of Grant Award; four applied and have been awarded funds. States and Territories are eligible for up to $1 million each from this grant announcement, which will extend for up to twelve months. *Form Number:* CMS–10337 (OCN: 0938–1101); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Number of Responses:* 594; *Total Annual Hours:* 277,533. (For policy questions regarding this collection, contact Katherine Harkins at (301) 492–4445. For all other issues call (410) 786–1326.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Consumer Assistance Program Grants; *Use:* Section 1002 of the Affordable Care Act provides for the establishment of consumer assistance (or ombudsman) programs, starting in FY 2010. Federal grants will support these programs. For FY 2010, $30 million is appropriated. These programs will assist consumers with filing complaints and appeals, assist consumers with enrollment into health coverage, collect data on consumer inquiries and complaints to identify problems in the marketplace, educate consumers on their rights and responsibilities, and starting in 2014, resolve problems with premium credits for Exchange coverage. Importantly, these programs must provide detailed reporting on the types of problems and questions consumers may experience with health coverage, and how these are resolved. In order to strengthen oversight, the law requires programs to report data to the Secretary of the Department of Health and Human Services (HHS) "As a condition of receiving a grant under subsection (a), an office of health insurance consumer assistance or ombudsman program shall be required to collect and report data to the Secretary on the types of problems and inquiries encountered by consumers" (Sec. 2793 (d)). *Form Number:* CMS–10333 (OMB–0938–1097); *Frequency:* Quarterly; *Affected Public:* Private Sector: State, Local, or Tribal Governments; *Number of Respondents:* 40; *Number of Responses:* 200; *Total Annual Hours:* 4,800 . (For policy questions regarding this collection, contact Eliza Bangit at (301) 492–4219. For all other issues call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *June 14, 2011:*

1. Electronically. You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–9208 Filed 4–14–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5055–N2]

Medicare Program; Solicitation for Proposals for the Medicare Community-Based Care Transitions Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply to participate in the Medicare Community-based Care Transitions Program, which was authorized by section 3026 of the Affordable Care Act.

DATES: Proposals will be accepted on a rolling basis. Acceptable applicants will be awarded on an ongoing basis as funds permit.

FOR FURTHER INFORMATION CONTACT: Juliana Tiongson, (410) 786–0342 or by e-mail at *CareTransitions@cms.hhs.gov.*

ADDRESSES: Proposals should be mailed to the following address:

Centers for Medicare & Medicaid Services, Attention: Juliana Tiongson, 7500 Security Boulevard, Mail Stop: C4–14–15, Baltimore, Maryland 21244–1850.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3026 of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010) (Affordable Care Act) authorized the Medicare Community-based Care Transitions Program (CCTP). The goals of the CCTP are to improve the quality of care transitions, reduce readmissions for high risk Medicare beneficiaries, and document measurable savings to the Medicare program by reducing unnecessary readmissions. The CCTP is part of Partnership for Patients, a national patient safety initiative through which the Administration is supporting broad-based efforts to reduce harm caused to patients in hospitals and improve care transitions.

II. Criteria for Applicants

We are seeking eligible organizations which are a subsection (d) hospital, as defined in section 1886(d)(1)(B) of the Social Security Act (the Act), with high readmission rates that partner with community-based organizations (CBOs) or CBOs that provide care transition services. CBOs are defined as community-based organizations that provide care transition services across the continuum of care through arrangements with subsection (d) hospitals and whose governing bodies include sufficient representation of multiple health care stakeholders, including consumers.

This program creates a source of funding for care transition services that effectively manage transitions from acute to community-based settings and report specified process and outcome measures on their results. CBOs will be paid on a per eligible discharge basis for eligible Medicare beneficiaries at high risk for readmission, including those with multiple chronic conditions, depression, or cognitive impairments.

In selecting CBOs to participate in the program, preference will be given to eligible entities that are Administration on Aging (AoA) grantees that provide concurrent care transition interventions with multiple hospitals and practitioners or entities that provide services to medically-underserved populations, small communities, and rural areas. The program will run for 5 years beginning April 11, 2011; however, participants will be awarded 2-year agreements that may be extended on an annual basis for the remaining 3 years based on performance.

Applicants must identify root causes of readmissions and define their target population and strategies for identifying high risk patients. Applicants must also specify care transition interventions including strategies for improving provider communications in care transitions and improving patient activation. Lastly, applicants will be required to provide a budget including a per eligible discharge rate for care transition services, provide an implementation plan with milestones, and demonstrate prior experience with effectively managing care transition services and reducing readmissions.

A competitive process will be used to select eligible organizations. We will accept proposals on a rolling basis. The program will continue through 2015.

For specific details regarding the CCTP and the application process, please refer to the solicitation on the CMS Web site at *http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?itemID=CMS1239313.*

III. Application Information

Please refer to file code [CMS–5055–N2] on the application. Proposals (an unbound original and 3 copies plus an electronic copy on CD–ROM) must be typed for clarity and should not exceed 30 double-spaced pages, exclusive of cover letter, the executive summary, resumes, forms, and supporting documentation. Because of staffing and resource limitations, we cannot accept proposals by facsimile (FAX) transmission. Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receive a proposal in the manner intended by the applicant (for example, collated, tabulated color copies). Hard copies and electronic copies must be identical.

IV. Eligible Organizations

As discussed above, subsection (d) hospitals with high readmission rates that partner with CBOs or CBOs that provide care transition services are eligible to participate in the CCTP. We anticipate that a wide variety of interested parties may be eligible to form a CBO in order to apply in collaboration with other organizations to perform the responsibilities specified. CBOs may be characterized as physician practices, particularly primary care practices, a corporate entity that has a separate quality improvement organization (QIO) contract with CMS under Part B of title XI of the Act, in situations that will not result in or create the appearance of a conflict of interest between the QIO's review tasks under title XI and the corporate entity's role as a CBO, an Aging and Disability Resource Center, Area Agency on Aging, or other appropriate organization that meets the statutory definition at section 3026(b)(1)(B) of the Act.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: December 27, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–9126 Filed 4–12–11; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of a new Privacy Act system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Centers for Medicare and Medicaid Services (CMS), Center for Consumer Information and Insurance Oversight (CCIIO) is establishing a new system of records (SOR) titled the "Health Insurance Assistance Database (HIAD)," System No. 09–70–0586. This SOR is established under the authority of Sections 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) (Public Law (Pub. L.) 97–35) and § 1321(c) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148). Section 1321(c) of the Affordable Care Act authorizes HHS (1) to ensure that States with Exchanges are substantially enforcing the Federal standards to be set for the Exchanges and (2) to set up Exchanges in States that elect not to do so or are not substantially enforcing related provisions. Sections 2723 and 2761 of the PHS Act authorize HHS to enforce provisions that apply to non-Federal governmental plans and to enforce PHS Act provisions that apply to other health insurance coverage in States that HHS has determined are not substantially enforcing those provisions. The HIAD database will be maintained by the Office of Consumer Support Health Insurance Assistance Team (the Team) to assist the Office of Oversight with its compliance activities. HIAD is the primary tool through which the Team will track information for the purposes of oversight.

The primary purpose of this system is to collect and maintain information on consumer inquiries and complaints regarding insurance issuers that will permit CCIIO to exercise its direct enforcement authority over non-Federal governmental health plans, investigate any inquiries or complaints from enrollees of those plans, to determine which States may not be substantially enforcing the Affordable Care Act and PHS Act provisions and to determine whether complaints that indicate

possible noncompliance with Federal law are resolved by the plans. In addition, information maintained will enable CCIIO to develop aggregate reports that will inform CMS and HHS about compliance issues. Information in this system will also be disclosed to: (1) Support regulatory and programmatic activities such as investigations and reporting activities performed by an Agency contractor, consultants, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees; (2) assist another Federal and/or State agency, agency of a State government, or an agency established by State law; (3) support litigation involving the Agency; (4) combat fraud, waste, and abuse in certain health benefits programs, and (5) assist in a response to a suspected or confirmed breach of the security or confidentiality of information. We have provided background information about this new system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that CMS provide an opportunity for interested persons to comment on the proposed routine uses, CMS invites comments on all portions of this notice. See "Effective Dates" section for information about the comment period.

DATES: *Effective Dates:* CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on *April 11, 2011.* To ensure that all parties have adequate time in which to comment, the new system, including routine uses, will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless CMS receives comments that require alterations to this notice.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Information Security and Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N1–24–08, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Tibbits, Team Leader, Health Insurance Assistance Team, Office of Consumer Support, Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244. His telephone number is 301–492–4229 or via e-mail at *paul.tibbits@hhs.gov.*

SUPPLEMENTARY INFORMATION: CCIIO has direct enforcement authority over non-Federal governmental health plans, and any inquiries or complaints from enrollees of those plans will be logged into this database for the purpose of following up to determine whether complaints that indicate possible noncompliance with Federal law are resolved by the plans. In addition, consumer inquiries and complaints regarding insurance issuers will be logged into the database in order to help CCIIO determine which States may not be substantially enforcing Affordable Care Act and PHS Act provisions, and, in the event Federal enforcement is necessary, in order to follow up to determine whether complaints that indicate possible noncompliance with Federal law are resolved by the issuers.

Section 1321(c) of the Affordable Care Act authorizes HHS (1) to ensure that States with Exchanges are substantially enforcing the Federal standards to be set for the Exchanges and (2) to set up Exchanges in States that elect not to do so or are not substantially enforcing related provisions. Sections 2723 and 2761 of the PHS Act authorize HHS to enforce PHS Act provisions that apply to non-Federal governmental plans and to enforce PHS Act provisions that apply to other health insurance coverage in States that HHS has determined are not substantially enforcing those provisions.

The database will be maintained by the Team to help CCIIO Office of Oversight with its compliance activities under the Affordable Care Act and PHS Act. Consumer inquiries and complaints addressed by the Team will help CCIIO conduct direct enforcement over non-Federal governmental health plans; the database will also help CCIIO determine which States are not substantially enforcing PHS Act provisions under HHS's Federal fallback authority in sections 2723 and 2761 of the PHS Act.

In the course of its work, the Team will: (1) Receive consumer inquiries; (2) respond to consumer inquiries in order to obtain the necessary information to determine the best course of action; (3) refer consumers to appropriate entities; and (4) when appropriate, gather information about consumers in order to assist CCIIO oversight capacity.

When responding to consumer contacts, the Team will pursue one of the following courses of action: (1) If it is determined that the consumer is covered by a non-Federal governmental plan, the Team will obtain enough information to determine whether the case merits referral to the Office of Oversight; (2) if it is determined that jurisdiction over a consumer's case lies with another entity, the Team will refer consumers to that entity, such as a State insurance department, the U.S. Department of Labor, or a State Consumer Assistance Program; or (3) if it is determined that the consumer seeks to file an appeal in a State or territory without an external appeals process in place, the Team will refer the consumer to the appropriate entity carrying out the Federal external appeals process.

As mentioned, the system will be used to create reports regarding the types of consumer inquiries and Affordable Care Act and PHS Act compliance issues that are brought to the attention of CCIIO by consumers. These reports will assist the Office of Oversight in identifying areas where compliance concerns may arise, and will be stripped of any information in identifiable form (IIF) and personal health information when written and prepared.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for System

Authority for the collection, maintenance, and disclosures from this system is provided under provisions of §§ 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) (Pub. L. 97–35) and § 1321(c) of the Patient Protection and Affordable Care Act (AFFORABLE CARE ACT) (Pub. L. 111—148).

B. Collection and Maintenance of Data in the System

The Health Insurance Assistance Database (HIAD) contains information on individuals who contact CCIIO's Health Insurance Assistance Team, complainants or other individuals with health insurance issues. The HIAD contains the name, address, State of residence and zip code; contact information such as telephone numbers, e-mail address, demographic information such as age, gender, ethnicity, family status, employment status, income level and veteran's status; and health insurance identification number, health insurance status, background, recent history and available options.

II. Agency Policies, Procedures, and Restrictions on Routine Uses

A. The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." The government will only release information collected in the HIAD that can be associated with an individual as provided for under "Section III. Proposed Routine Use Disclosures of Data in the System." Identifiable data may be disclosed under a routine use.

CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. In general, disclosure of information from the system will be approved only for the minimum information necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, *e.g.,* to collect, maintain, and process information on consumer inquiries and complaints regarding insurance issuers that will permit CCIIO to exercise its direct enforcement authority over non-Federal governmental health plans, if CMS;

2. Determines that:

a. the purpose of the disclosure can only be accomplished if the record is provided in an individually identifiable form;

b. the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual provider that additional exposure of the record might bring; and

c. there is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. remove or destroy at the earliest time all individually identifiable information; and

c. agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. Entities Who May Receive Disclosure Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the HIAD without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

1. To support Agency contractors, consultants, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees, and who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing a CMS function relating to purposes for this SOR.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor, consultant, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees whatever information is necessary for the contractor or consultant to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees from using or disclosing the information for any purpose other than that described in the contract and requires the contractor, consultant, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees to return or destroy all information at the completion of the contract.

2. To assist another Federal or State agency, agency of a State government, or an agency established by State law pursuant to agreements with CMS to:

a. Increase consumer assistance and accessibility to health care coverage by identifying insurer noncompliance with Federal, State and other applicable law, and

b. Assist Federally funded health insurance programs in administering functions tasked to them pursuant to the Affordable Care Act and other relevant Federal and State laws which may require CCIIO Program information related to this system.

c. Assist other Federal/State agencies that have the authority to perform collection of debts owed to the Federal government.

State Departments of Insurance can achieve greater regulation and oversight of the health insurance industry and strengthen enforcement in areas where problems arise by identifying trends and patterns in consumer inquiries and complaints.

The Internal Revenue Service (IRS), Department of the Treasury, can use CCIIO information for the purpose of resolving difficulties with obtaining premium tax credits under 36B of the Internal Revenue Code (IRC) of 1986 and to understand the consumer needs leading to the State health insurance Exchanges starting in 2014.

Federal, State, and local law enforcement agencies and private security contractors, may require CCIIO information to protect CCIIO employees and customers, provide security for CCIIO facilities or to assist investigations or prosecutions with respect to activities that affect such safety and security or activities that disrupts the operation of CCIIO operations and facilities.

3. To support the Department of Justice (DOJ), court, or adjudicatory body when:

a. the Agency or any component thereof, or

b. any employee of the Agency in his or her official capacity, or

c. any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

d. the United States Government,

is a party to litigation or has an interest in such litigation, and by careful review, HHS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

Whenever HHS is involved in litigation, or occasionally when another party is involved in litigation and HHS's policies or operations could be affected

by the outcome of the litigation, HHS would be able to disclose information to the DOJ, court, or adjudicatory body involved.

4. To assist a CMS contractor (including, but not limited to Medicare Administrative Contractors, fiscal intermediaries, and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contract or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste or abuse.

CMS occasionally contracts out certain of its functions when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

5. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

Other agencies may require CCIIO Program information for the purpose of combating fraud, waste or abuse in such Federally-funded programs.

6. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and unnecessary for the assistance.

Other Federal agencies and contractors may require CCIIO Program information for the purpose of assisting in a respond to a suspected or confirmed breach of the security or confidentiality of information.

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E–Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

V. Effects of the New System on the Rights of Individuals

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. We will only disclose the minimum personal data necessary to achieve the purpose of the data collection and the routine uses contained in this notice. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure. CMS has assigned a higher level of security clearance for the information maintained in this system in an effort to provide added security and protection of data in this system.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

Dated: March 18, 2011.

Steve Larsen,

Director, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services.

SYSTEM NUMBER:

09–70–0586.

SYSTEM NAME:

"Health Insurance Assistance Database" (HIAD), HHS/CMS/CCIIO.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various contractor sites.

Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, U.S. Department of Health & Human Services, Triple-I Core Site, 12100 Sunrise Valley Drive, Reston, Virginia 20191.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Information in this system is maintained on individuals who contact the CCIIO Health Insurance Assistance Team, complainants or other individuals with health insurance issues.

CATEGORIES OF RECORDS IN THE SYSTEM:

The HIAD contains the name, address, State of residence and zip code; contact information such as telephone numbers, e-mail address, demographic information such as age, gender, ethnicity, family status, employment status, income level and veteran's

status; and health insurance identification number, health insurance status, background, recent history and available options.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for the collection, maintenance, and disclosures from this system is provided under provisions of §§ 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) (Public Law (Pub. L.) 97–35) and § 1321(c) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148).

PURPOSE(S) OF THE SYSTEM:

The primary purposes of this system is to collect and maintain information on consumer inquiries and complaints regarding insurance issuers that will permit CCIIO to exercise its direct enforcement authority over non-Federal governmental health plans, investigate any inquiries or complaints from enrollees of those plans, to determine which States may not be substantially enforcing the Affordable Care Act and PHS Act provisions and to determine whether complaints that indicate possible noncompliance with Federal law are resolved by the plans. In addition, information maintained will enable CCIIO to develop aggregate reports that will inform CMS and HHS about compliance issues. Information in this system will also be disclosed to: (1) Support regulatory and programmatic activities such as investigations and reporting activities performed by an Agency contractor, consultants, CMS grantees, student volunteers, interns and other workers who do not have the status of Federal employees; (2) assist another Federal and/or State agency, agency of a State government, or an agency established by State law; (3) support litigation involving the Agency; (4) combat fraud, waste, and abuse in certain health benefits programs, and (5) assist in a response to a suspected or confirmed breach of the security or confidentiality of information.

I. PROPOSED ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

B. Entities Who May Receive Disclosure Under Routine Use

These routine uses specify circumstances, in addition to those provided by statute in the Privacy Act of 1974, under which CMS may release information from the HIAD without the consent of the individual to whom such information pertains. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. We propose to establish the following routine use disclosures of information maintained in the system:

3. To support Agency contractors, consultants, CMS grantees, student, volunteers, interns and other workers who do not have the status of Federal employees, who have been engaged by the Agency to assist in accomplishment of a CMS function relating to the purposes for this SOR and who need to have access to the records in order to assist CMS.

4. To assist another Federal or State agency, agency of a State government, or an agency established by State law pursuant to agreements with CMS to:

a. Increase consumer assistance and accessibility to health care coverage by identifying insurer noncompliance with Federal, State and other applicable law, and

b. Assist Federally funded health insurance programs in administering functions tasked to them pursuant to the Affordable Care Act and other relevant Federal and State laws which may require CCIIO Program information related to this system.

c. Assist other Federal/State agencies that have the authority to perform collection of debts owed to the Federal government.

5. To support the Department of Justice (DOJ), court, or adjudicatory body when:

e. The Agency or any component thereof, or

f. Any employee of the Agency in his or her official capacity, or

g. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or

h. The United States Government,

is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To assist a CMS contractor (including, but not limited to Medicare Administrative Contractors, fiscal intermediaries, and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such program.

7. To assist another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

8. To assist appropriate Federal agencies and Department contractors that have a need to know the information for the purpose of assisting the Department's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, and the information disclosed is relevant and unnecessary for the assistance.

II. SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also

applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained electronically in the CCIIO developed database for collection, tracking and storage of casework information and for reporting purposes. Any manually maintained records will be kept in locked cabinets or otherwise secured areas.

RETRIEVABILITY:

The records are retrieved electronically by a variety of fields, including but not limited to name, State, zip code, and health insurance identification number issued to the individual.

RETENTION AND DISPOSAL:

Records are maintained with identifiers for all transactions after they are entered into the system for a period of 10 years. Records are housed in both active and archival files. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from the Department of Justice.

SYSTEM MANAGER(S) AND ADDRESS:

Team Lead, Health Insurance Assistance Team, Office of Consumer Support, Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244.

NOTIFICATION PROCEDURE:

For purpose of notification, the subject individual should write to the system manager who will require the system name and the retrieval selection criteria (*e.g.,* name, health insurance claim number, SSN, *etc.*).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORD SOURCE CATEGORIES:

The identifying information contained in these records is provided voluntarily by the individual consumers, confidential informants, or by reports received from other sources . Additional case-relevant information may also be provided by the individual's employer or insurer to assist in achieving resolution of the specific case.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0264]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of existing FDA regulations regarding countries seeking to be designated as not subject to certain bovine spongiform encephalopathy (BSE)-related restrictions applicable to FDA-regulated human food and cosmetics.

DATES: Submit either electronic or written comments on the collection of information by June 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle—21 CFR 189.5 and 700.27 (OMB Control Number 0910–0623—Extension)

Section 801(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(a)) provides requirements with regard to imported food and cosmetics and provides for refusal of admission into the United States of human food and cosmetics that appear to be adulterated. Section 701(b) of the FD&C Act (21 U.S.C. 371(b)) authorizes the Secretaries of Treasury and Health and Human Services to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act. To address the potential risk of BSE in human food and cosmetics, FDA regulations in §§ 189.5 and 700.27 (21 CFR 189.5 and 700.27) designate certain materials from cattle as "prohibited cattle materials," including specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, and mechanically separated (MS) (Beef). Under the regulations no human food or cosmetic may be manufactured from, processed with, or otherwise contain prohibited cattle materials. However, the Agency may designate a country from which cattle materials inspected and passed for human consumption are not considered prohibited cattle materials and their use does not render a human food or cosmetic adulterated.

Sections 189.5(e) and 700.27(e) provide that a country seeking to be so designated must send a written request to the Director, Center for Food Safety and Applied Nutrition (CFSAN). The information the country is required to submit includes information about a country's BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and other information relevant to determining whether specified risk materials, the small intestine of cattle not otherwise excluded from being a prohibited cattle material, material from nonambulatory disabled cattle, or MS (Beef) from the country seeking designation should be considered prohibited cattle materials. FDA uses the information to determine whether to grant a request for designation, and whether to impose conditions if a request is granted.

Sections 189.5 and 700.27 further state that countries that have been designated under §§ 189.5(e) and 700.27(e) will be subject to future review by FDA to determine whether designation remains appropriate. As part of this process, FDA may ask designated countries to confirm that their BSE situation and the information submitted by them in support of their original application remain unchanged. FDA may revoke a country's designation if FDA determines that it is no longer appropriate. Therefore, designated countries may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. FDA uses the information to ensure that their designation remains appropriate.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 189.5 and 700.27— request for designation	1	1	1	80	80
§§ 189.5(e) and 700.27(e)—response to request for review by FDA	1	1	1	26	26
Total					106

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the average number of requests for designation under §§ 189.5 and 700.27 received in the past 3 years. FDA received one request for designation in 2009 and one in 2010. Based on this experience, FDA estimates the annual number of new requests for designation will be 1. FDA estimates that preparing the information required by §§ 189.5 and 700.27 and submitting it to the Agency in the form of a written request to the Director, CFSAN will require a burden of approximately 80 hours per request. Thus, the annual burden for new requests for designation is estimated to be 80 hours, as shown in table 1, row 1 of this document.

Under §§ 189.5(e) and 700.27(e), designated countries are subject to future review by FDA and may respond to periodic requests by FDA by submitting information to confirm that their designation remains appropriate. In the last 3 years, FDA has not requested any reviews. Thus, the Agency estimates that one or fewer will occur annually in the future. We estimate that the designated country undergoing a review in the future will need one third the time it took preparing its request for designation to respond to FDA's request for review, or 26 hours (80 hours x 0.33 = 26.4 hours, rounded to 26). The annual burden for reviews is estimated to be 26 hours, as shown in table 1, row 2 of this document. The total annual burden for this information collection is estimated to be 106 hours.

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9154 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0263]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on "Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak."

DATES: Submit either electronic or written comments on the collection of information by June 14, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experiment To Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak—(OMB Control Number 0910—NEW)

This proposed collection of information entitled "Experiment to Evaluate Risk Perceptions of Produce Growers, Food Retailers, and Consumers After a Food Recall Resulting From a Foodborne Illness Outbreak" will be conducted under a cooperative agreement between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Risk Communication Research (CRCR) at the University of Maryland. JIFSAN was established in 1996 and is a public and private partnership between FDA and the University of Maryland. The CRCR will design and administer the study.

FDA is requesting OMB approval under the PRA for the CRCR to conduct research with produce growers, food retailers, and consumers to gain information about these groups' risk perceptions associated with produce that has recently been subject to a food recall resulting from a foodborne illness outbreak. The purpose of this research is to help FDA better understand whether the magnitude and duration of the decline in commodity consumption following food recalls can be partly explained by grower and retailer speculations and projections about consumers' attitudes toward food recalls resulting from foodborne illness outbreaks. This research will be used to assess how grower, retailer, and consumer perceptions, attitudes, knowledge, and beliefs affect market recovery after a hypothetical fresh spinach recall.

Epidemiologists define foodborne illness outbreaks as two or more cases of a similar illness resulting from the ingestion of a common food (Ref. 1). Because many foodborne illness cases are mild, most outbreaks are never recognized or brought to the attention of public health authorities. When the outbreaks are large in scale or cause hospitalization, serious illness, or death, public health officials will inform the public in order to try to stop the spread of disease. A food recall can occur when a particular food in the marketplace is found to have a known contaminant, because either people have become sickened by it or pathogen testing has revealed contamination (Ref. 2). The purpose of a food recall is to rid retail establishments of the product and to inform consumers that they should discard the product if they have it in their homes. Although the purpose of a food recall is to keep consumers from becoming ill, food recalls can be costly to all sectors of the food distribution chain (Ref. 3). The goal of the proposed project is to test, by experimental study, whether the psychological tendency called "attribution error," contributes to unnecessarily prolonging the economic effects of a food recall. "Attribution error" is the tendency people have of overestimating others' negative response to situations compared to their own response. If industry decisionmakers' measures of consumer response are biased by "attribution error," industry could be contributing to its own slow recovery after a food recall.

When a widespread foodborne illness outbreak results in a food recall, the product can be out of the marketplace for an extended period of time; this occurred when fresh, bagged spinach was recalled in 2006 (Ref. 3). Tomatoes were also less available following the *Salmonella* Saintpaul outbreak in 2008 (Ref. 4). Although growers and retailers want to provide safe foods, decisions surrounding production, wholesale, and retail sales forecasting in response to a food recall affects how quickly the food is again available for consumption. We hypothesize that industry's over-attribution of consumers' fear of the food after such a food recall would result in the food being kept off of the market longer than necessary.

The CRCR plans to conduct an experiment using a Web-based questionnaire. The center will use a convenience sample of 900 participants (180 growers, 180 retailers, 540 consumers) drawn from industry networks (for the growers and retailers), and a Web-based panel of U.S. households (for the consumers). Participation in the study is voluntary.

This study will help FDA better understand the reasons for the time between a food recall resulting from a foodborne illness outbreak and market recovery. In order to understand the complexities of market recovery process, the CRCR will compare understandings and reactions of growers, retailers, and consumers to a hypothetical food recall resulting from a hypothetical foodborne illness outbreak. To make this comparison, individuals in each group will be assigned to one of the following experimental conditions (consisting of vignettes in the form of news articles on a hypothetical food recall): An "anger" scenario, a "fear" scenario, or a "control" scenario. After

reading the news article, participants will complete a questionnaire assessing their emotional response, appraisals, attribution of responsibility, perceptions about the safety of the affected produce, intentions to grow, sell, or buy the affected produce, perceived probability of a repeat event, and a measure of their innate ability to effectively respond to the information in the article.

To help design and refine the questionnaire, we will recruit 25 participants in order to conduct 10 cognitive interviews. We estimate cognitive interview recruitment will take 5 minutes (0.083 hours), for a total of 2 hours. The cognitive interviews are estimated at 1 hour per response for a total of 10 hours for the cognitive interview activities. We expect to send screeners to 800 members of a consumer panel, each taking 2 minutes (0.03 hours) to complete, for a total of 24 hours for the consumer panel screener activity. We also expect to administer 360 screeners to growers and retailers, each taking 2 minutes (0.033 hours) to complete, for a total of 24 hours (11 + 11 = 22). Twenty-four participants (20 consumers, 2 growers, 2 retailers) will complete the pre-test. Each pre-test will take 10 minutes (0.17 hours) for a total of 5 hours for the pre-test activity. We estimate that 900 individuals (540 consumers, 180 growers, and 180 retailers) will complete the questionnaire for the experiment, each taking 10 minutes (0.17 hours) for a total of 153 hours for the experimental study activities. The estimated total hour burden of the collection of information is 215 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Cognitive Interview Recruitment	25	1	25	5/60	2
Cognitive Interviews	10	1	10	1	10
Consumer Panel Screener	800	1	800	2/60	24
Grower Screener	360	1	360	2/60	11
Retailer Screener	360	1	360	2/60	11
Pre-tests	24	1	24	10/60	5
Experiment	900	1	900	10/60	153
Total					216

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

II. References

11. Olsen, S., L. MacKinon, *et al.,* "Surveillance for Foodborne Disease Outbreaks—United States, 1993 to1997," *Morbidity and Mortality Weekly Report* 49(SS01), pp. 1 through 51, 2000.
2. FDA 101: Product Recalls—From First Alert to Effectiveness Checks, Available at *http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm.*
3. Calvin, L., "Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices," *Amber Waves* 5(3), pp. 24 through 31, 2007.
4. Lucier, G. and R. Dettmann, "Vegetables and Melons Outlook," A Report From the United States Department of Agriculture, Economic Research Service, VGS–327, June 26, 2008.

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9155 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0241]

Determination of Regulatory Review Period for Purposes of Patent Extension; ATRYN; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 21, 2011 (76 FR 15323). The document announced the determination of the regulatory review period for ATRYN. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993–0002, 301–796–9138.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–6509, appearing on page 15323, in the **Federal Register** of Monday, March 21, 2011, the following correction is made:

1. On page 15323, in the first column, in the Docket No. heading, "[Docket No. FDA–2010–E–0241]" is corrected to read "[Docket No. FDA–2009–E–0241]".

Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9153 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Monday, May 16, 2011, from 8 a.m. to 3 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel's telephone number is 301–589–5200.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, Bldg. 32, rm. 5154, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0885, e-mail: *Walter.Ellenberg@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 16, 2011, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 110–85) for Bepreve (bepotastine besliate), Besivance (besifloxacin hydrochloride), Cetraxal (ciprofloxacin hydrochloride), Patanase Spray (olopatadine hydrochloride), Astepro Spray (azelastine hydrocholoride), Crestor (rosuvastatin calcium), Welchol (colesevelam hydrochloride), Intuniv (guanfacine), Lexapro (escitalopram oxalate), Actonel (risedronate), Hiberix [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)], and Valcyte (valganciclovir). The committee will also receive further followup on Topical Calcineurin Inhibitors: Elidel (pimecrolimus) and Protopic (tacrolimus).

The Pediatric Advisory Committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on May 11, 2011, regarding the Institutional Review Board process for clinical investigations that involve both an FDA regulated product and research involving children as subjects that is conducted or supported by HHS. The announcement of the May 11, 2011, Pediatric Ethics Subcommittee of the Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 2, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 25, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 26, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9150 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0184]

Pediatric Ethics Subcommittee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA and certain Department of Health and Human Services regulatory issues.

DATES: The meeting will be held on Wednesday, May 11, 2011, from 8 a.m. to 3 p.m.

FDA is opening a docket to allow for additional public comments to be submitted to the Agency on the issues before the Pediatric Ethics Subcommittee. Submit either electronic or written comments by May 5, 2011.

ADDRESSES: The meeting will be held at the North Marriott Hotel & Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993–0002, 301–796–0885, or by *e-mail: Walter.Ellenberg@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the

Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 11, 2011, the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss the general topic of the ethics of administering subtherapeutic doses of investigational products to children for the purpose of determining, for example, drug metabolism, disposition, and targeting (*e.g.,* exploratory investigational new drug (IND) studies). In this context, the subcommittee will also discuss the referral of such protocols by an Institutional Review Board for review by a Federal panel under 21 CFR 50.54.

The subcommittee's recommendations will then be presented to the FDA Pediatric Advisory Committee on Monday, May 16, 2011. The announcement of the May 16, 2011, Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before April 28, 2011. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on May 11, 2011. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 20, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 21, 2011.

Comments: FDA is opening a docket to allow for additional public comments to be submitted to the Agency on issues before the Pediatric Ethics Subcommittee beginning April 15, 2011, and closing May 5, 2011. All comments received on or before May 5, 2011, will be provided to the committee members. All comments received after May 5, 2011, will be taken into consideration by the Agency. Interested persons are encouraged to use the docket to submit either electronic or written comments regarding this meeting (*see* **ADDRESSES**). Submit electronic comments to *http://www.regulations.gov.* Submit written comments to Division of Dockets Management (*see* **ADDRESSES**). It is necessary to submit only one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets management between 9 a.m. and 4 p.m. Monday through Friday.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9149 Filed 4–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Food Reporting Comparison Study (FORCS) and Food and Eating Assessment Study (FEAST) (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Food Reporting Comparison Study (FORCS) and Food and Eating Assessment Study (FEAST) (NCI*). Type of Information Collection Request:* Extension. *Need and Use of Information Collection:* The title of this collection was previously, "24-hour Dietary Recall Method Comparison and the National Cancer Institute (NCI) Observational Feeding Studies." The objective of the two studies is to compare the performance of the newly developed computerized Automated Self-Administered 24-Hour Recall (ASA24) approach to collecting 24 hour recall (24HR) data with the current standard, the interviewer-administered Automated Multiple Pass Method (AMPM). The ultimate goal is to determine to what extent the new automated instrument can be used instead of the more expensive interviewer-administered instrument in the collection of dietary intake data. *Frequency of Response:* Twice. *Affected Public:* Individuals. *Type of Respondents:* For the FORCS study, approximately 1,200 adult members from three health maintenance organization plans (in Minnesota, California, and Michigan) between ages 20 and 70 years. For the FEAST study, approximately 90 adult residents from the Washington, DC metropolitan area between ages 20 and 70 years. The annual reporting burden is estimated at 866 hours (see table below). This amounts to an estimated 2,598 burden hours over the 3-year data collection period with a total cost to the respondents of $54,293. There are no Capital costs, Operating costs, and/or Maintenance Costs to report.

Participants and study	Questionnaire	Number of respondents	Frequency of response	Average time per response minutes/hour	Annual hour burden
General Public for FORCS ...	Refusal Reasons and Demographics (Attach 4A, Screen 8).	1,770	1	5/60 (0.083)	148
	Contact Information (Attach 4A, Screen 5).	400	1	5/60 (0.083)	33
	Screener (Attach 5)	400	1.00	5/60 (0.083)	33
	AMPM (Attach 1)	400	1.00	30/60 (0.50)	200
	ASA24 (Attach 2)	400	1.00	30/60 (0.50)	200
	Demographics and Health Questionnaire (Attach 6).	360	1.00	10/60 (0.167)	60
	Demographics, Health and Preference Questionnaire (Attach 7).	360	1.00	15/60 (0.25)	90
General Public for FEAST	Screener (Attach 8)	33	1.00	5/60 (0.083)	6
	Reminder Telephone Call (Attach 10).	33	1.00	5/60 (0.083)	6
	Eating 3 meals	33	1.00	135/60 (2.25)	151
	Either AMPM or ASA24 (Attach 1 or 2).	33	1.00	30/60 (0.50)	34
	Demographics and Health Questionnaire (Attach 12).	33	1.00	10/60 (0.167)	11
	.....	3,485	.....	.....	866

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans, contact Frances E. Thompson, PhD, Project Officer, National Cancer Institute, NIH, EPN 4095A, 6130 Executive Boulevard MSC 7335, Bethesda, Maryland 20892–7335, or call non-toll-free number 301–594–4410, or FAX your request to 301–435–3710, or e-mail your request, including your address, to *thompsof@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of this publication.

Dated: April 8, 2011.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011–9204 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Council of Councils.

Date: June 29, 2011.

Open: 8:30 a.m. to 12:30 p.m.

Agenda: Call to Order and Introductions; Announcements and Future Meeting Dates; DPCPSI Update; Remarks by the Director, NIH; and Review of NIH Common Fund Initiative Concepts: Process and Criteria.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: 1:30 p.m. to 2:20 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Open: 2:20 p.m. to 5:30 p.m.

Agenda: Overall Discussion & Recommendations and Closing Remarks.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Robin Kawazoe, Executive Secretary, Division Of Program Coordination, Planning, And Strategic Initiatives, Office Of The Director, NIH, Building 1, Room 260B, Bethesda, MD 20892. *kawazoer@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/,* where an agenda and proposals to be discussed will be posted before the meeting date.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license,

or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9131 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders, Special Emphasis Panel, R21/R33.

Date: May 12, 2011.

Time: 11:30 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call.)

Contact Person: Shiguang Yang, DVM, PhD, Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6120 Executive Blvd., Bethesda, MD 20892. 301–496–8683.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9129 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Deafness and Other Communication Disorders Advisory Council.

Date: May 20, 2011.

Closed: 8:30 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Open: 10 a.m. to 2:30 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, Ph.D., Director, Division of Extramural Activities, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892–7180. 301–496–8693. *jordanc@nidcd.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nidcd.nih.gov/about/groups/ndcdac/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9128 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Musculoskeletal, Oral and Skin Sciences.

Date: May 13, 2011.

Time: 8 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Rajiv Kumar, PhD, Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4216, MSC 7802, Bethesda, MD 20892, 301–435–1212, *kumarra@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience

Integrated Review Group, Neurobiology of Learning and Memory Study Section.

Date: May 26, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, NW., Washington, DC 20037.

Contact Person: John Bishop, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9132 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Protein Technologies.

Date: May 2, 2011.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Blvd., Room 8018, Rockville, MD 20852.

Contact Person: Shamala K. Srinivas, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8123, Bethesda, MD 20892, 301–594–1224, *ss537t@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9134 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Brain Development and Neurodegeneration.

Date: April 25, 2011.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jerry L Taylor, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892. 301–435–1175. *taylorje@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9133 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging

Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Organelle Lifespan Mechanism II.

Date: June 15, 2011.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, PhD, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814. 301–402–7701. *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Pathways To Healthy Old Age.

Date: June 15, 2011.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jeannette L. Johnson, PhD, Scientific Review Officer, National Institutes on Aging, National Institutes of Health, 7201 Wisconsin Avenue, SuitE 2C212, Bethesda, MD 20892, 301–402–7705. *Johnsonj9@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Dietary Restriction & Nonhuman Primate Aging I.

Date: June 30, 2011.

Time: 12:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, PhD, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814. 301–402–7701. *nakhaib@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9138 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Research Consortium for Bisphenol A Toxicity Study.

Date: May 10–11, 2011.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 530 Davis Drive, Research Triangle Park, NC 27709.

Contact Person: Janice B. Allen, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Science, P.O. Box 12233, MD EC–30/Room 3170 B, Research Triangle Park, NC 27709, (919) 541–7556.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Innovative Bioavailable Assays for Remediation.

Date: May 24, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Durham Southpoint, 7007 Fayetteville Road, Durham, NC 27713.

Contact Person: Sally Eckert-Tilotta, PhD, Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233 MD EC–30, Research Triangle Park, NC 27709, (919) 541–1446, *eckertt1@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 7, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9136 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute;

Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; BABYHUG Data Coordinating Center.

Date: May 17, 2011.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Youngsuk Oh, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924, 301–435–0277. *yoh@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; BABYHUG Clinical Center Contract Review.

Date: May 20, 2011.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Youngsuk Oh, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892–7924. 301–435–0277. *yoh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 8, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–9135 Filed 4–14–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5477–N–15]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7266, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were

reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Rita, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Air Force:* Mr. Robert Moore, Air Force Real Property Agency, 143 Billy Mitchell Blvd., San Antonio, TX 78226, (210) 925–3047; *COE:* Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street, NW, Washington, DC 20314; (202) 761–5542; *Energy:* Mr. Mark Price, Department of Energy, Office of Engineering & Construction Management, MA–50, 1000 Independence Ave, SW, Washington, DC 20585: (202) 586–5422; *GSA:* Mr. Gordon Creed, Acting Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th & F Streets, NW., Washington, DC 20405; (202) 501–0084;

Interior: Mr. Michael Wright, Acquisition & Property Management, Department of the Interior, 1801 Pennsylvania Ave, NW., 4th Floor, Washington, DC 20006: (202) 208–5399;

Dated: April 7, 2011.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 04/15/2011

Suitable/Available Properties

Building

Nebraska

10 Bldgs.
Temp. Lodging
Offutt NE 68113
Landholding Agency: Air Force
Property Number: 18201120014
Status: Excess
Directions: 5089, 5090, 5091, 5092, 5093, 5094, 5095, 5097, 5098, 5099
Comments: Off-site removal only, sq. ft. varies btw. each bldg., current-use: temp. lodging, good to fair conditions for all bldgs.

Texas

FAA RML Facility
11262 N. Houston Rosslyn Rd.
Houston TX 77086
Landholding Agency: GSA
Property Number: 54201110016
Status: Surplus
GSA Number: 7–U–TX–1129
Comments: 448 sq. ft., recent use: storage, asbestos has been identified in the floor.

Suitable/Available Properties

Land

Colorado

Common Pt. Shooting Rng.
Bureau of Reclamation
Drake CO 80515
Landholding Agency: GSA
Property Number: 54201120003
Status: Excess
GSA Number: 7–1–CO—0678
Comments: 35.88 acres; If the purchaser ceases using the property as a firing range they will be held to a higher standard of lead remediation by the local and Federal environmental protection agencies.

Louisiana

Almonaster
4300 Almonaster Ave.
New Orleans LA 70126
Landholding Agency: GSA
Property Number: 54201110014
Status: Surplus
GSA Number: 7–D–LA–0576
Comments: 9.215 acres.

New York

Floyd Wknd Training Site
Koenig Rd
Floyd NY 13440
Landholding Agency: GSA
Property Number: 54201120002
Status: Excess
GSA Number: 1–D–NY–0958
Comments: The bldgs. on this land were deemed "unsuitable" due to extensive deterioration (property # 54201120001); however the land was deemed "suitable/available", .+/− 51.2 acres, current-use: field training.

Suitable/Unavailable Properties

Building

Georgia

Ft. Benning Railroad Corridor
Cusseta Road
Columbus GA 31401
Landholding Agency: GSA
Property Number: 54201030006
Status: Excess
GSA Number: 4–D–GA–0518AD
Comments: 55 linear acres, multiple easements, most recent use—railroad/utility corridor, portion is under lease until 12/31/2010.

Iowa

Former SSA Bldg.
3012 Division Street
Burlington IA 52601
Landholding Agency: GSA
Property Number: 54201020005

Status: Excess
GSA Number: 7–G–IA–0508
Comments: 5060 sq. ft., most recent use—office.

Louisiana

FAA Outermarker
St. Charles Parish
New Orleans LA 70094
Landholding Agency: GSA
Property Number: 54201030007
Status: Excess
GSA Number: 7–U–LA–574–1
Comments: 48 sq. ft., legal constraints, mining leases, located near landfill/airport, most recent use—storage.

Maryland

Appraisers Store
Baltimore MD 21202
Landholding Agency: GSA
Property Number: 54201030016
Status: Excess
GSA Number: 4–G–MD–0623
Comments: Redetermination: 169,801 sq. ft., most recent use—federal offices, listed in the Nat'l Register of Historic Places, use restrictions.

Michigan

CPT George S. Crabbe USARC
2901 Webber Street
Saginaw MI
Landholding Agency: GSA
Property Number: 54201030018
Status: Excess
GSA Number: 1–D–MI–835
Comments: 3891 sq. ft., 3-bay garage maintenance building.

North Carolina

Greensboro Federal Bldg.
320 Federal Place
Greensboro NC 27401
Landholding Agency: GSA
Property Number: 54201040018
Status: Excess
GSA Number: 4–G–NC–750
Comments: 94,809 sq. ft. office bldg., major structural issues exist with exterior brick facade.

Ohio

Belmont City Memorial USAR Ctr
5305 Guernsey St.
Bellaire OH 43906
Landholding Agency: GSA
Property Number: 54201020008
Status: Excess
GSA Number: 1–D–OH–837
Comments: 11,734 sq. ft.—office/drill hall; 2,519 sq. ft.—maint. shop.

Army Reserve Center
5301 Hauserman Rd.
Parma OH 44130
Landholding Agency: GSA
Property Number: 54201020009
Status: Excess
GSA Number: I–D–OH–842
Comments: 29, 212, and 6,097 sq. ft.; most recent use: office, storage, classroom, and drill hall; water damage on 2nd floor; and wetland property.

2LT George F. Pennington USARC
2164 Harding Hwy. E.
Marion OH 43302
Landholding Agency: GSA
Property Number: 54201020010
Status: Excess
GSA Number: I–D–OH–838
Comments: 4,396 and 1,325 sq. ft; current use: office and storage; asbestos identified.

Oregon

Residence
140 Government Road
Malheur Nat'l Forest
John Day OR 97845
Landholding Agency: GSA
Property Number: 54201040012
Status: Excess
GSA Number: 9–A–OR–0786–AA
Comments: 1560 sq. ft., presence of asbestos/lead paint, off-site use only.

South Carolina

Naval Health Clinic
3600 Rivers Ave.
Charleston SC 29405
Landholding Agency: GSA
Property Number: 54201040013
Status: Excess
GSA Number: 4–N–SC–0606
Comments: Redetermination: 399,836 sq. ft., most recent use: office.

Virginia

Sewell's Point Substation
Hampton Blvd.
Norfolk VA 23505
Landholding Agency: GSA
Property Number: 54201030009
Status: Excess
GSA Number: 4–N–VA–0753
Comments: 400 sq. ft., permanent utility easement, most recent use—electrical substation.

Washington

Fox Island Naval Lab
630 3rd Ave.
Fox Island WA 98333
Landholding Agency: GSA
Property Number: 54201020012
Status: Surplus
GSA Number: 9–D–WA–1245
Comments: 6405 sq. ft.; current use: office and lab.

West Virginia

Harley O. Staggers Bldg.
75 High St.
Morgantown WV 26505
Landholding Agency: GSA
Property Number: 54201020013
Status: Excess
GSA Number: 4–G–WV–0557
Comments: 57,600 sq. ft; future owners must maintain exposure prevention methods (details in deed); most recent use: P.O. and federal offices.

Suitable/Unavailable Properties Land

Arizona

0.30 acre
Bethany Home Road
Glendale AZ 85306
Landholding Agency: GSA
Property Number: 54201030010
Status: Excess
GSA Number: 9–I–AZ–0859
Comments: 10 feet wide access road.

California

Parcel F–2 Right of Way
Seal Beach CA 90740
Landholding Agency: GSA
Property Number: 54201030012
Status: Surplus
GSA Number: 9–N–CA–1508–AI
Comments: Correction: 631.62 sq. ft., encroachment.

Parcel F–4 Right of Way
Seal Beach CA
Landholding Agency: GSA
Property Number: 54201030014
Status: Surplus
GSA Number: 9–N–CA–1508–AK
Comments: 126.32 sq. ft., within 3 ft. set back required by City.

Drill Site #3A
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040004
Status: Surplus
GSA Number: 9–B–CA–1673–AG
Comments: 2.07 acres, mineral rights, utility easements.

Drill Site #4
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040005
Status: Surplus
GSA Number: 9–B–CA–1673–AB
Comments: 2.21 acres, mineral rights, utility easements.

Drill Site #6
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040006
Status: Surplus
GSA Number: 9–B–CA–1673–AC
Comments: 2.13 acres, mineral rights, utility easements.

Drill Site #9
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040007
Status: Surplus
GSA Number: 9–B–CA–1673–AH
Comments: 2.07 acres, mineral rights, utility easements.

Drill Site #20
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040008
Status: Surplus
GSA Number: 9–B–CA–1673–AD
Comments: 2.07 acres, mineral rights, utility easements.

Drill Site #22
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040009
Status: Surplus
GSA Number: 9–B–CA–1673–AF
Comments: 2.07 acres, mineral rights, utility easements.

Drill Site #24
Ford City CA 93268
Landholding Agency: GSA
Property Number: 54201040010
Status: Surplus
GSA Number: 9–B–CA–1673–AE
Comments: 2.06 acres, mineral rights, utility easements.

Drill Site #26
Ford City CA 93268
Landholding Agency: GSA

Property Number: 54201040011
Status: Surplus
GSA Number: 9–B–CA–1673–AA
Comments: 2.07 acres, mineral rights, utility easements.

Kentucky

Tract 2625
Barkley Lake, Kentucky, and Tennessee
Cadiz KY 42211
Landholding Agency: COE
Property Number: 31199010025
Status: Excess
Directions: Adjoining the village of Rockcastle.
Comments: 2.57 acres; rolling and wooded.

Tract 2709–10 and 2710–2
Barkley Lake, Kentucky and Tennessee
Cadiz KY 42211
Landholding Agency: COE
Property Number: 31199010026
Status: Excess
Directions: 2½ miles in a southerly direction from the village of Rockcastle.
Comments: 2.00 acres; steep and wooded.

Tract 2708–1 and 2709–1
Barkley Lake, Kentucky and Tennessee
Cadiz KY 42211
Landholding Agency: COE
Property Number: 31199010027
Status: Excess
Directions: 2½ miles in a southerly direction from the village of Rockcastle.
Comments: 3.59 acres; rolling and wooded; no utilities.

Tract 2800
Barkley Lake, Kentucky and Tennessee
Cadiz KY 42211
Landholding Agency: COE
Property Number: 31199010028
Status: Excess
Directions: 4½ miles in a southeasterly direction from the village of Rockcastle.
Comments: 5.44 acres; steep and wooded.

Tract 2915
Barkley Lake, Kentucky and Tennessee
Cadiz KY 42211
Landholding Agency: COE
Property Number: 31199010029
Status: Excess
Directions: 6½ miles west of Cadiz.
Comments: 5.76 acres; steep and wooded; no utilities.

Tract 2702
Barkley Lake, Kentucky and Tennessee
Cadiz KY 42211
Landholding Agency: COE
Property Number: 31199010031
Status: Excess
Directions: 1 mile in a southerly direction from the village of Rockcastle.
Comments: 4.90 acres; wooded; no utilities.

Tract 4318
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199010032
Status: Excess
Directions: Trigg Co. adjoining the city of Canton, KY. on the waters of Hopson Creek.
Comments: 8.24 acres; steep and wooded.

Tract 4502
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199010033
Status: Excess
Directions: 3½ miles in a southerly direction from Canton, KY.
Comments: 4.26 acres; steep and wooded.

Tract 4611
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199010034
Status: Excess
Directions: 5 miles south of Canton, KY.
Comments: 10.51 acres; steep and wooded; no utilities.

Tract 4619
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199010035
Status: Excess
Directions: 4½ miles south from Canton, KY.
Comments: 2.02 acres; steep and wooded; no utilities.

Tract 4817
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199010036
Status: Excess
Directions: 6½ miles south of Canton, KY.
Comments: 1.75 acres; wooded.

Tract 1217
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010042
Status: Excess
Directions: On the north side of the Illinois Central Railroad.
Comments: 5.80 acres; steep and wooded.

Tract 1906
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010044
Status: Excess
Directions: Approximately 4 miles east of Eddyville, KY.
Comments: 25.86 acres; rolling steep and partially wooded; no utilities.

Tract 1907
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42038
Landholding Agency: COE
Property Number: 31199010045
Status: Excess
Directions: On the waters of Pilfen Creek, 4 miles east of Eddyville, KY
Comments: 8.71 acres; rolling steep and wooded; no utilities.

Tract 2001 #1
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010046
Status: Excess
Directions: Approximately 4½ miles east of Eddyville, KY.
Comments: 47.42 acres; steep and wooded; no utilities.

Tract 2001 #2
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010047
Status: Excess
Directions: Approximately 4½ miles east of Eddyville, KY.
Comments: 8.64 acres; steep and wooded; no utilities.

Tract 2005
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010048
Status: Excess
Directions:Approximately 5½ miles east of Eddyville, KY.
Comments: 4.62 acres; steep and wooded; no utilities.

Tract 2307
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010049
Status: Excess
Directions: Approximately 7½ miles southeasterly of Eddyville, KY.
Comments: 11.43 acres; steep; rolling and wooded; no utilities.

Tract 2403
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010050
Status: Excess
Directions: 7 miles southeasterly of Eddyville, KY.
Comments: 1.56 acres; steep and wooded; no utilities.

Tract 2504
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010051
Status: Excess
Directions: 9 miles southeasterly of Eddyville, KY.
Comments: 24.46 acres; steep and wooded; no utilities.

Tract 214
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199010052
Status: Excess
Directions: South of the Illinois Central Railroad, 1 mile east of the Cumberland River.
Comments: 5.5 acres; wooded; no utilities.

Tract 215
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199010053
Status: Excess
Directions: 5 miles southwest of Kuttawa
Comments: 1.40 acres; wooded; no utilities.

Tract 241
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199010054
Status: Excess
Directions: Old Henson Ferry Road, 6 miles west of Kuttawa, KY.
Comments: 1.26 acres; steep and wooded; no utilities.

Tracts 306, 311, 315 and 325
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199010055
Status: Excess
Directions: 2.5 miles southwest of Kuttawa, KY on the waters of Cypress Creek.
Comments: 38.77 acres; steep and wooded; no utilities.

Tracts 2305, 2306, and 2400–1
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42030
Landholding Agency: COE
Property Number: 31199010056
Status: Excess
Directions: 6½ miles southeasterly of Eddyville, KY.
Comments: 97.66 acres; steep rolling and wooded; no utilities.

Tracts 5203 and 5204
Barkley Lake, Kentucky and Tennessee
Linton KY 42212
Landholding Agency: COE
Property Number: 31199010058
Status: Excess
Directions: Village of Linton, KY state highway 1254.
Comments: 0.93 acres; rolling, partially wooded; no utilities.

Tract 5240
Barkley Lake, Kentucky and Tennessee
Linton KY 42212
Landholding Agency: COE
Property Number: 31199010059
Status: Excess
Directions: 1 mile northwest of Linton, KY.
Comments: 2.26 acres; steep and wooded; no utilities.

Tract 4628
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199011621
Status: Excess
Directions: 4½ miles south from Canton, KY.
Comments: 3.71 acres; steep and wooded; subject to utility easements.

Tract 4619–B
Barkley Lake, Kentucky and Tennessee
Canton KY 42212
Landholding Agency: COE
Property Number: 31199011622
Status: Excess
Directions: 4½ miles south from Canton, KY.
Comments: 1.73 acres; steep and wooded; subject to utility easements.

Tract 2403–B
Barkley Lake, Kentucky and Tennessee
Eddyville KY 42038
Landholding Agency: COE
Property Number: 31199011623
Status: Unutilized
Directions: 7 miles southeasterly from Eddyville, KY.
Comments: 0.70 acres, wooded; subject to utility easements.

Tract 241–B
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199011624
Status: Excess
Directions: South of Old Henson Ferry Road, 6 miles west of Kuttawa, KY.
Comments: 11.16 acres; steep and wooded; subject to utility easements.

Tract 215–B
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199011626
Status: Excess
Directions: 5 miles southwest of Kuttawa
Comments: 1.00 acres; wooded; subject to utility easements.

Tract N–819
Dale Hollow Lake Project
Illwill Creek, Hwy 90
Hobart KY 42601
Landholding Agency: COE
Property Number: 31199140009
Status: Underutilized
Directions:
Comments: 91 acres, most recent use—hunting, subject to existing easements

Tracts 212 and 237
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199011625
Status: Excess
Directions: Old Henson Ferry Road, 6 miles west of Kuttawa, KY.
Comments: 2.44 acres; steep and wooded; subject to utility easements.

Tract 233
Barkley Lake, Kentucky and Tennessee
Grand Rivers KY 42045
Landholding Agency: COE
Property Number: 31199011627
Status: Excess
Directions: 5 miles southwest of Kuttawa
Comments: 1.00 acres; wooded; subject to utility easements.

Tennessee

Tract 6827
Barkley Lake
Dover TN 37058
Landholding Agency: COE
Property Number: 31199010927
Status: Excess
Directions: 2½ miles west of Dover, TN.
Comments: .57 acres; subject to existing easements.

Tracts 6002–2 and 6010
Barkley Lake
Dover TN 37058
Landholding Agency: COE
Property Number: 31199010928
Status: Excess
Directions: 3½ miles south of village of Tabaccoport.
Comments: 100.86 acres; subject to existing easements.

Tract 11516
Barkley Lake
Ashland City TN 37015
Landholding Agency: COE
Property Number: 31199010929
Status: Excess
Directions: 1/2 mile downstream from Cheatham Dam
Comments: 26.25 acres; subject to existing easements.

Tract 2319
J. Percy Priest Dam and Reservoir
Murfreesboro TN 37130
Landholding Agency: COE
Property Number: 31199010930
Status: Excess
Directions: West of Buckeye Bottom Road
Comments: 14.48 acres; subject to existing easements.

Tract 2227
J. Percy Priest Dam and Reservoir
Murfreesboro TN 37130
Landholding Agency: COE
Property Number: 31199010931
Status: Excess
Directions: Old Jefferson Pike
Comments: 2.27 acres; subject to existing easements.

Tract 2107
J. Percy Priest Dam and Reservoir
Murfreesboro TN 37130
Landholding Agency: COE
Property Number: 31199010932
Status: Excess
Directions: Across Fall Creek near Fall Creek camping area.
Comments: 14.85 acres; subject to existing easements.

Tracts 2601,2602,2603,2604
Cordell Hull Lake and Dam Project
Doe Row Creek
Gainesboro TN 38562
Landholding Agency: COE
Property Number: 31199010933
Status: Unutilized
Directions: TN Highway 56
Comments: 11 acres; subject to existing easements.

Tract 1911
J. Percy Priest Dam and Reservoir
Murfreesboro TN 37130
Landholding Agency: COE
Property Number: 31199010934
Status: Excess
Directions: East of Lamar Road
Comments: 6.92 acres; subject to existing easements.

Tract 7206
Barkley Lake
Dover TN 37058
Landholding Agency: COE
Property Number: 31199010936
Status: Excess
Directions: 2½ miles SE of Dover, TN.
Comments: 10.15 acres; subject to existing easements.

Tracts 8813, 8814
Barkley Lake
Cumberland TN 37050
Landholding Agency: COE
Property Number: 31199010937
Status: Excess
Directions: 1½ miles East of Cumberland City.
Comments: 96 acres; subject to existing easements.

Tract 8911
Barkley Lake
Cumberland City TN 37050
Landholding Agency: COE
Property Number: 31199010938
Status: Excess
Directions: 4 miles east of Cumberland City.
Comments: 7.7 acres; subject to existing easements.

Tract 11503
Barkley Lake
Ashland City TN 37015

Landholding Agency: COE
Property Number: 31199010939
Status: Excess
Directions: 2 miles downstream from Cheatham Dam.
Comments: 1.1 acres; subject to existing easements.

Tracts 11523, 11524
Barkley Lake
Ashland City TN 37015
Landholding Agency: COE
Property Number: 31199010940
Status: Excess
Directions: 2½ miles downstream from Cheatham Dam.
Comments: 19.5 acres; subject to existing easements.

Tract 6410
Barkley Lake
Bumpus Mills TN 37028
Landholding Agency: COE
Property Number: 31199010941
Status: Excess
Directions: 4½ miles SW. of Bumpus Mills.
Comments: 17 acres; subject to existing easements.

Tract 9707
Barkley Lake
Palmyer TN 37142
Landholding Agency: COE
Property Number: 31199010943
Status: Excess
Directions: 3 miles NE of Palmyer, TN. Highway 149
Comments: 6.6 acres; subject to existing easements.

Tract 6949
Barkley Lake
Dover TN 37058
Landholding Agency: COE
Property Number: 31199010944
Status: Excess
Directions: 1½ miles SE of Dover, TN.
Comments: 29.67 acres; subject to existing easements.

Tracts K–1191, K–1135
Old Hickory Lock and Dam
Hartsville TN 37074
Landholding Agency: COE
Property Number: 31199130007
Status: Underutilized
Directions:
Comments: 54 acres, (portion in floodway), most recent use—recreation.

Tracts 6005 and 6017
Barkley Lake
Dover TN 37058
Landholding Agency: COE
Property Number: 31199011173
Status: Excess
Directions: 3 miles south of Village of Tobaccoport.
Comments: 5 acres; subject to existing easements.

Tract A–102
Dale Hollow Lake Project
Canoe Ridge, State Hwy 52
Celina TN 38551
Landholding Agency: COE
Property Number: 31199140006
Status: Underutilized
Directions:
Comments: 351 acres, most recent use—hunting, subject to existing easements.

Tract A–120
Dale Hollow Lake Project
Swann Ridge, State Hwy No. 53
Celina TN 38551
Landholding Agency: COE
Property Number: 31199140007
Status: Underutilized
Directions:
Comments: 883 acres, most recent use—hunting, subject to existing easements.

Tract D–185
Dale Hollow Lake Project
Ashburn Creek, Hwy No. 53
Livingston TN 38570
Landholding Agency: COE
Property Number: 31199140010
Status: Underutilized
Directions:
Comments: 97 acres, most recent use—hunting, subject to existing easements.

Texas

FAA Outermarker—Houston
Spring TX 77373
Landholding Agency: GSA
Property Number: 54201040001
Status: Surplus
GSA Number: 7–U–TX–1110
Comments: 0.2459 acres, subject to restrictions/regulations regarding the Houston Intercontinental Airport, may not have access to a dedicated roadway.

Utah

Processing and Disposal Site
Monticello UT 84535
Landholding Agency: GSA
Property Number: 54201030008
Status: Surplus
GSA Number: 7–B–UT–431–AO
Comments: 175.41 acres, permanent utility easement, small portion may have contaminated groundwater, most recent use—grazing/farming.

Unsuitable Properties

Building

Arizona

Storage Bldg.
Bureau of Reclamation
Peoria AZ 85383
Landholding Agency: Interior
Property Number: 61201120001
Status: Unutilized
Reasons: Secured Area, Extensive deterioration.

California

Bldg. 1055
7910 Arnold Ave.
Beale CA 95903
Landholding Agency: Air Force
Property Number: 18201120001
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material, Extensive deterioration, Secured Area.

Bldg. 3304
4850 Camp Beale Hwy
Beale CA 95903
Landholding Agency: Air Force
Property Number: 18201120002
Status: Unutilized
Reasons: Extensive deterioration.

Bldg. 1056
7944 Arnold Ave.
Beale CA 95903
Landholding Agency: Air Force
Property Number: 18201120004
Status: Unutilized
Reasons: Extensive deterioration, Secured Area Floodway, Within 2000 ft. of flammable or explosive material.

Bldg. 2457
17700 25th St.
Beale CA 95903
Landholding Agency: Air Force
Property Number: 18201120008
Status: Unutilized
Reasons: Extensive deterioration.

Nebraska

Bldg. 481
AFB
Offutt NE 68113
Landholding Agency: Air Force
Property Number: 18201120010
Status: Excess
Reasons: Within airport runway clear zone, Secured Area.

New Mexico

Bldg. 867
1293 Bong St.
Holloman NM 88330
Landholding Agency: Air Force
Property Number: 18201120017
Status: Unutilized
Reasons: Within airport runway clear zone, Extensive deterioration, Secured Area.

New York

Bldg. 0368
Brookhaven Nat'l Lab
Upton NY 11973
Landholding Agency: Energy
Property Number: 41201110006
Status: Excess
Reasons: Extensive deterioration.

Floyd Wknd Training Site
Koenig Rd.
Floyd NY
Landholding Agency: GSA
Property Number: 54201120001
Status: Excess
GSA Number: 1–D–NY–0958
Directions: 1300, 1302, 1303, 1304, 1305, 1306 w/shed, 1307 w/shed
Comments: The land was deemed "suitable" (property #54201120002); however, the bldgs. are deteriorated beyond repair
Reasons: Extensive deterioration.

Oregon

Residence No. 0112001200B
Bureau of Reclamation
Madras OR 97741
Landholding Agency: Interior
Property Number: 61201120002
Status: Underutilized
Reasons: Extensive deterioration.

South Carolina

Shaw AFB
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201120006
Status: Excess
Reasons: Secured Area.

B823
518 Polifka St.
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201120007

Status: Excess
Reasons: Secured Area.

Bldg. 408
Shaw AFB
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201120011
Status: Excess
Reasons: Secured Area.

Bldg. 1422
515 Exchange St.
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201120012
Status: Excess
Reasons: Secured Area.

B1425
516 Exchange St.
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201120015
Status: Excess
Reasons: Extensive deterioration.

B409
421 Johnson St.
Sumter SC 29152
Landholding Agency: Air Force
Property Number: 18201120018
Status: Excess
Reasons: Secured Area.

Virginia

Bldg. 405
Kerr Rd.
Ft. Eustis VA 23604
Landholding Agency: Air Force
Property Number: 18201120003
Status: Underutilized
Reasons: Extensive deterioration.

Ft. Eustis
801 Lee Blvd.
Eustis VA 23604
Landholding Agency: Air Force
Property Number: 18201120005
Status: Underutilized
Reasons: Extensive deterioration.

Bldg. 2738
Harrison Loop
Ft. Eustis VA 23604
Landholding Agency: Air Force
Property Number: 18201120009
Status: Underutilized
Reasons: Extensive deterioration.

Bldg. 435
Joint Base Langley Eustis
Eustis VA
Landholding Agency: Air Force
Property Number: 18201120013
Status: Unutilized
Reasons: Extensive deterioration.

Facility 999
400 Clarke Ave.
Langley VA 23665
Landholding Agency: Air Force
Property Number: 18201120016
Status: Underutilized
Reasons: Secured Area, Extensive deterioration.

[FR Doc. 2011–8777 Filed 4–14–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation and Enforcement

[Docket ID No. BOEM–2011–0017]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), Interior.

ACTION: Notice of an extension of an information collection (1010–0082).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BOEMRE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements related to leasing for minerals other than oil, gas and sulphur in the Outer Continental Shelf.

DATES: Submit written comments by June 14, 2011.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulation that requires the subject collection of information.

ADDRESSES: You may submit comments by either of the following methods listed below.

- *Electronically:* go to *http://www.regulations.gov.* In the entry titled "Enter Keyword or ID," enter BOEM–2011–0017 then click search. Follow the instructions to submit public comments and view supporting and related materials available for this collection. BOEMRE will post all comments.
- *E-mail cheryl.blundon@boemre.gov.* Mail or hand-carry comments to the Department of the Interior; Bureau of Ocean Energy Management, Regulation and Enforcement; *Attention:* Cheryl Blundon; 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference ICR 1010–0082 in your comment and include your name and return address.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 281, Leasing for Minerals Other than Oil, Gas, and Sulphur in the Outer Continental Shelf.

OMB Control Number: 1010–0082.

Abstract: Section 8(k) of the Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1337), authorizes the Secretary of the Interior (Secretary) to grant to the qualified persons offering the highest cash bonuses on a basis of competitive bidding leases of any mineral other than oil, gas, and sulphur. This applies to any area of the Outer Continental Shelf not then under lease for such mineral upon such royalty, rental, and other terms and conditions as the Secretary may prescribe at the time of offering the area for lease. The Secretary is to administer the leasing provisions of the Act and prescribe the rule and regulations necessary to carry out those provisions.

Regulations at 30 CFR 281 implement these statutory requirements. The regulations at 30 CFR 281 concern leasing activities of minerals other than oil, gas or sulphur and are the subject of this collection.

BOEMRE uses the information required by 30 CFR 281 to determine if statutory requirements are met prior to the issuance of a lease. Specifically, BOEMRE uses the information to:

- Evaluate the area and minerals requested by the lessee to assess the viability of offering leases for sale.
- Allow the State(s) to initiate the establishment of a joint group.
- Ensure excessive overriding royalty interests are not created that would put economic constraints on all parties involved.
- Document that a leasehold or geographical subdivision has been surrendered by the record title holder.

We protect proprietary information according to the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR 2), and 30 CFR parts 280 and 282. No items of a sensitive nature are collected. Responses are mandatory.

Frequency: On occasion.

Description of Respondents: As there are no active respondents, we estimate the potential annual number of respondents to be one. Potential respondents are OCS lease requestors, state governments, and OCS lessees.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is 1,248 hours. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 281	Reporting and/or recordkeeping requirement	Hour burden / Non-hour cost burden
Subpart A—General		
6	Appeal decisions	Exempt under 5 CFR 1320.4(a)(2), (c).
Subpart B—Leasing Procedures		
11(a), (c)	Request approval for mineral lease with relevant information	60.
All sections	Submit response to Call for Information and Interest on areas for leasing of minerals (other than oil, gas, sulphur) in accordance with approved lease program, including information from States/local governments.	120.
13	States or local governments submit comments/recommendations on planning, coordination, consultation, and other issues that may contribute to the leasing process.	200.
All sections	Submit suggestions and relevant information in response to request for comments on proposed lease including information form States/local governments.	160.
18(a), (b), (c); 20(e), (f); 26(a), (b)	Submit bids (oral or sealed) and required information	250.
18(c); 20(e), (f)	Tie bids—submit oral bids for highest bidder	20.
20(a), (b), (c); 41(a)	Establish a Company File for qualification; submit updated information, submit qualifications for lessee/bidder.	58.
21(a); 47(c)	Request for reconsideration of bid rejection/cancellation. Not considered information collection as defined under 5 CFR 1320.3(h)(9).	0.
21(b), (e); 23; 26; 40(b); 41(b)	Execute lease (includes submission of evidence of authorized agent and request for dating of leases); maintain auditable records re 30 CFR Chapter II, Subchapter A—[burden under ONRR requirements].	100.
Subpart C—Financial Considerations		
31(b); 41	File application and required information for assignment or transfer for approval..	160. $50 required or non-required filing document fee.
32(b), (c)	File application for waiver, suspension, or reduction and supporting documentation.	80.
33; 41(c)	Submit surety or personal bond	Burden covered under 1010–0081.
Subpart E—Termination of Leases		
46(a)	File written request for relinquishment.	40.

Estimated Reporting and Recordkeeping "Non-Hour Cost" Burden: We have identified one non-hour cost burden for this collection, a $50 required or non-required filing document fee under § 281.41. We have not identified any other non-hour paperwork cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency "* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *". Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Agencies must also estimate the non-hour cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information, monitoring, and record storage facilities. You should not include estimates for equipment or services purchased: (i) Before October 1, 1995; (ii) to comply with requirements not associated with the information collection; (iii) for reasons other than to provide information or keep records for the Government; or (iv) as part of customary and usual business or private practices.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that

your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

BOEMRE Information Collection Clearance Officer: Arlene Bajusz (703) 787–1025.

Dated: April 7, 2011.

Sharon Buffington,

Acting Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2011–9197 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation and Enforcement

[Docket ID No. BOEM–2011–0010]

BOEMRE Information Collection Activity; 1010–0141, Subpart D, Oil and Gas Drilling Operations, Extension of a Collection; Comment Request

AGENCY: Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), Interior.

ACTION: Notice of extension of an information collection (1010–0141).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), BOEMRE is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements related to oil and gas drilling operations, and related forms.

DATES: Submit written comments by June 14, 2011.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulations and the forms that require the subject collection of information.

ADDRESSES: You may submit comments by either of the following methods listed below.

- *Electronically:* go to *http://www.regulations.gov.* In the entry titled "Enter Keyword or ID," enter BOEM–2010–0010 then click search. Follow the instructions to submit public comments and view supporting and related materials available for this collection. BOEMRE will post all comments.
- E-mail *cheryl.blundon@boemre.gov.* Mail or hand-carry comments to the Department of the Interior; Bureau of Ocean Energy Management, Regulation and Enforcement; *Attention:* Cheryl Blundon; 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference ICR 1010–0141 in your comment and include your name and return address.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR Part 250, Subpart D, Oil and Gas Drilling Operations.

BOEMRE Form(s): MMS–123, MMS–123S, MMS–124, MMS–125, MMS–133, MMS–133S, and MMS–144.

OMB Control Number: 1010–0141.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. Section 1332(6) states that "operations in the Outer Continental Shelf should be conducted in a safe manner by well trained personnel using technology, precautions, and other techniques sufficient to prevent or minimize the likelihood of blowouts, loss of well control, fires, spillages, physical obstructions to other users of the waters or subsoil and seabed, or other occurrences which may cause damage to the environment or to property or endanger life or health."

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and OMB Circular A–25, authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's implementing policy, BOEMRE is required to charge fees for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those which accrue to the public at large. Applications for permits to drill and modification approvals are subject to cost recovery, and BOEMRE regulations specify service fees for these requests.

This authority and responsibility are among those delegated to BOEMRE. The regulations at 30 CFR 250, subpart D, concern oil and gas drilling operations and are the subject of this collection. This request also covers the related Notices to Lessees and Operators (NTLs) that BOEMRE issues to clarify, supplement, or provide additional guidance on some aspects of our regulations.

Regulations at 30 CFR 250, subpart D, implement these statutory requirements. We use the information to ensure safe drilling operations and to protect the human, marine, and coastal environment. Among other things, BOEMRE specifically uses the information to ensure: The drilling unit is fit for the intended purpose; the lessee or operator will not encounter geologic conditions that present a hazard to operations; equipment is maintained in a state of readiness and meets safety standards; each drilling crew is properly trained and able to promptly perform well-control activities at any time during well operations; compliance with safety standards; and the current regulations will provide for safe and proper field or reservoir development, resource evaluation, conservation, protection of correlative rights, safety, and environmental protection. We also review well records to ascertain whether drilling operations have encountered hydrocarbons or H_2S and to ensure that H_2S detection equipment, personnel protective equipment, and training of the crew are adequate for safe operations in zones known to contain H_2S and zones where the presence of H_2S is unknown.

The following forms are also submitted to BOEMRE under subpart D. The forms and their purposes are:

Application for Permit To Drill (APD), Forms MMS–123 and MMS–123S

BOEMRE uses the information from these forms to determine the conditions of a drilling site to avoid hazards inherent in drilling operations. Specifically, we use the information to evaluate the adequacy of a lessee's plan and equipment for drilling, sidetracking or bypass operations. This includes the adequacy of the proposed casing design, casing setting depths, drilling fluid (mud), and cementing programs to ascertain that the proposed operations will be conducted in an operationally safe manner that provides adequate protection for the environment. BOEMRE also reviews the information to ensure conformance with specific provisions of the lease. In addition, except for proprietary data, BOEMRE is required by the OCS Lands Act to make available to the public certain

information submitted on forms MMS–123 and MMS–123S.

Application for Permit To Modify (APM), Form MMS–124

The information on this form is used to evaluate and approve the adequacy of the equipment, materials, and/or procedures that the lessee plans to use during such post APD modifications or operations as plugging back or temporary abandonment where the well bore will be reentered and completed or permanently plugged. In addition, except for proprietary data, BOEMRE is required by the OCS Lands Act to make available to the public certain information submitted on form MMS–124.

End of Operations Report, Form MMS–125

BOEMRE uses this information to ensure that we have accurate and up-to-date data and information on wells and leasehold activities under our jurisdiction and to ensure compliance with approved plans and any conditions placed upon a suspension or temporary prohibition. It is also used to evaluate the remedial action in the event of well equipment failure or well control loss. Form MMS–125 is updated and resubmitted in the event the well status changes. The information keeps us aware of the status of drilling and completion operations. In addition, except for proprietary data, BOEMRE is required by the OCS Lands Act to make available to the public certain information submitted on form MMS–125.

Well Activity Report, Forms MMS–133 and MMS–133S

BOEMRE uses this information to monitor the conditions of a well and status of drilling operations. We review the information to be aware of the well conditions and current drilling activity (i.e., well depth, drilling fluid weight, casing types and setting depths, completed well logs, and recent safety equipment tests and drills). The engineer uses this information to determine how accurately the lessee anticipated well conditions and if the lessee is following the approved APD. The information is also used for review of an APM (form MMS–124). With the information collected on form MMS–133 available, the reviewers can analyze the proposed revisions (i.e., revised grade of casing or deeper casing setting depth) and make a quick and informed decision on the request. In addition, except for proprietary data, BOEMRE is required by the OCS Lands Act to make available to the public certain information submitted on forms MMS–133 and MMS–133S.

Rig Movement Notification Report, Form MMS–144

As activity increased over the years in the Gulf of Mexico (GOM), the rig notification requirement became essential for BOEMRE inspection scheduling and has become a standard condition of approval for certain permits. BOEMRE needs the information on Form MMS–144 to schedule inspections and verify that the equipment being used complies with approved permits. In reporting rig movements respondents have the option of submitting the form or using a Web-based system for electronic data submissions. The information on this form is used primarily in the GOM to ascertain the precise arrival and departure of all rigs in OCS waters in the GOM. The accurate location of these rigs is necessary to facilitate the scheduling of inspections by BOEMRE personnel.

It is noted that the U.S. Coast Guard (USCG) also requires notification of rig movement and that there is some duplication of information reported. Therefore, there are some data elements in the form that are "optional" for BOEMRE reporting purposes, since we do not need this information. These optional data elements in the form satisfy any concerns in reporting rig movement information to both BOEMRE and the USCG.

Out of the seven forms associated with this collection, we have made some minor editorial changes for clarity purposes to forms MMS–123 and MMS–123S and we have added plug information to be submitted via form MMS–125. The information is on the schematic that is submitted as an attachment to the form.

We will protect proprietary information according to 30 CFR 250.197, "Data and information to be made available to the public or for limited inspection," 30 CFR part 252, "OCS Oil and Gas Information Program," and the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR 2). No items of a sensitive nature are collected. Responses are mandatory.

Frequency: Frequency of response is generally on occasion, weekly, monthly, semi-annually, annually, and varies by section.

Description of Respondents: Potential respondents comprise Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved annual reporting burden for this collection is 147,014 hours. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 250 Subpart D and NTL(s)	Reporting and recordkeeping requirement	Hour burden
		Non-hour cost burdens
General Requirements		
402(b)	Request approval to use blind or blind-shear ram or pipe rams and inside BOP.	0.25.
403	Notify BOEMRE of drilling rig movement on or off drilling location	0.1.
	In Gulf of Mexico OCS Region, rig movements reported on Form MMS–144.	6 mins.
404	Perform operational check of crown block safety device; record results (weekly).	0.25.
408, 409	Apply for use of alternative procedures and/or departures not requested in BOEMRE forms (including discussions with BOEMRE or oral approvals).	5.

Citation 30 CFR 250 Subpart D and NTL(s)	Reporting and recordkeeping requirement	Hour burden
		Non-hour cost burdens
Apply for a Permit to Drill		
410–418, 420(a)(6); 423(b)(3), (c)(1); 449(j), (k); 456(j); plus various references in subparts A, B, D, E, H, P, Q..	Apply for APD/revised APD that includes any/all supporting documentation/evidence [test results, calculations, verifications, procedures, criteria, qualifications, etc, and request for various approvals required in subpart D (including §§ 250.424; 425; 427; 428; 432; 442(c); 447; 448(c); 451(g); 460; 490(c)) and submitted via BOEMRE forms MMS–123 (APD) and MMS–123S (Supplemental APD Information Sheet), and supporting information and notices to BOEMRE.	6. $1,959 application fee. MMS–123S 1.5+.*
410(b); 417(b)	Reference to Exploration Plan, Development and Production Plan, Development Operations Coordination Document (30 CFR 250, subpart B)—burden covered under 1010–00151.	
416(g)(2)	Provide 24 hour advance notice of location of shearing ram tests or inspections; allow BOEMRE access to witness testing, inspections and information verification.	10 mins.
417(a), (b)	Collect and report additional information on case-by-case basis if sufficient information is not available.	4.
417(c)	Submit 3rd party review of drilling unit according to 30 CFR 250, subpart I—burden covered under 1010–0149.	
418(e)	Submit welding and burning plan according to 30 CFR 250, subpart A—burden covered under 1010–0114.	
Casing and Cementing Requirements		
420(b)(3)	Submit dual mechanical barrier documentation after installation	30 mins.
421; 423; 428	Submit casing and cementing program and revisions or changes.	2.
423(b)(4), (c)(2)	Perform pressure casing test; document results and make available to BOEMRE upon request.	30 mins.
424	Caliper, pressure test, or evaluate casing; submit evaluation results; request approval before resuming operations or beginning repairs (every 30 days during prolonged drilling).	4.
426	Perform pressure test on all casing strings and drilling liner lap; record results.	2.
427(a)	Perform pressure-integrity tests and related hole-behavior observations; record results.	4.
Diverter System Requirements		
434; 467	Perform diverter tests when installed and once every 7 days; actuate system at least once every 24-hour period; record results (average 2 per drilling operation); retain all charts/reports relating to diverter tests/actuations at facility for duration of drilling well.	2.
Blowout Preventer (BOP) System Requirements		
442(h)	Label all functions on all panels	30 mins.
442(i)	Develop written procedures for management system for operating the BOP stack and LMRP.	4.
442(j)	Establish minimum requirements for authorized personnel to operate critical BOP equipment; require training.	Burden covered under 1010–0128.
446(a)	Document BOP maintenance and inspection procedures used; record results of BOP inspections and maintenance actions; maintain records for 2 years; make available to BOEMRE upon request.	1.
449(j)(2)	Test all ROV intervention functions on your subsea BOP stack; document all test results; make available to BOEMRE upon request.	10.
449(k)(2)	Function test autoshear and deadman on your subsea BOP stack during stump test; document all test results; make available to BOEMRE upon request.	30 mins.
450; 467	Perform BOP pressure tests, actuations and inspections when installed; at a minimum every 14 days; as stated for components; document and record actions/results, sign as correct.	10.
450, 467	Function test annulars and rams; document results every 7 days between BOP tests (biweekly), retain records at facility for drilling duration. Note: this test is part of BOP test when BOP test is conducted.	0.5.
451(c)	Record reason for postponing BOP test (on occasion—approx. 2/year)	0.25.
Drilling Fluid Requirements		
456(b), (i); 458(b)	Record each drilling fluid circulation; test drilling fluid, record results; record daily inventory of drilling fluid/materials; test and recalibrate gas detectors; record results (on occasion, daily, weekly, quarterly).	2.

Citation 30 CFR 250 Subpart D and NTL(s)	Reporting and recordkeeping requirement	Hour burden Non-hour cost burdens
456(c)	Perform various calculations; post information (on occasion, daily, weekly)	0.5.
459(a)(3)	Request exception to procedure for protecting negative pressure area	2.
Other Drilling Requirements		
460; 465; 250.449(j), (k); 456(j) plus various references in subparts A, D, E, F, H, P, and Q.	Submit revised plans, changes, well/drilling records, procedures, certifications that include any/all supporting documentation etc., and request for various approvals required in subpart D on forms MMS–124 (APM) or MMS–125 (End of Operations Report) and supporting information.	MMS–124 4. $116 application fee. MMS–125 1.6+.*
460	Submit plans for well testing and notify BOEMRE before test	2.
461(a–b); 466(e); 468(a)	Record and submit well logs, survey results, etc	1.5.
	Record and submit directional and vertical-well surveys	1.
	Record and submit velocity profiles and surveys	1.
	Record and submit core analyses	1.
461(e)	Provide copy of well directional survey to affected leaseholder	1.
462(a)	Prepare and post well control drill plan for crew members	3.
462(c)	Perform well-control drills; record results (2 crews weekly)	1.
463(b)	Request field drilling rules be established, amended, or canceled	2.5.
Applying for a Permit To Modify and Well Records		
466, 467	Retain drilling records for 90 days after drilling is complete; retain casing/liner pressure, diverter, and BOP records for 2 years; retain well completion/well workover until well is permanently plugged/abandoned or lease is assigned.	1.5.
468(b); 465(b)(3)	In the GOM OCS Region, submit drilling activity reports weekly on forms MMS–133 (Well Activity Report) and MMS–133S (Bore Hole Data) and supporting information.	MMS–133 1+.* MMS–133S 1+.*
468(c)	In the Pacific and Alaska OCS Regions during drilling operations, submit daily drilling reports. N/A in GOM.	1.
469	As specified by region, submit well records, paleontological interpretations or reports, service company reports, and other reports or records of operations.	1.5.
Hydrogen Sulfide		
490(c), (d)	Submit request for reclassification of H_2S zone; notify BOEMRE if conditions change.	2.
490(f); also referenced in 418(d)	Submit contingency plans for operations in H_2S areas (16 drilling, 5 workover, 6 production).	25.
490(g)	Conduct H_2S training; post safety instructions; document training on occasion and annual refresher (approx. 2/year).	4.
490(h)(2)	Conduct weekly drills and safety meetings; document attendance for drilling, well completion, well workover at facility until operations completed; production attendance documentation for 1 year nearest field office.	2.
490(i)	Display warning signs—no burden as facilities would display warning signs and use other visual and audible systems.	
490(j)(7–8)	Test H_2S detection and monitoring sensors during drilling; record testing and calibrations on occasion, daily during drilling (approx. 12 sensors per rig).	4.
490(j)(7–8)	Test H_2S detection and monitoring sensors every 14 days during production; record testing and calibrations (approx. 30 sensors/5 platforms + approx. 42 sensors/23 platforms).	3.5.
490(j)(12)	Propose alternatives to minimize or eliminate SO_2 hazards—submitted with contingency plans—burden covered under 250.490(f).	
490(j)(13)(vi)	Label breathing air bottles—no burden as supplier normally labels bottles; facilities would routinely label if not.	
490(l)	Notify (phone) BOEMRE of unplanned H_2S releases (approx. 2/year)	Oral—0.2. Written—4.
490(o)(5)	Request approval to use drill pipe for well testing	2.
490(q)(1)	Seal and mark for the presence of H_2S cores to be transported—no burden as facilities would routinely mark transported cores.	
490(q)(9)	Request approval to use gas containing H_2S for instrument gas	2.

Citation 30 CFR 250 Subpart D and NTL(s)	Reporting and recordkeeping requirement	Hour burden
		Non-hour cost burdens
490(q)(12)	Analyze produced water disposed of for H_2S content and submit results to BOEMRE on occasion (approx. weekly).	2.8.
Miscellaneous		
400–490	General departure or alternative compliance requests not specifically covered elsewhere in subpart D.	2.
NTL	Voluntary submittal to USCG read only access to the EPIRB data for their moored drilling rig fleet before hurricane season.	.25.

* The hour burdens are an average of the estimate due to the fact that a large percentage of the submittals are reported electronically, which in some cases takes less time than the percentage of the submittals that are reported in paper form.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: The currently approved non-hour cost burden for this collection is $1,789,340. We have identified two non-hour cost burdens. Section 250.410(d) requires a fee ($1,959) for an APD. Section 250.460 requires a fee ($116) for an APM the drilling application. We have not identified any other non-hour paperwork cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency "* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *." Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Agencies must also estimate the non-hour paperwork cost burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information, monitoring, and record storage facilities. You should not include estimates for equipment or services purchased: (i) Before October 1, 1995; (ii) to comply with requirements not associated with the information collection; (iii) for reasons other than to provide information or keep records for the Government; or (iv) as part of customary and usual business or private practices.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

BOEMRE Information Collection Clearance Officer: Arlene Bajusz (703) 787–1025.

Dated: April 7, 2011.

Sharon Buffington,

Acting Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2011–9196 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2011–N071; 30120–1113–0000–F6]

Endangered and Threatened Wildlife and Plants; Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (Act) prohibits activities with endangered and threatened species unless a Federal permit allows such activity. The Act requires that we invite public comment before issuing these permits.

DATES: We must receive any written comments on or before May 16, 2011.

ADDRESSES: Send written comments by U.S. mail to the Regional Director, Attn: Lisa Mandell, U.S. Fish and Wildlife Service, Ecological Services, 1 Federal Drive, Fort Snelling, MN 55111–4056; or by electronic mail to *permitsR3ES@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Lisa Mandell,(612) 713–5343.

SUPPLEMENTARY INFORMATION:

Background

We invite public comment on the following permit applications for certain activities with endangered species authorized by section 10(a)(1)(A) of the Act (16 U.S.C. 1531 *et seq.*) and our regulations governing the taking of endangered species in the Code of Federal Regulations (CFR) at 50 CFR 17. Submit your written data, comments, or request for a copy of the complete application to the address shown in **ADDRESSES.**

Permit Applications

Permit Application Number: TE38769A.

Applicant: Sarah A. Bradley, Salem, MO.

The applicant requests a permit renewal to take (capture and release) Indiana bats (*Myotissodalis*) and gray bats (*Myotisgrisescens*) on the Mark Twain National Forest. Proposed activities are for the enhancement of survival of the species in the wild.

Permit Application Number: TE38785A.

Applicant: Merrill B. Tawse, Mansfield, OH.

The applicant requests a permit renewal to take (capture and release) Indiana bats within Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38789A.

Applicant: BHE Environmental, Inc., Cincinnati, OH.

The applicant requests a permit renewal to take (capture and release) Indiana bats and gray bats throughout the range of the species (within IL, IN, IA, MI, MO, OH, KY, TN, AL, GA, AR, MS, NC, SC, FL, PA, and NY). Permit renewal is also requested for threatened and endangered mussel species within AZ, NM, OK, TX, IL, IN, IA, MI, MN, MO, OH, WI, AL, AR, FL, GA, KY, LA, MS, NC, SC, TN, CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI, VT, VA, and WV and threatened and endangered fish species within those States and CO, KS, MT, NE, ND, SD, UT, and WY. Proposed activities are for enhancement of survival of the species in the wild through studies to monitor habitat use, surveys to document presence of the species, and through population assessments.

Permit Application Number: TE38793A.

Applicant: Kenneth S. Mierzwa, Eureka, CA.

The applicant requests a permit renewal to take (capture and release of larvae; collection of excuviae) Hine's emerald dragonfly (*Somatochlorahineana*) in Will County, Illinois. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38821A.

Applicant: Stantec Consulting Services, Louisville, KY.

The applicant requests a permit renewal/amendment to take (capture and release) Indiana bats, gray bats, Ozark big-eared bats (*Corynorhinustownsendiiingens*), Virginia big-eared bats (*Corynorhinustownsendiivirginianus*), the Copperbelly water snake (*Nerodiaerythrogasterneglecta*), Carolina Northern flying squirrel (*Glaucomyssabrinuscoloratus*), and the bog turtle (*Clemmysmuhlenbergii*) throughout their range within OK, IL, IN, IA, MI, MO, OH, AL, AR, GA, KY, MS, NC, SC, TN, CT, DE, MA, MD,NH, NJ, NY, PA, RI, VT, VA, and WV. Permit renewal is also requested for threatened and endangered mussel and fish species within those States. Proposed activities are for enhancement of survival of the species in the wild through studies to monitor habitat use, surveys to document presence of the species, and through population assessments.

Permit Application Number: TE38835A.

Applicant: Land Conservancy of West Michigan, Grand Rapids, MI.

The applicant requests a permit renewal/amendment to take (habitat management; presence/absence surveys; prescribed fire) Karner blue butterfly (*Lycaeidesmelissasamuelis*) on the Maas Preserve, Kent County, Michigan. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38837A.

Applicant: J.F. New Associates, Inc., Walkerton, IN.

The applicant requests a permit renewal/amendment to take (capture and release) Indiana bats and gray bats within Kentucky, Illinois, Indiana, Iowa, Michigan, Missouri, Ohio, and Wisconsin. The applicant requests a permit amendment to include Virginia big-eared bats and to expand the geographic scope of the permit to include the range of all three species within States above and Alabama, Arkansas, Connecticut, Florida, Georgia, Maryland, Mississippi, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Tennessee, Vermont, Virginia, and West Virginia. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38838A.

Applicant: Dr. Michael Hoggarth, Westerville, OH.

The applicant requests a permit renewal to take (capture and release) Federally listed mussels within Ohio. Species included on Dr. Hoggarth's existing permit are: purple catspaw pearlymussel (*Epioblasma obliquata obliquata*), fanshell (*Cyprogeniastegaria*), white catspaw (*Epioblasmaobliquataperobliqua*), pink mucket pearly mussel (*Lampsilisabrupta*), rayed bean (*Villosafabalis*), sheepnose (*Plethobasuscyphyus*), clubshell (*Pluerobemaclava*), rabbitsfoot (*Quadrulacylindricacylindrica*), and snuffbox mussel (*Epioblasmatriquetra*). The applicant requests a permit amendment to take Federally listed mussels within an expanded geographic scope including: Indiana, Michigan, Kentucky, and West Virginia. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38842A.

Applicant: Sanders Environmental Inc., Bellefonte, PA.

The applicant requests a permit renewal/amendment to take (capture; radio-tag; release) Indiana bats within Illinois, Indiana, Iowa, Michigan, Missouri, Ohio, and Wisconsin. The applicant requests a permit amendment to include gray bats and to expand the geographic scope of the permit to include the range of both species within the States above and Alabama, Arkansas, Florida, Georgia, Kentucky, Mississippi, North Carolina, and Tennessee. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38849A.

Applicant: Macalester College, St. Paul, MN.

The applicant requests a permit renewal/amendment to take (capture and release) Higgins' eye pearlymussel (*Lampsilishigginsi*), winged mapleleaf mussel (*Quadrulafragosa*), sheepnose mussel, snuffbox mussel, and spectaclecasemussel (*Cumberlandiamonodonta*) within the Chippewa River, Mississippi River, and the St. Croix River within Minnesota and Wisconsin. The proposed research involves community monitoring and habitat analysis. The applicant also requests authority to conduct host suitability trials and brooding studies on sheepnose mussels collected in the Mississippi River Basin in Minnesota and Wisconsin; this research involves temporarily holding females and collecting glochidia. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38856A.

Applicant: Skelly and Loy, Inc., Harrisburg, PA.

The applicant requests a permit to take (capture and release) Indiana bats and Virginia big-eared bats throughout the range of the species within Illinois, Indiana, Iowa, Michigan, Missouri, Ohio, Arkansas, Georgia, Kentucky, Mississippi, North Carolina, Tennessee, Connecticut, Maryland, New Jersey, New York, Pennsylvania, Vermont,

Virginia, and West Virginia. The proposed activities are for the enhancement of survival of the species in the wild.

Permit Application Number: TE38858A.

Applicant: The Holden Arboretum, Kirtland, OH.

The applicant requests a permit to take (survey and collect seed) Houghton's goldenrod (*Oligoneuronhoughtonii*) on lands within Crawford and Kalkaska Counties, Michigan. Proposed activities are for enhancement of survival of the species in the wild.

Permit Application Number: TE38860A.

Applicant: Jason M. Garvon, Sault Sainte Marie, MI.

The applicant requests a permit to take (conduct habitat surveys; monitor nesting sites; erect nesting enclosures) Piping plover (*Charadriusmelodus*) throughout the Upper Peninsula of Michigan. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE38862A.

Applicant: George R. Cunningham, Omaha, NE.

The applicant requests a permit to take (capture and release) Topeka shiners (*Notropistopeka*) throughout Nebraska, South Dakota, Missouri, Iowa, Kansas, and Minnesota. Proposed activities are for the recovery and enhancement of survival of the species in the wild.

Permit Application Number: TE38866A.

Applicant: David Mech, U.S. Geological Survey, St. Paul, MN.

The applicant requests a permit to take (capture, radio-tag, use chemical immobilization, assess and treat health conditions, implant isotopes, salvage, and release) gray wolf (*Canis lupus*) in Minnesota, and other locations within the 48 continental States of the United States to monitor the status of the species. The proposed research is for the recovery of the species in the wild.

Public Comments

We seek public review and comments on these permit applications. Please refer to the permit number when you submit comments. Comments and materials we receive are available for public inspection, by appointment, during normal business hours at the address shown in the **ADDRESSES** section. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

National Environmental Policy Act (NEPA)

In compliance with NEPA (42 U.S.C. 4321 *et seq.*), we have made an initial determination that the proposed activities in these permits are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement (516 DM6 Appendix 1, 1.4C(1)).

Dated: April 7, 2011.

Lynn Lewis,

Assistant Regional Director, Ecological Services, Region 3.

[FR Doc. 2011–9151 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNMP02000 L71220000.EX0000 LVTFGX9G4200]

Notice of Availability of the Draft EIS for the HB In-Situ Solution Mine Project, Eddy County, NM

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the HB In-Situ Solution Mine Project, and by this Notice is announcing the opening of the comment period.

DATES: To ensure comments will be considered, the BLM must receive written comments on the HB In-Situ Solution Mine Project Draft EIS within 60 days following the date of publication of this Notice of Availability in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to the HB In-Situ Solution Mine Project by any of the following methods:

- *Web site: http://www.nm.blm.gov/cfo/HBIS/index.html*
- *E-mail: nmcfo_comment@blm.gov*
- *Fax:* 575–885–9264
- *Mail:* Bureau of Land Management, 620 E. Greene St., Carlsbad, New Mexico 88220

Copies of the HB In-Situ Solution Mine Project proposal are available in the Carlsbad Field Office at the above address.

FOR FURTHER INFORMATION CONTACT: Contact David Alderman, Assistant Project Manager; telephone 575–234–6232; address 620 E. Greene St., Carlsbad, New Mexico 88220; e-mail *david_alderman@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Intrepid Potash, Inc. (Intrepid) is proposing to extract potash, a potassium compound commonly used for fertilizer, remaining in inactive underground mine workings using solution mining methods. Intrepid proposes to construct and operate a solution mining project in an existing deep mine located approximately 20 miles northeast of Carlsbad in Eddy County, New Mexico, in the Secretary's Potash Area.

The potash left in the pillars and walls of the inactive underground mine workings is not accessible through conventional methods. The proposed action is to inject saline water into the mine workings, dissolve potash, and extract the mineral solution. This mineral-rich solution would be pumped to the surface and transported through a series of surface pipelines to evaporation ponds. Once the solution evaporates in the ponds, the potassium-bearing salts would be harvested from the ponds and transported to a newly constructed mill for ore refinement.

The project area is located in portions of Township 19 South, Range 30 and 31 East, Township 20 South, Ranges 29, 30 and 31 East and Township 21 South, Ranges 29 and 30 East, New Mexico Principal Meridian. The project area, which encompasses the proposed facilities and inactive workings under consideration, includes a total of 38,453 acres, of which 82 percent is on public lands managed by the U.S. Department of the Interior, Bureau of Land Management. Four thousand three hundred and thirty acres of open mine workings are targeted for flooding but the total surface footprint of the project would be 822 acres.

The BLM initiated the NEPA process for the HB In-Situ Solution Mine Project by preparing an environmental assessment (EA) in 2008. Two public scoping meetings were held on September 16, 2008, to receive public input and comments on the proposed project. During development of the EA and prior to publication, the BLM determined that the preparation of an EIS would be required for the proposed project. The Notice of Intent to prepare an EIS for the HB In-Situ Solution Mine Project was published in the **Federal Register** on January 12, 2010, and two public scoping meetings were conducted on January 26, 2010. A scoping report was compiled and published on April 1, 2010. Major issues identified for this project include water use, ground subsidence, and the concurrent development of oil and gas resources in the same area.

Alternatives developed include the proposed action (Alternative A) which uses non-potable water supplied by seven wells in the Rustler formation. Alternative B includes six of the seven wells from the proposed action but also considers that a substantial portion of the water needed for the project would be supplied from fresh water wells in the Caprock formation (Ogallala Aquifer) 30 miles northeast of the project area. Alternative C buries the pipelines to reduce surface impacts. An alternate routing of pipelines to the Caprock is also being considered under Alternative B.

Currently, a preferred alternative has not been selected. Alternative A uses a greater quantity of non-potable saline water; however, this has impacts to the environment from the drawdown of the aquifer. Alternative B uses a greater quantity of potable fresh water but impacts from drawdown of the aquifers would be reduced.

Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review and disclosure at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6 and 1506.10.

Linda S.C. Rundell,

State Director.

[FR Doc. 2011–9074 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–OX–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA 048649, LLCAD06000, L51010000. FX0000, LVRWB09B2490]

Notice of Availability of the Final Environmental Impact Statement for the Desert Sunlight Holdings, LLC, Desert Sunlight Solar Farm and Proposed California Desert Conservation Area Plan Amendment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Proposed California Desert Conservation Area (CDCA) Plan Amendment/Final Environmental Impact Statement (EIS) for the Desert Sunlight Solar Farm (DSSF) project and by this notice is announcing its availability.

DATES: The BLM planning regulations state that any person who meets the conditions as described in the regulations may protest the BLM's Proposed CDCA Plan Amendment/Final EIS. A person who meets the conditions and files a protest must file the protest within 30 days of the date that the Environmental Protection Agency (EPA) publishes its notice in the **Federal Register**. The protest procedures are described in the "Dear Reader" letter accompanying the Proposed Plan Amendment/Final EIS.

ADDRESSES: Copies of the DSSF Proposed CDCA Plan Amendment/Final EIS have been sent to affected Federal, state, and local government agencies and to other stakeholders. Copies are available for public inspection at the Palms Springs South Coast Field Office, 1201 Bird Center Drive, Palm Springs, California 92262. Interested persons may also review the document at the following Web site: *http://www.blm.gov/ca/st/en/fo/palmsprings/Solar_Projects/Desert_Sunlight.html.* All protests must be in writing and mailed to one of the following addresses:

Regular Mail: BLM Director (210), *Attention:* Brenda Williams, P.O. Box 71383, Washington, DC 20024–1383;

Overnight Mail: BLM Director (210), *Attention:* Brenda Williams, 20 M Street, S.E., Room 2134LM, Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: For further information contact Allison Shaffer, BLM Project Manager, telephone (760) 833–7100; address (*see* above); or e-mail *CAPSSolarFirstSolar DesertSunlight@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Desert Sunlight Holdings, LLC has submitted a right of way (ROW) application to the BLM to construct the proposed DSSF which includes a 550-megawatt (MW) solar photovoltaic (PV) facility and associated 220- kilovolt (kV) interconnection line (gen-tie line), and to facilitate the construction and operation by Southern California Edison (SCE) of the new 500/220-kV Red Bluff Substation, where the project would interconnect with the SCE regional transmission system. The total project footprint consists of approximately 4,165 acres of BLM-managed lands with a proposed ROW encompassing approximately 4,317 acres. The power generation site would consist of several components: A main generation area which includes PV arrays, combining switchgear, overhead lines, and access corridors; an operations and maintenance facility; a solar energy visitor center; an on-site substation; and site security and fencing. The gen-tie line ROW from the project to the proposed Red Bluff Substation would cover 256 acres with a 12-mile long, 160-foot wide corridor. The gen-tie line would transmit power to SCE's existing Devers-Palo Verde 1 (DPV1) 500-kV transmission line.

The Red Bluff Substation would consist of a 500/220-kV substation on approximately 76 acres, with an additional 73 acres for related features including access roads and drainage control. Substation features would include: connection of the project transmission line into the substation; transmission lines to connect the substation to the DPV1 line; modification of DPV1 towers near the substation; construction of an electric

distribution line for substation light and power; and installation of telecommunications facilities.

The project site is located approximately 6 miles north of Interstate 10 and the rural community of Desert Center in Riverside County. The project area is within 2 miles of Joshua Tree National Park.

The BLM's purpose and need for the DSSF project is to respond to an application for a ROW grant to construct, operate, maintain, and decommission a solar photovoltaic facility on public lands in compliance with FLPMA, BLM ROW regulations, and other applicable Federal laws. The BLM will decide whether to approve, approve with modification, or deny the ROW for the proposed DSSF project. The BLM will also consider amending the CDCA Plan in this analysis. The CDCA Plan (1980, as amended), while recognizing the potential compatibility of solar generation facilities on public lands, requires that all sites associated with power generation or transmission not identified in that plan be considered through the plan amendment process. If the BLM decides to grant a ROW, the BLM would also amend the CDCA Plan as required.

In the Final EIS, the proposed action is to authorize the DSSF project and approve a CDCA Plan amendment in response to the application received from Desert Sunlight Holdings, LLC. The BLM's preferred alternative is the proposed action, which consists of the power generation site (Solar Farm Layout B), Gen-Tie Line GT–A–1 (which parallels Kaiser Road), Substation A, and Access Road 2, aggregating 4,165 acres of permanent ground disturbance. Other alternatives to authorizing the proposed DSSF project include: (1) Authorize the Solar Farm Layout B, Gen-Tie Line GT–B–2, and Red Bluff Substation B, aggregating 4,100 acres of permanent ground disturbance; and (2) authorize a reduced footprint alternative with a reduced output including Solar Farm Layout C (413 MW), Gen-Tie Line GT–A–2, Red Bluff Substation A, and Access Road 1, aggregating 3,292 acres of permanent ground disturbance. Additionally, the Final EIS analyzes two no project alternatives: (1) Deny the project but amend the CDCA Plan to allow other solar energy power generation projects on the project site; and (2) deny the project and amend the CDCA Plan to prohibit solar energy projects on the project site. As required under NEPA, the Final EIS analyzes a no action alternative (no ROW grant and no CDCA Plan amendment).

The Final EIS evaluates the potential impacts of the proposed DSSF and CDCA Plan Amendment on air quality, biological resources, cultural resources, water resources, geological resources and hazards, land use, noise, paleontological resources, public health, socioeconomics, soils, traffic and transportation, visual resources, wilderness characteristics, and other resources.

A Notice of Availability for the DSSF Draft CDCA Plan Amendment/Draft EIS was published by the EPA in the **Federal Register** on August 27, 2010 (75 FR 52736). The formal 90-day comment period ended on November 26, 2010. Comments were considered and incorporated as appropriate into the Proposed CDCA Plan Amendment/Final EIS. Public comments resulted in the addition of clarifying text, but did not significantly change proposed land use plan decisions.

Instructions for filing a protest with the Director of the BLM regarding the DSSF project may be found in the "Dear Reader" letter of the Proposed CDCA Plan Amendment/Final EIS and at 43 CFR 1610.5–2. E-mail and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, the BLM will consider the e-mail or faxed protest as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at 202–912–7212, and e-mails to *Brenda_Hudgens-Williams@blm.gov.* All protests, including the follow-up letter to e-mails or faxes, must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section above.

Before including your phone number, e-mail address, or other personal identifying information in your protest, you should be aware that your entire protest–including your personal identifying information–may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6 and 1506.10; 43 CFR 1610.2 and1610.5.

Thomas Pogacnik,

Deputy State Director, California.

[FR Doc. 2011–9076 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV010000.L19900000.EX0000 241A; 11–08807; MO# 4500017134; TAS: 14X1109]

Notice of Availability of the Final Environmental Impact Statement for the Genesis Project, Eureka County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM), Elko District Office has prepared a Final Environmental Impact Statement (EIS) for the Newmont Mining Corporation's proposed Genesis Project and by this notice is announcing its availability.

DATES: The BLM will not issue a final decision on the proposal for a minimum of 30 days following the date the Environmental Protection Agency publishes its notice in the **Federal Register**.

ADDRESSES: Printed copies of the Genesis Project Final EIS are available for public inspection at the BLM Elko District Office, 3900 E. Idaho Street, Elko, Nevada during regular business hours of 7:30 a.m. to 4:30 p.m., Monday through Friday, except holidays. The Final EIS is also available on-line at: *http://www.blm.gov/nv/st/en/fo/elko_field_office.html.*

FOR FURTHER INFORMATION CONTACT: Kirk Laird, Project Manager, (775) 753–0200, address: 3900 E. Idaho, Elko, NV 89801, or e-mail: *Kirk_Laird@blm.gov.*

Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Newmont Mining Corporation's Genesis-Bluestar mining operations area is located in northeastern Nevada on the Carlin Trend, a 50-mile-long by 10-mile-wide geologic area that has produced more than 60 million ounces of gold from numerous mines over the last 30 years. The proposed action is to expand the Genesis Pit, develop the new Bluestar Ridge Pit, backfill the Beast and Bluestar pits and partially backfill the Genesis

Pit to prevent development of a pit lake in the Genesis pit, expand the Section 36 and Section 5 waste rock disposal facilities, construct the necessary haul roads and access roads, and process 60 million tons of gold-bearing ore. The proposed project would disturb an additional 43 acres (25 acres of public land and 18 acres of private land) and provide for continued mining activities on approximately 1,092 acres of previously disturbed lands. The Draft EIS analyzed impacts of the proposed action and no action alternatives, and identified measures to mitigate adverse impacts. Major issues addressed in the Draft EIS include: (1) The cumulative impacts of mining and related actions on affected resources, for example water quality and quantity, in the Carlin Trend; (2) the release of mercury associated with processing the 60 million tons of ore; (3) the impacts of 12 additional years of mining as it relates to continued employment and economic activity for the local area; and (4) the impact of a pit lake forming under the no action alternative, but not in the action alternative. The NEPA analysis considered wilderness characteristics and complies with Secretarial Order 3310.

The proposed action includes an adaptive management plan which was analyzed in the Draft EIS and included as an appendix to the Draft EIS. The Draft EIS was released for public review on April 23, 2010, for a 45-day comment period. A public comment meeting was held in Elko, Nevada on May 19, 2010.

The Final EIS has been prepared in an abbreviated format, and includes comments on the Draft EIS and the BLM's responses along with minor modifications and corrections to the Draft EIS.

Authority: 40 CFR 1506.6 and 1506.10.

Kenneth E. Miller,

District Manager, Elko.

[FR Doc. 2011–9075 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–ROMO–1210–6463;1526–0002–SZP]

Final Environmental Impact Statement for the Long Draw Reservoir Special Use Authorization, Rocky Mountain National Park

AGENCY: National Park Service, Interior.

ACTION: [Notice of Availability] Notice of Availability of a Record of Decision on the Final Environmental Impact Statement for the Long Draw Reservoir Special Use Authorization, Rocky Mountain National Park.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of the Record of Decision for the Long Draw Reservoir Special Use Authorization, Rocky Mountain National Park, Colorado. On September 17, 2010, the Regional Director, Intermountain Region approved the Record of Decision for the project. As soon as practicable, the National Park Service will begin to implement the Preferred Alternative contained in the FEIS issued on March 27, 2009.

FOR FURTHER INFORMATION CONTACT: Lawrence Gamble, Chief of Planning and Compliance, Rocky Mountain National Park, Estes Park, CO 80517, telephone 970–586–1320, e-mail *larry_gamble@nps.gov;* Dyce Gayton, Forest Planner, Arapaho and Roosevelt National Forests and Pawnee National Grassland, 2150 Centre Avenue, Building E, Fort Collins, Colorado 80526, telephone 970–295–6761, e-mail *dgayton@fs.fed.us;* or Tom Ford, Group Leader for Recreation, Planning and Design, 2150 Centre Avenue, Building E, Fort Collins, Colorado 80526, telephone 970–295–6610, e-mail *tford01@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The United States Department of Agriculture, Forest Service, is the lead agency for this project and was responsible for preparation of the EIS because Long Draw Reservoir is located on National Forest System lands. The NPS is a cooperating agency on this project because the operations of Long Draw Reservoir affect lands within Rocky Mountain National Park managed by the NPS, and two alternatives considered in the EIS propose actions within the park. A total of four alternatives were considered: A no-action alternative and three action alternatives.

With the Record of Decision, the National Park Service approves the implementation of Alternative 3 within the park. This decision is being made in conjunction with the Forest Service's decision to apply terms and conditions to the 30-year authorization for Long Draw Reservoir and is necessary for the Forest Service to implement the selected alternative. The National Park Service is approving implementation of native greenback cutthroat trout restoration in the headwaters of the Cache la Poudre River within Rocky Mountain National Park by the Forest Service, Water Supply and Storage Company of Fort Collins, Colorado, and their project partners, with oversight provided by the National Park Service. In addition to the activities associated with implementation of the terms and conditions for the Long Draw reservoir authorization, the NPS will implement native fish restoration in Cascade Creek.

The Record of Decision includes a description of the background of the project; a statement of the decision made including key actions and mitigating measures/monitoring to minimize environmental harm; the basis for the decision; an overview of public involvement and agency consultation in the decision-making process; a description of other alternatives considered; a description of the environmentally preferred alternative; and a findings on impairment of park resources and values.

Copies of the Record of Decision may be obtained from the contact listed above or online at *http://parkplanning.nps.gov/romo.*

Dated: March 1, 2011.

John Wessels,

Regional Director, Intermountain Region, National Park Service.

[FR Doc. 2011–9178 Filed 4–14–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKR–GAAR–0328–7059; 9924–PYS]

National Park Service Alaska Region's Subsistence Resource Commission (SRC) Program

AGENCY: National Park Service, Interior.

ACTION: Notice of public meeting for the National Park Service Alaska Region's Subsistence Resource Commission (SRC) program.

SUMMARY: The Gates of the Arctic National Park SRC will meet to develop and continue work on National Park Service (NPS) subsistence hunting program recommendations and other related subsistence management issues. The NPS SRC program is authorized under Title VIII, Section 808 of the Alaska National Interest Lands Conservation Act, Public Law 96–487, to operate in accordance with the provisions of the Federal Advisory Committee Act.

Public Availability of Comments: This meeting is open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. This meeting will be recorded and

meeting minutes will be available upon request from the park superintendent for public inspection approximately six weeks after each meeting. Before including your address, telephone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Gates of the Arctic National Park SRC Meeting Date and Location: The Gates of the Arctic National Park SRC will meet at the Shungnak Public School, 907–437–2151, in Shungnak, Alaska on Wednesday, May 11, 2011 and Thursday, May 12, 2011, from 9 a.m. to 5 p.m. If the meeting dates and location are changed, a notice will be published in local newspapers and announced on local radio stations prior to the meeting date. SRC meeting location and dates may need to be changed based on lack of quorum, inclement weather or local circumstances.

For Further Information on the Gates of the Arctic National Park SRC Meeting Contact: Greg Dudgeon, Superintendent, and Dave Krupa, Subsistence Manager, (907) 457–5752, Gates of the Arctic National Park and Preserve, 4175 Geist Road, Fairbanks, Alaska 99709, or Clarence Summers, Subsistence Manager, NPS Alaska Regional Office, at (907) 644–3603.

Proposed SRC Meeting Agenda

The proposed meeting agenda includes the following:

1. Call to order
2. SRC Roll Call and Confirmation of Quorum
3. Welcome and Introductions
4. Approval of Minutes
5. Administrative Announcements
6. Approve Agenda
7. Review SRC Purpose
8. SRC Member Reports
9. Public and Other Agency Comments
10. Federal Subsistence Board Update
11. Alaska Board of Game Update
12. Old Business
13. New Business
    a. Subsistence Manager Report
    b. Ranger Report
    c. Resource Management Program Update
13. Subsistence Uses of Horns, Antlers, Bones and Plants EA Update
14. Public and other Agency Comments
15. SRC Work Session
16. Set Time and Place for next SRC Meeting
17. Adjournment

Sue E. Masica,

Regional Director, Alaska.

[FR Doc. 2011–9179 Filed 4–14–11; 8:45 am]

BILLING CODE 4310–HK–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act; Clean Water Act; and Oil Pollution Act

Notice is hereby given that on April 6, 2011, a proposed Consent Decree (the "Consent Decree") in *United States of America, on Behalf of the National Oceanic and Atmospheric Administration and the United States Department of the Interior; State of Washington through the Washington Department of Ecology; Muckleshoot Indian Tribe; and Puyallup Tribe of Indians* v. *Foss Maritime Company and Maritime Industries Northwest, Inc.,* No. 11-cv-5263, was lodged with the United States Western District of Washington. The Complaint alleged claims under section 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9607(a); section 311 of the Clean Water Act (CWA), 33 U.S.C. 1321; and section 1002(b) of the Oil Pollution Act (OPA), 33 U.S.C. 2702(b), for damages for injury to, destruction of, or loss of natural resources resulting from the release of hazardous substances and discharges of oil into the Middle Waterway of the Commencement Bay/Nearshore Tideflats Superfund site in Tacoma, Washington.

In settlement of the claims for injury to, destruction of, or loss of natural resources, the Defendants have agreed to preserve the site of a former marine dock at the mouth of Middle Waterway in perpetuity for use as a habitat restoration site, and will pay $7,802,081.29 in cash. In addition, the Defendants will pay $300,000.00 toward the Trustees' long-term restoration project oversight and stewardship activities and $700,000.00 to reimburse Trustee damage assessment costs.

During the public comment period, the Consent Decree may be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, United States Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, United States Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Foss Maritime Company, et al.* DJ. Ref. 90–11–2–729/2.

In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $10.75 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–9139 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Network Centric Operations Industry Consortium, Inc.

Notice is hereby given that, on March 16, 2011, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Network Centric Operations Industry Consortium, Inc. ("NCOIC") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Telos, Simi Valley, CA; Stevens Institute, Hoboken, NJ; and FacetApps, Seattle, WA, have been added as parties to this venture.

Also, EDISOFT S.A., Caparica, Setubal, PORTUGAL; COMCARE, Washington, DC; ASELASAN Elektronik Sanayi ve Ticaret A.S., Ankara, TURKEY; MilSOFT ICT-Iletisim Teknolojileri A.S., Ankara TURKEY; Terrestar Networks, Inc,. Reston, VA;

ABG SPIN S.A., Warsaw, POLAND; AMPER Programas de Electronica y Cominicaciones S.A., Getafe, Madrid, SPAIN; Technopole Defence & Security, Quebec, CANADA; and Mark A. Wainwright (individual member), Nashua, NH, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Network Centric Operations Industry Consortium, Inc. intends to file additional written notifications disclosing all changes in membership.

On November 19, 2004, NCOIC filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 2, 2005 (70 FR 5486).

The last notification was filed with the Department on December 20, 2010. A notice was filed with the Department on December 20, 2010. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act February 1, 2011 (76 FR 5610).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2011–9042 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–40]

Michael J. Aruta, M.D.; Decision and Order

ACTION: Correction.

On Thursday, April 7, 2011, the Drug Enforcement Administration published the above-titled Decision and Order, as well as the Decision of the Administrative Law Judge (76 FR 19420). In preparing the document for publication, the files were merged resulting in the footnotes of the Administrative Law Judge's Decision being numbered sequentially to follow the footnote numbers of the Decision and Order rather than beginning with the number 1 as they did in the ALJ's slip opinion.

Therefore, this notice corrects footnotes 4 through 69 appearing in the Decision signed by the U.S. Administrative Law Judge to be footnotes 1 through 66 beginning at 76 FR 19420 under the third column.

Dated: April 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–9173 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–35]

Beau Boshers, M.D.; Decision and Order

ACTION: Correction.

On Thursday, April 7, 2011, the Drug Enforcement Administration published the above-titled Decision and Order, as well as the Decision of the Administrative Law Judge (76 FR 19401). In preparing the document for publication, the files were merged resulting in the footnotes of the Administrative Law Judge's Decision being numbered sequentially to follow the footnote numbers of the Decision and Order rather than beginning with the number 1 as they did in the ALJ's slip opinion.

Therefore, this notice corrects footnotes 10 through 84 appearing in the Decision signed by the U.S. Administrative Law Judge to be footnotes 1 through 75 beginning at 76 FR 19404 under the third column.

Dated: April 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–9172 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–34]

Cynthia M. Cadet, M.D.; Decision and Order

ACTION: Correction.

On Thursday, April 7, 2011, the Drug Enforcement Administration published the above-titled Decision and Order, as well as the Decision of the Administrative Law Judge (76 FR 19450). In preparing the document for publication, the files were merged resulting in the footnotes of the Administrative Law Judge's Decision being numbered sequentially to follow the footnote numbers of the Decision and Order rather than beginning with the number 1 as they did in the ALJ's slip opinion.

Therefore, this notice corrects footnotes 4 through 67 appearing in the Decision signed by the U.S. Administrative Law Judge to be footnotes 1 through 64 beginning at 76 FR 19451 under the second column.

Dated: April 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–9170 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–37]

Roni Dreszer, M.D.; Decision and Order

ACTION: Correction.

On Thursday, April 7, 2011, the Drug Enforcement Administration published the above-titled Decision and Order, as well as the Decision of the Administrative Law Judge (76 FR 19434). In preparing the document for publication, the files were merged resulting in the footnotes of the Administrative Law Judge's Decision being numbered sequentially to follow the footnote numbers of the Decision and Order rather than beginning with the number 1 as they did in the ALJ's slip opinion.

Therefore, this notice corrects footnotes 11 through 71 appearing in the Decision signed by the U.S. Administrative Law Judge to be footnotes 1 through 61 beginning at 76 FR 19437 under the second column.

Dated: April 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–9174 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–36]

Jacobo Dreszer, M.D.; Decision and Order

ACTION: Correction.

On Thursday, April 7, 2011, the Drug Enforcement Administration published the above-titled Decision and Order, as well as the Decision of the Administrative Law Judge (76 FR 19386). In preparing the document for publication, the files were merged resulting in the footnotes of the Administrative Law Judge's Decision

being numbered sequentially to follow the footnote numbers of the Decision and Order rather than beginning with the number 1 as they did in the ALJ's slip opinion.

Therefore, this notice corrects footnotes 12 through 67 appearing in the Decision signed by the U.S. Administrative Law Judge to be footnotes 1 through 56 beginning at 76 FR 19390 under the first column.

Dated: April 8, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–9171 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Registration

By Notice dated November 19, 2010, and published in the **Federal Register** on December 3, 2010, 75 FR 75497, Siegfried (USA), Inc., 33 Industrial Park Road, Pennsville, New Jersey 08070, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Hydromorphinol (9301), a basic class of controlled substance in schedule I.

The company plans to manufacture small quantities of the listed controlled substance in bulk for distribution to its customers for use as reference standards.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Siegfried (USA), Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Siegfried (USA), Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: April 8, 2011.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2011–9175 Filed 4–14–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Current Population Survey—Basic Labor Force

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Bureau of Labor Statistics (BLS) sponsored information collection request (ICR) titled, "Current Population Survey—Basic Labor Force," to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Submit comments on or before May 16, 2011.

ADDRESSES: A copy of this ICR, with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an e-mail to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, *Attn:* OMB Desk Officer for the Department of Labor, Bureau of Labor Statistics (BLS), Office of Management and Budget, Room 10235, Washington, DC 20503, *Telephone:* 202–395–6929/*Fax:* 202–395–6881 (these are not toll-free numbers), e-mail: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by e-mail at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The labor force data collected in the Current Population Survey (CPS) help to determine the employment situation of specific population groups as well as general trends in employment and unemployment. The survey is the only source of monthly data on total employment and unemployment. The *Employment Situation* report contains data from this survey and is designated as a Principle Federal Economic Indicator; moreover, the survey also yields data on the basic status and characteristics of persons not in the labor force. CPS data are used monthly, in conjunction with data from other sources, to analyze the extent to which, and with what success, the various components of the American population are participating in the economic life of the nation.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid OMB control number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under OMB Control Number 1220–0100. The current OMB approval is scheduled to expire on May 31, 2011; however, it should be noted that information collections submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on December 17, 2011 (75 FR 79027).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to ensure appropriate consideration, comments should reference OMB Control Number 1220–0100. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: Bureau of Labor Statistics (BLS).

Title of Collection: Current Population Survey—Basic Labor Force.

OMB Control Number: 1220–0100.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 55,000.

Total Estimated Number of Responses: 660,000.

Total Estimated Annual Burden Hours: 82,500.

Total Estimated Annual Costs Burden: $0.

Dated: April 11, 2011.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2011–9169 Filed 4–14–11; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of March 28, 2011 through April 1, 2011.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the

Federal Register under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
74,817	Kidde-Fenwal, UTC Fire and Security, Davis, Account Temps, Kelly, John, Winter.	Ashland, MA	November 1, 2009.
74,955	Canal Sportswear, Inc.	New York, NY	November 22, 2009.
75,157	Smethport and Lauri Toys, Patch Products, Inc., On-Site Leased Workers from Adecco Employment Service.	Smethport, PA	January 28, 2010.
75,208	Apex Industries, Inc., Labor Finders/LF Staffing and Labor Ready	Spokane Valley, WA	February 8, 2010.
75,209	Raxon Fabrics, Vescom North America, Inc.	Allentown, PA	February 28, 2011.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
74,927	Pfizer, Inc., Pfizer Global Manufacturing, Pfizer Research and Development, etc.	Pearl River, NY	October 26, 2009.
75,012	Research In Motion Limited, Former Workers from Dataviz, Inc	Milford, CT	December 16, 2009.
75,077	Dama Jewelry Technology, Leased Workers From Vincent Porcaro, Inc. and Coworx Staffing Services.	Johnston, RI	January 7, 2010.
75,198	ACS Outsourcing Solutions, Inc., A Xerox Company	Pittsburgh, PA	February 8, 2010.
75,210	PricewaterhouseCoopers LLP, Human Resources Shared Services Center, Talent Acquisition Associates, etc.	Tampa, FL	February 8, 2010.
75,258	Kaz, Inc	Hudson, NY	September 20, 2010.
75,261	Highmark West Virginia, Inc., Health Plan Operations, Workers Working from Their Homes in WV and OH.	Parkersburg, WV	February 11, 2010.
75,288	AT&T Operations, Inc., ABS–GCS Managed Services, GM/GMAC Account, Zerochaos, Allegis Group.	Detroit, MI	February 11, 2010.
75,301	Springs Global US, Inc., Grace Complex, Springs Global Participacoes, Defender Industries.	Lancaster, SC	February 14, 2010.
75,301A	Springs Global US, Inc., Riverlawn Distribution Center, Springs Global Participacoes, Defender.	Fort Lawn, SC	February 14, 2010.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or (b)(1), or (c)(1)(employment decline or threat of separation) of section 222 has not been met.

TA–W No.	Subject firm	Location	Impact date
75,199	Dell USA LP, Dell, Inc. Identity and Directory Services—Account Mgt	Round Rock, TX.	
75,251	JPMorgan Chase and Company, Treasury and Securities, Core Cash Group, Receivable Technology (IT).	Fort Worth, TX.	

The investigation revealed that the criteria under paragraphs(a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
74,738	Bombardier Mass Transit Corporation, Overhaul Division	Bath, NY.	
74,765	Patriot Antenna Systems, Inc., Cobham PLC	Albion, MI.	
75,197	Regence Blue Cross Blue Shield of Utah, IT, KForce, Inc., Personnel Source, and IBM.	Salt Lake City, UT.	
75,240	International Business Machines (IBM), GTS NA West IMT Region Maintenance and Technical Support.	Milwaukee, WI.	

TA–W No.	Subject firm	Location	Impact date
75,264	City of Firsts Community Federal Credit Union, South Branch	Kokomo, IN.	

I hereby certify that the aforementioned determinations were issued during the period of March 28, 2011 through April 1, 2011. Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's website at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: April 8, 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–9168 Filed 4–14–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0133]

Proposed Extension of Existing Information Collection; Hazard Communication (HazCom)

AGENCY: Mine Safety and Health Administration, Department of Labor.

ACTION: Notice of request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 [44 U.S.C. 3506(c)(2)(A)]. This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the extension of the information collection for 30 CFR part 47.

DATES: All comments must be postmarked or received by midnight Eastern Standard Time on June 14, 2011.

ADDRESSES: Comments must be clearly identified with the rule title and may be submitted to MSHA by any of the following methods:

(1) *Electronic mail: zzMSHA-Comments@dol.gov.*

(2) *Facsimile:* 202–693–9441.

(3) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, VA 22209–3939.

(4) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, VA 22209–3939. Sign in at the receptionist's desk on the 21st floor.

FOR FURTHER INFORMATION CONTACT: Mario Distasio, Chief of the Economic Analysis Division, Office of Standards, Regulations, and Variances, MSHA, at *distasio.mario@dol.gov* (e-mail), 202–693–9445 (voice mail), 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(a)(7) of the Federal Mine Safety and Health Act of 1977, as amended (Mine Act) requires, in part, that mandatory standards prescribe the use of labels or other appropriate forms of warning as are necessary to insure that miners are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions for safe use or exposure.

MSHA collected evidence from the National Institute for Occupational Safety and Health's (NIOSH) Occupational Health Survey of Mining and other sources indicating that there were chemical exposures occurring in every type of mine, although every miner may not have been exposed. MSHA became concerned that miners were being exposed to chemicals and may not have known the hazards of those chemicals or the appropriate precautions to prevent injury or illness caused by exposure to a hazardous chemical.

II. Desired Focus of Comments

MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

A copy of the information collection request can be obtained by contacting the person listed in the **FOR FURTHER INFORMATION** section of this notice, or viewed on the Internet at *http://www.msha.gov* and by selecting "FedReg. Docs" under "Rules & Regs" on the right side of the screen. On the next screen, select "Information Collection Requests" to view documents supporting this **Federal Register** notice.

III. Current Actions

This notice contains the request for an extension of the existing collection of information in 30 CFR Part 47. MSHA does not intend to publish the results from this information collection and is not seeking approval to either display or not display the expiration date for the OMB approval of this information collection.

There are no certification exceptions identified with this information collection and the collection of this information does not employ statistical methods.

Type of Review: Renewal.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0133.

Frequency: Daily, weekly, monthly, semi-annually, and on occasion.

Affected Public: Business or other for-profit.

Cost to Federal Government: There are no costs to the federal government.

Total Number of Respondents: 22,381.

Total Number of Responses: 813,753.

Total Burden Hours: 177,668 hours.

Total Hour Burden Cost (operating/maintaining): $13,199.

Comments submitted in response to this notice will be summarized and included in the request for Office of

Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: April 12, 2011.

Patricia W. Silvey,

Certifying Officer.

[FR Doc. 2011–9192 Filed 4–14–11; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (11–041)]

NASA Advisory Council; Science Committee; Planetary Protection Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Planetary Protection Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

DATES: Tuesday, May 10, 2011, 9 a.m. to 5 p.m., and Wednesday, May 11, 2011, 9 a.m. to 1 p.m., Local Time.

ADDRESSES: NASA Headquarters, 300 E Street, SW., Rooms 5H45 and 9H40 consecutively, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

— Mars Missions: Status and Plans
— Planetary Science Decadal Survey
— Planetary Protection Context for International and Commercial Activities
— Agency Planetary Protection Integration/Coordination Activities

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID, before receiving an access badge. Foreign nationals attending this meeting will be required to provide a copy of their passport, visa, or green card in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa/green card information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, attendees with U.S. citizenship can provide identifying information 3 working days in advance by contacting Marian Norris via e-mail at *mnorris@nasa.gov* or by telephone at (202) 358–4452.

Dated: April 8, 2011.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration and Space Administration.

[FR Doc. 2011–9122 Filed 4–14–11; 8:45 am]

BILLING CODE P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: U.S. Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This gives notice of OPM decisions granting authority to make appointments under Schedules A, B, and C in the excepted service as required by 5 CFR 213.103.

FOR FURTHER INFORMATION CONTACT: Roland Edwards, Senior Executive Resource Services, Executive Resources and Employee Development, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: Appearing in the listing below are the individual authorities established under Schedules A, B, and C between February 1, 2011, and February 28, 2011. These notices are published monthly in the **Federal Register** at *http://www.federalregister.gov/.* A consolidated listing of all authorities as of June 30 is also published each year. The following Schedules are *not* codified in the Code of Federal Regulations. These are agency-specific exceptions.

Schedule A

No Schedule A authorities to report during February 2011.

Schedule B

No Schedule B authorities to report during February 2011.

Schedule C

The following Schedule C appointments were approved during February 2011.

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF COMMERCE	Office of Legislative and Intergovernmental Affairs.	Director of Legislative Affairs	DC110032	2/2/2011
	Office of the Under Secretary	Speechwriter	DC110034	2/4/2011
	Office of the Chief of Staff	Director, National Export Events	DC110027	2/4/2011
	Office of Assistant Secretary for Legislative and Intergovernmental Affairs.	Associate Director of Legislative and Intergovernmental Affairs.	DC110038	2/4/2011
	Office of Assistant Secretary for Legislative and Intergovernmental Affairs.	Associate Director of Legislative Affairs.	DC110037	2/9/2011
COMMISSION ON CIVIL RIGHTS	Staff Members	Special Assistant	CC110005	2/7/2011
DEPARTMENT OF DEFENSE	Office of Assistant Secretary of Defense (Legislative Affairs).	Special Assistant	DD110041	2/28/2011
	Office of the Under Secretary of Defense (Personnel and Readiness).	Special Assistant for Reserve Affairs.	DD110042	2/28/2011
DEPARTMENT OF THE NAVY	Office of the Under Secretary of the Navy.	Special Assistant	DN110012	2/8/2011

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF EDUCATION	Office of English Language Acquisition, Language Enhancement, and Academic Achievement for Limited English Proficient Students.	Deputy Director	DB110025	2/4/2011
	Office of Special Education and Rehabilitative Services.	Confidential Assistant	DB110015	2/8/2011
	Department of Education	Deputy Director Program Mgmt and Performance Unit.	DB110021	2/8/2011
	Office of the Secretary	Special Assistant	DB110019	2/10/2011
	Office of Planning, Evaluation and Policy Development.	Confidential Assistant	DB110031	2/11/2011
	Office of Legislation and Congressional Affairs.	Confidential Assistant	DB110030	2/11/2011
	Office of Safe and Drug-Free Schools.	Special Assistant	DB110020	2/11/2011
	Office of Legislation and Congressional Affairs.	Special Assistant	DB110029	2/11/2011
	Office of Elementary and Secondary Education.	Confidential Assistant	DB110032	2/23/2011
DEPARTMENT OF ENERGY	National Nuclear Security Administration.	Deputy Director of Public Affairs	DE110041	2/23/2011
	Loan Programs Office	Assistant Director for External Relations.	DE110036	2/23/2011
	National Nuclear Security Administration.	Director of Congressional Affairs	DE110047	2/23/2011
ENVIRONMENTAL PROTECTION AGENCY.	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Senior Advisor	EP110018	2/18/2011
GENERAL SERVICES ADMINISTRATION.	Mid-Atlantic Region	Special Assistant	GS110024	2/18/2011
	Office of Congressional and Intergovernmental Affairs.	Deputy Associate Administrator for Legislative Affairs.	GS110026	2/18/2011
	Office of Congressional and Intergovernmental Affairs.	Deputy Associate Administrator for Policy.	GS110025	2/18/2011
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of Public Affairs	Senior Advisor, Office of Public Affairs, Administration for Children and Families.	DH110053	2/28/2011
	Center for Consumer Information and Insurance Oversight.	Senior Advisor	DH110057	2/28/2011
DEPARTMENT OF HOMELAND SECURITY.	Office of the Assistant Secretary for Policy.	Special Assistant	DM110033	2/2/2011
	Office of the Chief of Staff	White House Liaison	DM110075	2/11/2011
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of Sustainable Housing and Communities.	Senior Counsel	DU110016	2/18/2011
DEPARTMENT OF THE INTERIOR	Office of the Solicitor	Attorney-Advisor	DI110032	2/4/2011
	Assistant Secretary—Indian Affairs	Deputy Chief of Staff	DI110033	2/17/2011
	Office of Congressional and Legislative Affairs.	Special Assistant	DI110037	2/23/2011
DEPARTMENT OF JUSTICE	Office of Public Affairs	Deputy Speechwriter	DJ110054	2/18/2011
DEPARTMENT OF LABOR	Wage and Hour Division	Senior Advisor	DL110012	2/17/2011
	Bureau of International Labor Affairs	Deputy Chief of Staff	DL110009	2/25/2011
OFFICE OF MANAGEMENT AND BUDGET.	Office of the Director	Confidential Assistant, Government Reorganization Initiative.	BO110012	2/22/2011
	Office of the Director	Confidential Assistant	BO110010	2/23/2011
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.	Office of the Ambassador	Special Assistant for Scheduling	TN110003	2/2/2011
SECURITIES AND EXCHANGE COMMISSION.	Office of the Chairman	Confidential Assistant	SE110002	2/17/2011
SMALL BUSINESS ADMINISTRATION.	Office of the Administrator	Special Assistant	SB110018	2/17/2011
	Office of Management and Administration.	Senior Advisor for Management and Administration.	SB110019	2/23/2011
	Office of the Administrator	Special Assistant and Scheduler	SB110021	2/28/2011
DEPARTMENT OF STATE	Office of the Counselor	Special Assistant	DS110046	2/23/2011
UNITED STATES INTERNATIONAL TRADE COMMISSION.	Office of the Chairman	Staff Assistant	TC110003	2/25/2011
DEPARTMENT OF VETERANS AFFAIRS.	Office of the Assistant Secretary for Public and Intergovernmental Affairs.	Special Assistant	DV110004	2/7/2011
	Office of the Secretary and Deputy	Special Assistant, White House Liaison.	DV110017	2/23/2011

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218.

John Berry,

Director, U.S. Office of Personnel Management.

[FR Doc. 2011–9202 Filed 4–14–11; 8:45 am]

BILLING CODE 6325–39–P

POSTAL REGULATORY COMMISSION

[Docket No. MC2011–24; Order No. 714]

Classification Changes for Competitive Mail Services

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service notice of two classification changes concerning certain competitive mail services. This notice informs the public of the filing, addresses preliminary procedural matters, and invites public comment.

DATES: *Comments are due:* April 22, 2011.

ADDRESSES: Submit comments electronically by accessing the "Filing Online" link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at 202–789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: On April 8, 2011, the Postal Service filed a notice of two classification changes pursuant to 39 CFR 3020.90 and 3020.91 concerning certain competitive mail services.[1] The first change modifies the size and weight limitation table for Global Express Guaranteed (GXG) in the Mail Classification Schedule (MCS) with the addition of a note to reflect that country-specific restrictions may apply as designated in the International Mail Manual. The Postal Service states that this minor change is proposed to reflect changes to country-specific size and weight restrictions imposed by the Postal Service's delivery carrier. *Id.* at 1. It relates that a note reflecting restrictions applicable to Express Mail International (EMI) is currently included in the MCS and the change for GXG is intended to parallel the EMI restrictions. *Id.* The Postal Service states that it intends to publish the country-specific restrictions in the *Postal Bulletin* on June 2, 2011, with an effective date of June 6, 2011. *Id.*

The second change adds another dimensional option to the large Flat Rate Box for Priority Mail and Outbound Priority Mail International services. *Id.* at 1. The Postal Service explains that the current dimensions are 12.25 x 12.25 x 6.0 inches and the new option of 11.875 x 3.125 x 24.0625 inches is suited for board games. *Id.* at 2. It states that the cubic size of the new large Flat Rate Box remains the same. The Postal Service states that inadvertently it did not advise the Commission that this dimension option is currently available on *http://www.usps.com.* Therefore, it proposes that the change to the MCS reflecting this change be effective as soon as possible. *Id.*

The Postal Service asserts these classification changes are consistent with the requirements of 39 U.S.C. 3642, and further proposes conforming MCS language. *Id.* at 2.

The Commission establishes Docket No. MC2011–24 for consideration of matters related to the proposed classification change identified in the Postal Service's Notice.

Interested persons may submit comments on whether the Postal Service's request is consistent with the policies of 39 U.S.C. 3642 and generally with the provisions of title 39. Comments are due no later than April 22, 2011. The Postal Service's Notice can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jeremy Simmons to serve as Public Representative in the captioned proceeding.

It is ordered:

1. The Commission establishes Docket No. MC2011–24 for consideration of matters raised by the Postal Service's Notice.

2. Comments by interested persons are due no later than April 22, 2011.

3. Pursuant to 39 U.S.C. 505, Jeremy Simmons is appointed to serve as the officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2011–9145 Filed 4–14–11; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Classification Changes, April 8, 2011 (Notice).

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review, Request for Comments

Summary: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Railroad Retirement Board (RRB) is forwarding an Information Collection Request (ICR) to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) to request an extension without change of a currently approved collection of information: 3220–0176, Representative Payee Parental Custody Report. Out ICR describes the information we seek to collect from the public. Review and approval by OIRA ensures that we impose appropriate paperwork burdens.

The RRB invites comments on the proposed collection of information to determine (1) the ractical utility of the collection; (2) the accuracy of the estimated burden of the collection; (3) ways to enhance the quality, utility and clarity of the information that is the subject of collection; and (4) ways to minimize the burden of collections on respondents, including the use of automated collection techniques or other forms of information technology. Comments to RRB or OIRA must contain the OMB control number of the ICR. For proper consideration of your comments, it is best if the RRB and OIRA receive them within 30 days of publication date.

Under Section 12(a) of the Railroad Retirement Act (RRA), the RRB is authorized to select, make payments to, and to conduct transactions with, a beneficiary's relative or some other person willing to act on behalf of the beneficiary as a representative payee. The RRB is responsible for determining if direct payment to the beneficiary or payment to a representative payee would best serve the beneficiary's interest. Inherent in the RRB's authorization to select a representative payee is the responsibility to monitor the payee to assure that the beneficiary's interests are protected. The RRB utilizes Form G–99D, Parental Custody Report, to obtain information needed to verify that a parent-for-child representative payee still has custody of the child. One response is required from each respondent. The RRB proposes no changes to Form G–99D.

Previous Requests for Comments: The RRB has already published the initial 60-day notice (75 FR 79056 on December 17, 2010) required by 44 U.S.C. 3506(c)(2). That request elicited no comments.

Information Collection Request (ICR)

Title: Representative Payee Parental Custody Monitoring.

OMB Control Number: 3220–0176.

Form(s) submitted: G–99D.

Type of request: Extension without change of a currently approved collection.

Affected public: Individuals or households.

Abstract: Under Section 12(a) of the Railroad Retirement Act, the RRB is authorized to select, make payments to, and conduct transactions with an annuitant's relative or some other person willing to act on behalf of the annuitant as a representative payee. The collection obtains information needed to verify the parent-for-child payee still retains custody of the child.

Changes proposed: The RRB proposes no changes to Form G–99D.

The Burden Estimate for the ICR Is as Follows

Estimated Completion Time for Form(s): Completion time for Form G–99D is estimated at 5 minutes.

Estimated annual number of respondents: 1,030.

Total annual responses: 1,030.

Total annual reporting hours: 86.

Additional Information or Comments: Copies of the forms and supporting documents can be obtained from Charles Mierzwa, the RRB Clearance Officer, at (312) 751–3363 or *Charles.Mierzwa@RRB.GOV.*

Comments regarding the information collection should be addressed to Patricia Henaghan, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or *Patricia.Henaghan@RRB.GOV* and to the OMB Desk Officer for the RRB, Fax: 202–395–6974, E-mail address: *OIRA_Submission@omb.eop.gov.*

Charles Mierzwa,

Clearance Officer.

[FR Doc. 2011–9157 Filed 4–14–11; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 101, SEC File No. 270–408, OMB Control No. 3235–0464.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the existing collection of information provided for in the following rule: Rule 101 of Regulation M (17 CFR 242.101).

Rule 101 prohibits distribution participants from purchasing activities at specified times during a distribution of securities. Persons otherwise covered by these rules may seek to use several applicable exceptions such as a calculation of the average daily trading volume of the securities in distribution, the maintenance of policies regarding information barriers between their affiliates, and the maintenance a written policy regarding general compliance with Regulation M for de minimus transactions.

There are approximately 1588 respondents per year that require an aggregate total of 31,309 hours to comply with this rule. Each respondent makes an estimated 1 annual response. Each response takes approximately 20 hours to complete. Thus, the total compliance burden per year is 31,309 burden hours. The total estimated internal labor compliance cost for the respondents is approximately $1,783,673.73, resulting in a cost of compliance for the respondent per response of approximately $1123.22 (i.e., $1,783,673.73/1588 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *http://www.reginfo.gov.* Comments should be directed to (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted within 30 days of this notice.

Dated: April 11, 2011.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–9186 Filed 4–14–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 103; SEC File No. 270–410; OMB Control No. 3235–0466.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the existing collection of information provided for in the following rule: Rule 103 of Regulation M (17 CFR 242.103).

Rule 103 permits passive market-making in Nasdaq securities during a distribution. A distribution participant that seeks use of this exception would be required to disclose to third parties its intention to engage in passive market making.

There are approximately 298 respondents per year that require an aggregate total of 298 hours to comply with this rule. Each respondent makes an estimated 1 response annually. Each response takes approximately 1 hour to complete. Thus, the total hourly burden per year is 298 hours. The total estimated internal labor cost for the respondents is approximately $19,966.00, resulting in an estimated internal labor cost per response of approximately $67.00 (*i.e.,* $19,966.00/298 responses).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. Background documentation for this information collection may be viewed at the following link, *http://www.reginfo.gov.*

Comments should be directed to (i) Desk Officer for the Securities and Exchange Commission, Office of

Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted within 30 days of this notice.

April 11, 2011.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–9187 Filed 4–14–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17d–1; SEC File No. 270–505; OMB Control No. 3235–0562.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for extension of the previously approved collection of information discussed below.

Section 17(d) (15 U.S.C. 80a–17(d)) of the Investment Company Act of 1940 (15 U.S.C. 80a *et seq.*) (the "Act") prohibits first- and second-tier affiliates of a fund, the fund's principal underwriters, and affiliated persons of the fund's principal underwriters, acting as principal, to effect any transaction in which the fund or a company controlled by the fund is a joint or a joint and several participant in contravention of the Commission's rules. Rule 17d–1 (17 CFR 270.17d–1) prohibits an affiliated person of or principal underwriter for any fund (a "first-tier affiliate"), or any affiliated person of such person or underwriter (a "second-tier affiliate"), acting as principal, from participating in or effecting any transaction in connection with a joint enterprise or other joint arrangement in which the fund is a participant, unless prior to entering into the enterprise or arrangement "an application regarding [the transaction] has been filed with the Commission and has been granted by an order." In reviewing the proposed affiliated transaction, the rule provides that the Commission will consider whether the proposal is (i) consistent with the provisions, policies, and purposes of the Act, and (ii) on a basis different from or less advantageous than that of other participants in determining whether to grant an exemptive application for a proposed joint enterprise, joint arrangement, or profit-sharing plan.

Rule 17d–1 also contains a number of exceptions to the requirement that a fund must obtain Commission approval prior to entering into joint transactions or arrangements with affiliates. For example, funds do not have to obtain Commission approval for certain employee compensation plans, certain tax-deferred employee benefit plans, certain transactions involving small business investment companies, the receipt of securities or cash by certain affiliates pursuant to a plan of reorganization, certain arrangements regarding liability insurance policies and transactions with "portfolio affiliates" (companies that are affiliated with the fund solely as a result of the fund (or an affiliated fund) controlling them or owning more than five percent of their voting securities) so long as certain other affiliated persons of the fund (*e.g.,* the fund's adviser, persons controlling the fund, and persons under common control with the fund) are not parties to the transaction and do not have a "financial interest" in a party to the transaction. The rule excludes from the definition of "financial interest" any interest that the fund's board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material, as long as the board records the basis for its finding in their meeting minutes.

Thus, the rule contains two filing and recordkeeping requirements that constitute collections of information. First, rule 17d–1 requires funds that wish to engage in a joint transaction or arrangement with affiliates to meet the procedural requirements for obtaining exemptive relief from the rule's prohibition on joint transactions or arrangements involving first- or second-tier affiliates. Second, rule 17d–1 permits a portfolio affiliate to enter into a joint transaction or arrangement with the fund if a prohibited participant has a financial interest that the fund's board determines is not material and records the basis for this finding in their meeting minutes. These requirements of rule 17d–1 are designed to prevent fund insiders from managing funds for their own benefit, rather than for the benefit of the funds' shareholders.

Based on an analysis of past filings, Commission staff estimates that 8 funds file applications under section 17(d) and rule 17d–1 per year. The staff understands that funds that file an application generally obtain assistance from outside counsel to prepare the application. The cost burden of using outside counsel is discussed below. Based on a limited survey of persons in the mutual fund industry, the Commission staff estimates that each applicant will spend an average of 154 hours to comply with the Commission's applications process. The Commission staff therefore estimates the annual burden hours per year for all funds under rule 17d–1's application process to be 1,232 hours at a cost of $445,328.[1] The Commission, therefore, requests authorization to increase the inventory of total burden hours per year for all funds under rule 17d–1 from the current authorized burden of 616 hours to 1,232 hours. The increase is due to an increase in the number of funds that filed applications for exemptions under rule 17d–1.

As noted above, the Commission staff understands that funds that file an application under rule 17d–1 generally use outside counsel to assist in preparing the application.[2] The staff estimates that, on average, funds spend an additional $93,131 for outside legal services in connection with seeking Commission approval of affiliated joint transactions. Thus, the staff estimates that the total annual cost burden imposed by the exemptive application requirements of rule 17d–1 is $745,048.[3] Based on staff discussions with fund representatives, we estimate that funds currently do not rely on the exemption from the term "financial interest" with respect to any interest that the fund's

[1] The Commission staff estimates that a senior executive, such as the fund's chief compliance officer, will spend an average of 62 hours and a mid-level compliance attorney will spend an average of 92 hours to comply with this collection of information: 62 hours + 92 hours = 154 hours. 8 funds × 154 burden hours = 1,232 burden hours. The Commission staff estimate that the chief compliance officer is paid $423 per hour and the compliance attorney is paid $320 per hour. ($423 per hour × 62 hours) + ($320 per hour × 92 hours) = $55,666 per fund. $55,666 × 8 funds = $445,328. The $423 and $320 per hour figures are based on salary information compiled by SIFMA's *Management & Professional Earnings in the Securities Industry, 2010.* The Commission staff has modified SIFMA's information to account for an 1800-hour work year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

[2] This understanding is based on conversations with representatives from the fund industry.

[3] The estimate is based on the following calculation: $93,131 × 8 funds = $745,048.

board of directors (including a majority of the directors who are not interested persons of the fund) finds to be not material. Accordingly, we estimate that annually there will be no transactions under rule 17d–1 that will result in this aspect of the collection of information.

Based on these calculations, the total annual hour burden is estimated to be 1,232 hours and the total annual cost burden is estimated to be $745,048.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act. The estimate is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Complying with these collections of information requirements is necessary to obtain the benefit of relying on rule 17d–1. Responses will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following Web site, *http//www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted to OMB within 30 days of this notice.

April 11, 2011.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–9189 Filed 4–14–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: U.S. Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 104; SEC File No. 270–411; OMB Control No. 3235–0465.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the existing collection of information provided for in the following rule: Rule 104 of Regulation M (17 CFR 242.104).

Rule 104 permits stabilizing by a distribution participant during a distribution so long as the distribution participant discloses information to the market and investors. This rule requires disclosure in offering materials of the potential stabilizing transactions and that the distribution participant inform the market when a stabilizing bid is made. It also requires the distribution participants (*i.e.* the syndicate manager) to maintain information regarding syndicate covering transactions and penalty bids.

There are approximately 745 respondents per year that require an aggregate total of 149 hours to comply with this rule. Each respondent makes an estimated 1 annual response. Each response takes approximately 0.20 hours (12 minutes) to complete. Thus, the total compliance burden per year is 149 burden hours. The total internal labor compliance cost for the respondents is approximately $9,983.00, resulting in an estimate of $13.40 (*i.e.,* $9,983.00/745 responses) per response.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. Background documentation for this information collection may be viewed at the following link, *http://www.reginfo.gov.*

Comments should be directed to (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Thomas Bayer, Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov.* Comments must be submitted within 30 days of this notice.

April 11, 2011.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–9188 Filed 4–14–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64292; File No. SR–ISE–2011–22]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Network Fees

April 11, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 7, 2011, the International Securities Exchange, LLC (the "Exchange" or the "ISE") filed with the Securities and Exchange Commission the proposed rule change, as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE is proposing to adopt fees for a 10 Gigabit network connection. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend the Exchange's Schedule of Fees to adopt fees for a 10 Gigabit (GB) network connection. The Exchange currently has a tiered

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

structure for the Ethernet/Managed Service Provider fee charged to Members. The Ethernet/Managed Service Provider fee is a fee charged to ISE Members to access the ISE's trading system via an Ethernet connection or via a third-party managed service provider. The Ethernet/Managed Service Provider connection carries the same information (such as quotation and trade information) as other forms of connection (such as T–1 and T–3 point-to-point connections).

An Ethernet/Managed Service Provider connection enables users to acquire bandwidth in megabit increments. The Exchange currently charges Members $100 per month for a member's purchase of up to 10 Megabits (MBs) of connection speed, $250 per month for the purchase of 11–100 MBs of connection speed and $500 per month for the purchase of 101 MBs—1 GB of connection speed. These fees are charged on a per connection basis.

The Exchange is scheduled to launch an enhanced trading platform called Optimise on April 11, 2011. Upon transitioning to the Optimise trading platform, ISE will offer a new network connectivity option for Members. One of the many perceived advantages that the Optimise trading platform will offer is greatly improved capacity and throughput. To allow Members to maximize Optimise's low latency, ISE will offer a connectivity option of 10 GBs. ISE proposes to charge Members a fee of $4,000 per month for this 10 GB connection. ISE will retain the current Ethernet connectivity options that are available to Members today.

Once Optimise is rolled out, and until the Exchange has fully transitioned from the current trading platform to the Optimise trading platform, market makers will be required to maintain connections to both trading systems. Therefore, ISE proposes to waive the new 10 GB fee for all members until the migration is entirely completed. The Exchange notes that the fees proposed herein are intended to cover and are reasonably related to ISE's costs of rolling out and supporting the new service.

The Exchange has designated this proposal to be operative on April 11, 2011.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[3] in general, and with Section 6(b)(4) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among Exchange members and other persons using its facilities. In particular, the proposed rule change will provide greater transparency into the connectivity options available to market participants. The proposed rule change treats similarly situated Members in the same manner by assessing the same fees to all Members based on their connectivity needs. The Exchange notes that the 10 GB connectivity option proposed herein is similar to that currently in place at other exchanges. For example, NASDAQ OMX PHLX, Inc. ("PHLX"), NASDAQ OMX BX, Inc. ("BX") and the NASDAQ Stock Market LLC ("NASDAQ") each offer a 10GB network connection option to their members, albeit at a higher cost than that proposed by ISE.[5]

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[6] At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form *http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–ISE–2011–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2011–22. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the ISE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2011–22 and should be submitted by May 6, 2011.

[3] 15 U.S.C. 78f .

[4] 15 U.S.C. 78f(b)(4).

[5] *See* Exchange Act Release Nos. 62639 (August 4, 2010), 75 FR 48391 (August 10, 2010) (SR–PHLX–2010–89); 62969 (September 22, 2010), 75 FR 59777 (September 28, 2010) (SR–BX–2010–064); and 62663 (August 9, 2010), 75 FR 49543 (August 13, 2010) (SR–NASDAQ–2010–077). PHLX, BX and NASDAQ each charges $5,000 per month for a 10 GB connection.

[6] 15 U.S.C. 78s(b)(3)(A)(ii).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Cathy Ahn,

Deputy Secretary.

[FR Doc. 2011–9121 Filed 4–14–11; 8:45 am]

BILLING CODE 8011–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Fiscal Year 2011 Allocation of Additional Tariff-Rate Quota Volume for Raw Cane Sugar and Reallocation of Unused Fiscal Year 2011 Tariff-Rate Quota Volume for Raw Cane Sugar

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country allocations of additional Fiscal Year (FY) 2011 in-quota quantity of the tariff-rate quota (TRQ) for imported raw cane sugar and of country-by-country reallocations of the FY 2011 in-quota quantity of the tariff-rate quota for imported raw cane sugar.

DATES: Effective Date: April 15, 2011.

ADDRESSES: Inquiries may be mailed or delivered to Ann Heilman-Dahl, Director of Agricultural Affairs, Office of Agricultural Affairs, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Ann Heilman-Dahl, Office of Agricultural Affairs, 202–395–6127.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to Chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains TRQs for imports of raw cane and refined sugar.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On April 11, 2011, The Secretary of Agriculture announced an additional in-quota quantity of the TRQ for raw cane sugar for the remainder of FY 2011 (ending September 30, 2011) in the amount of 294,835 metric tons, raw value (MTRV). This quantity is in addition to the minimum amount to which the United States has already committed to pursuant to the World Trade Organization (WTO) Uruguay Round Agreements (1,117,195 MTRV as announced by **Federal Register** notice on August 5, 2010). Finally, USTR has determined to reallocate 102,177 MTRV of the minimum amount of the original TRQ for raw cane sugar from countries that have stated they will be unable to fill previously allocated FY 2011 raw sugar TRQ quantities. USTR is allocating this total quantity of 397,012 MTRV to the following countries in the amounts specified below:

Country	Combined FY 2011 re-allocation and increase
Argentina	21,395
Australia	41,299
Belize	5,474
Bolivia	3,980
Brazil	72,148
Colombia	11,941
Costa Rica	7,463
Dominican Republic	20,000
Ecuador	5,474
El Salvador	12,937
Guatemala	23,884
Guyana	5,971
Honduras	5,000
India	3,980
Jamaica	5,000
Malawi	4,976
Mauritius	2,000
Mozambique	6,469
Nicaragua	10,449
Panama	14,430
Peru	20,400
Philippines	60,000
South Africa	11,444
Swaziland	7,961
Thailand	6,966
Zimbabwe	5,971

These allocations are based on the countries' historical shipments to the United States. The allocations of the raw cane sugar TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin and certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

Conversion factor: 1 metric ton = 1.10231125 short tons.

Ronald Kirk,

United States Trade Representative.

[FR Doc. 2011–9163 Filed 4–14–11; 8:45 am]

BILLING CODE 3190–W1–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending April 2, 2011

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2011–0067.

Date Filed: March 28, 2011.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 18, 2011.

Description: Application of PrivaJet Ltd ("PrivaJet") requesting an exemption and a foreign air carrier permit permitting PrivaJet to conduct charter foreign air transportation of persons, property, and mail to the full extent authorized by the Air Transport Agreement between the United States and the European Community and the Member States of the European Community ("U.S.-E.U. Agreement"). PrivaJet requests authority to the extent necessary for it to engage in: (i) Charter foreign air transportation of persons, property, and mail between any point or points behind any Member State of the European Union via any point or points in any Member State and via intermediate points to any point or point in the United States or beyond; (ii) charter foreign air transportation of persons, property, and mail between any point or points in the United States and any point or points in any Member of the European Common Aviation Area; (iii) other charters pursuant to the prior approval requirements; and (iv) transportation authorized by any additional route rights that may be made available to European Union carriers in the future. PrivaJet also requests an exemption to the extent necessary to enable it to provide the service described above pending issuance of PrivaJet's foreign air carrier permit and

[7] 17 CFR 200.30–3(a)(12).

such other relief as the Department may deem necessary or appropriate.

Docket Number: DOT–OST–2011–0068.

Date Filed: March 29, 2011.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 19, 2011.

Description: Application of American Eagle Airlines, Inc. requesting a certificate of public convenience and necessity authorizing scheduled foreign air transportation of person, property, and mail from a point or points in the United States, via intermediate points, to a point or points in any open skies country.

Docket Number: DOT–OST–2011–0073.

Date Filed: April 1, 2011.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 22, 2011.

Description: Application of Orange Air, LLC requesting a certificate of public convenience and necessity authorizing Orange Air to engage in interstate charter air transportation of persons, property and mail.

Docket Number: DOT–OST–2011–0074.

Date Filed: April 1, 2011.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 22, 2011.

Description: Application of Orange Air, LLC requesting a certificate of public convenience and necessity authorizing Orange Air to engage in foreign charter air transportation of persons, property, and mail between any place in the United States and any place outside thereof.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2011–9162 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending April 2, 2011

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number DOT–OST–2011–0069.

Date Filed March 30, 2011.

Parties Members of the International Air Transport Association.

Subject (a) TC23 between Middle East, Africa and TC3 (except South West Pacific) Flex Fares Resolutions, Geneva, 14–15 June 2010 (Memo 0449/0447), TC23 between Middle East, Africa and TC3 (except South West Pacific) Flex Fares, Geneva, 14–15 June 2010 (Memo 0454/0452), TC23 between Middle East, Africa and TC3 (except South West Pacific) Minutes (Memo 0450/0448).

(b) TC23 Middle East/Africa—TC3 (except South West Pacific) Flex Fare Resolution 111tt, Mail Vote 673 (Memo 0458/0454), Intended Effective Date: 1 April 2011.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2011–9164 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map; Louisville Interntional Airport, Louisville, KY

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the Noise Exposure Maps submitted by Louisville Regional Airport Authority for Louisville International Airport under the provisions of 49 U.S.C. 47501 *et. seq* (Aviation Safety and Noise Abatement Act) and 14 CFR part 150 are in compliance with applicable requirements.

DATES: *Effective Date:* The effective date of the FAA's determination on the noise exposure maps is April 7, 2011.

FOR FURTHER INFORMATION CONTACT: Phillip J. Braden, Federal Aviation Administration, Memphis Airports District Office, 2862 Business Park Drive, Building G, Memphis, Tennessee 38118, 901–322–8181.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the Noise Exposure Maps submitted for Louisville International Airport are in compliance with applicable requirements of Title 14 Code of Federal Regulations (CFR) part 150, effective April 7, 2011. Under 49 U.S.C. section 47503 of the Aviation Safety and Noise Abatement Act (the Act), an airport operator may submit to the FAA Noise Exposure Maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted Noise Exposure Maps that are found by FAA to be in compliance with the requirements of 14 CFR part 150, promulgated pursuant to the Act, may submit a Noise Compatibility Program for FAA approval which sets forth the measures the airport operator has taken or proposes to take to reduce existing noncompatible uses and prevent the introduction of additional noncompatible uses.

The FAA has completed its review of the Noise Exposure Maps and accompanying documentation submitted by Louisville Regional Airport Authority. The documentation that constitutes the "Noise Exposure Maps" as defined in Section 150.7 of 14 CFR part 150 includes: Figure 11, "Existing Condition 2011 Noise Exposure Map"; Figure 12, "Forecast Condition 2012 Noise Exposure Map"; Figure 4, "Existing 2011 North Flow Arrival and Departure Tracks"; Figure 5, "Existing 2011 South Flow Arrival and Departure Tracks"; Figure 6, "Forecast 2016 North Flow Arrival and Departure RNAV Tracks"; Figure 7, "Forecast 2016 South Flow Arrival and Departure RNAV Tracks"; Figure 8, "Military Arrival and Departure Tracks"; Figure 13, "Comparison of Existing 2011 and Forecast 2016 Noise Exposure Maps"; Table 4, "2011 Operations Summary"; Table 5, "Modeled Average Daily Aircraft Operations for 2011"; Table 6, "2016 Operations Summary"; Table 7, "Modeled Average Daily Aircraft Operations for 2016"; Table 9, "Overall Runway Use Percentages for 2011"; Table 10, "Modeled Average Daily Runway Use for 2011"; Table 14, "Overall Runway Use Percentages for 2016"; Table 15, "Modeled Average Daily Runway Use for 2016"; Table 21, "Military Helicopter Flight Tracks and Use"; Table 25, "Estimated Residential Population within 2011 and 2016 DNL Contours". The FAA has determined that these Noise Exposure Maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on April 7, 2011.

FAA's determination on the airport operator's Noise Exposure Maps is limited to a finding that the maps were developed in accordance with the

procedures contained in Appendix A of 14 CFR part 150. Such determination does not constitute approval of the airport operator's data, information or plans, or a commitment to approve a Noise Compatibility Program or to fund the implementation of that Program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a Noise Exposure Map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise exposure contours, or in interpreting the Noise Exposure Maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under 14 CFR part 150 or through FAA's review of Noise Exposure Maps.

Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21 of 14 CFR part 150, that the statutorily required consultation has been accomplished.

Copies of the full Noise Exposure Maps documentation and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, Memphis Airports District Office, 2862 Business Park Drive, Building G, Memphis, Tennessee 38118.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Memphis, Tennessee on April 7, 2011.

Phillip J. Braden,

Manager, Memphis Airports District Office.

[FR Doc. 2011–9224 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2011–0361]

Policy and Procedures Concerning the Use of Airport Revenue; Policy Regarding Airport Rates and Charges: Petition of the Clark County Department of Aviation To Use a Weight-Based Air Service Incentive Program

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of petition; request for comments.

SUMMARY: This notice requests comments on a petition to accept an air service incentive program at McCarran International Airport (Airport) as consistent with Federal law and policies on the use of airport revenue and on airport rates and charges. The petitioner Clark County Department of Aviation is the owner and operator of the Airport. The petitioner is the recipient of Federal grants under the Airport Improvement Program (AIP), and is subject to obligations under AIP grant agreements, including Federal law and policy on the use of airport revenue and on airport rates and charges. The FAA has interpreted these policies, and the underlying Federal statutes, to permit a temporary waiver of standard airport fees for carriers that provide new air service at an airport, as an incentive to begin or expand air service. The agency recently issued the Air Carrier Incentive Program Guidebook to provide specific guidance to airport operators on the use of air service incentive programs. That guidance restates FAA's previously issued opinions regarding what constitutes new service as characterized in the FAA's *Policy and Procedures Concerning the Use of Airport Revenue* (*Revenue Use Policy*) (64 FR 7696). Since the inception of the *Revenue Use Policy in 1999,* the FAA has defined new air service as: (a) Service to an airport destination not currently served, (b) nonstop service where no nonstop service is currently offered, (c) new entrant carrier, and/or (d) increased frequency of flights to a specific destination. The FAA's interpretation has not permitted an airport operator to offer an incentive program that provides discounts based on increased aircraft weight or an increased number of seats on existing flights. The petitioner proposes an incentive program that would reward air carriers for an increase in landed weight. An increase in landed weight could result from an increase in the size of aircraft used, or "upgauging," on existing flights as well as from added flights. The petitioner requests that the FAA amend existing guidance to make clear that its proposed incentive plan is consistent with Federal law and general agency policies on the use of airport revenue and on airport rates and charges. The FAA is publishing this notice of the petition for public comment on whether agency guidance should be interpreted or amended as requested.

DATES: Send your comments on or before May 31, 2011.

ADDRESSES: You may send comments [identified by Docket Number FAA–2011–0361] using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Operations, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Fax:* 1–202–493–2251.
- *Hand Delivery:* To Docket Operations, Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Stacy Swigart, Airport Compliance Division, ACO–100, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8725; facsimile: (202) 267–5257; e-mail: *Stacy.Swigart@faa.gov.*

SUPPLEMENTARY INFORMATION: An air service incentive program is a temporary reduction in the fees that an airport operator charges air carriers at the airport, or other temporary benefits for carriers, for the purpose of promoting new or additional air service.

While incentive programs can take many forms, they may involve a waiver of fees that would otherwise be due, such as landing fees; cooperation and assistance in marketing new service; and a subsidy of air service if airport revenue is not used for that purpose. Because incentive fee waivers can result in differential fees charged to different air carriers for similar use of the airport, incentive programs can involve issues of compliance with Federal obligations regarding discriminatory treatment of air carriers and use of airport revenue.

On February 14, 2011, the Federal Aviation Administration (FAA) received a letter from counsel for the Clark County Department of Aviation, the owner and operator of McCarran International Airport in Las Vegas, Nevada, requesting a determination from the FAA that the Department of Aviation's proposed air service incentive program does not conflict with Federal obligations. As a matter of process, the agency has elected to treat the request as a petition to amend agency policy, and is publishing notice of the request for public comment before making a determination. However, the agency has made no determination on whether granting the Department of Aviation's request would or would not actually require amendment of any existing agency policy statements.

Background: FAA policy on use of airport revenue and airport rates and charges.

Airport sponsors that accept grants under the Airport Improvement Program agree to a set of standard grant assurances, as required by 49 U.S.C. 47107. These include an assurance that airport revenue will be used for the capital and operating costs of the airport or airport system, or certain other purposes. They also include assurances that fees charged air carriers will be reasonable, not unjustly discriminatory, and substantially comparable to fees charged other carriers making similar use of the airport. The FAA has issued comprehensive policies on each of these assurances.

The Department of Transportation published the Policy Regarding Airport Rates and Charges on June 21, 1996 (61 FR 31994). Portions of the policy were subsequently vacated by the United States Court of Appeals for the District of Columbia Circuit in *Air Transport Ass'n of America* v. *DOT,* 119 F.3d 38, amended by 129 F.3d 625 (DC Cir. 1997). In July 2008, the Department published a notice in the **Federal Register** adopting three amendments to the 1996 Rates and Charges Policy (73 FR 40430, July 14, 2008). The amendments are intended to provide greater flexibility to operators of congested airports to use landing fees to provide incentives to air carriers to use the airport at less congested times or to use alternate airports to meet regional air service needs. The policy as amended does not specifically refer to incentive programs or fee waivers, but provides in part:

> 3. Aeronautical fees may not unjustly discriminate against aeronautical users or user groups.
>
> 3.1 The airport proprietor must apply a consistent methodology in establishing fees for comparable aeronautical users of the airport. When the airport proprietor uses a cost-based methodology, aeronautical fees imposed on any aeronautical user or group of aeronautical users may not exceed the costs allocated to that user or user group under a cost allocation methodology adopted by the airport proprietor that is consistent with this guidance, unless aeronautical users otherwise agree.
>
> 3.1.1 The prohibition on unjust discrimination does not prevent an airport proprietor from making reasonable distinctions among aeronautical users (such as signatory and non-signatory carriers) and assessing higher fees on certain categories of aeronautical users based on those distinctions (such as higher fees for non-signatory carriers, as compared to signatory carriers).

The Department of Transportation and the FAA published the Policy and Procedures for the Use of Airport Revenue on February 16, 1999 (64 FR 7696). That policy, in paragraph VI.B.12, *Prohibited Uses of Airport Revenue,* prohibits the direct subsidy of air carriers with airport revenues, but notes:

> Prohibited direct subsidies do not include waivers of fees or discounted landing or other fees during a promotional period. Any fee waiver or discount must be offered to all users of the airport, and provided to all users that are willing to provide the same type and level of new services consistent with the promotional offering. [64 FR 7720]

In September 2010, the FAA published the *Air Carrier Incentive Program Guidebook: A Reference for Airport Sponsors.* The Guidebook is available on the FAA Airports Web site. The Guidebook was issued to bring together in one place the principles behind FAA policy decisions on individual air carrier incentive programs. The Guidebook is intended to interpret existing policies on use of airport revenue and airport rates and charges, and not to establish new policy. Several statements in the Guidebook have possible relevance to the Department of Aviation's proposed incentive plan.

Specifically, for example, the Guidebook states that promotional incentives are limited to *new* service, and provides a definition of new service:

> FAA defines new service as (a) service to an airport destination not currently served, (b) nonstop service where no nonstop service is currently offered, (c) new entrant carrier, and/or (d) increased frequency of flights to a specific destination. (In the last case, the incentive would be available only on the added flights.) FAA does not recognize repeated seasonal service, upgrade of equipment type, or increased number of seats on existing flights as new service.

The summary of prohibited practices reaffirms that incentives are not available for an increase in aircraft weight or seating not associated with an added flight:

Your Incentive Program may NOT:

- Offer incremental discounts based on weight for existing service
- Offer incentives based on incremental weight or increased number of seats on existing flights.

The Petition

The February 14, 2011, letter from counsel for the Clark County Department of Aviation requests that FAA determine that the Department's proposed air service incentive program does not conflict with Federal obligations, and attaches a 13-page memorandum in support of that request. The letter and memorandum are available for review on the FAA Airports *Web* site, as well as in the docket locations described under **ADDRESSES** in this document.

In brief, the Department of Aviation states that the "objective of the proposed Incentives Program is to provide an incentive at the margin to promote additions to scheduled air service seat capacity." The program provides, subject to certain terms and exceptions, that:

> * * * all monthly scheduled service landed weight, by airline, in excess of that operated in the same month of the prior year, would receive a credit of up to 100% of the landing fee (currently $2.26 per 1,000 pounds of landed weight) paid on the incremental landed weight.

In addition to new flights, the credit would apply to existing flights for which an increase in aircraft size resulted in an increase in landing weight.

Request for comments

The FAA requests comments on whether the petition can be considered consistent with agency policy on use of airport revenue and airport rates and charges, including policy statements contained in the *Air Carrier Incentive Program Guidebook,* and if so, whether

the stated agency policy should be revised to permit the kind of air service incentive program proposed by the Clark County Department of Aviation.

Issued in Washington, DC on April 11, 2011.

Randall Fiertz,

Director, Airport Compliance and Operations.

[FR Doc. 2011–9229 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice To Rescind a Notice of Intent to Prepare a Tiered Environmental Impact Statement

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice to Rescind a Notice of Intent to Prepare a Tiered Environmental Impact Statement.

SUMMARY: The FHWA is issuing this notice to advise the public and other agencies that the Notice of Intent published January 16, 2009, DOCID: fr16ja09–155, to prepare a tiered EIS for the Northwest Loop in Sandoval and Bernalillo Counties, New Mexico, is being rescinded.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Heitmann, Environmental Specialist, Federal Highway Administration, New Mexico Division Office, 4001 Office Court Drive, Suite 801, Santa Fe, NM 87507 Telephone (505) 820–2027.

SUPPLEMENTARY INFORMATION: The scope of the project has been adjusted to include only the construction of a 2-lane all-weather roadway within existing right-of-way owned by Sandoval County.

The project will begin 3.06 miles north of the Bernalillo County line and extend north for 2.12 miles to Alice King Way. The proposed roadway will consist of two 12-ft driving lanes and 3.7-ft shoulders. The roadway will have a gravel surface and will be designed to meet a design speed of 50 miles per hour. Drainage improvements will be provided where the roadway crosses existing water flows.

Pursuant to the National Environmental Policy Act, as amended, FHWA, in cooperation with the NMDOT, is preparing a categorical exclusion for the proposed improvements. While hard copy comments are preferred, comments by electronic mail may be sent to *Greg.Heitmann@dot.gov.*

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on March 30, 2011.

J. Don Martinez,

Division Administrator, Federal Highway Administration, Santa Fe, New Mexico.

[FR Doc. 2011–9124 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2011–0046]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes an Information Collection Request (ICR) for which NHTSA intends to seek OMB approval.

DATES: Comments must be submitted on or before June 14, 2011.

ADDRESSES: Direct all written comments to the U.S. Department of Transportation Dockets, 1200 New Jersey Ave., SE., Washington, DC 20590. You may also submit comments electronically at *http://www.regulations.gov.* All comments should refer to the Docket No. NHTSA–2011–0046.

FOR FURTHER INFORMATION CONTACT: Jessica Cicchino, PhD, Contracting Officer's Technical Representative, Office of Behavioral Safety Research (NTI–131), National Highway Traffic Safety Administration, 1200 New Jersey Ave., SE., W46–491, Washington, DC, 20590. Dr. Cicchino's phone number is 202–366–2752 and her e-mail address is *jessica.cicchino@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Evaluation of Impaired Riding Interventions.

Type of Request: New information collection request.

OMB Clearance Number: None.

Form Number: This collection of information uses no standard forms.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from the public to evaluate intervention programs in multiple locations designed to reduce impaired motorcycle riding. NHTSA anticipates that the programs will take place over the 2012 riding season. In-person interviews will be conducted with motorcycle riders in up to 4 program sites, and in up to 2 control sites not carrying out an intervention. Motorcycle riders will be interviewed at locations within the sites where riders congregate. Interview length will average 5 minutes and will collect information on attitudes, awareness, knowledge, and behavior related to the intervention.

The interviews will follow a pre-post design where they are administered prior to the implementation of the intervention and after its conclusion. Up

to 2 waves of program activity are planned in each program site, and thus interviews will be administered a maximum of 4 times in each site (before and after each of 2 program waves). Sample size will be up to 500 riders per interview administration, for a total maximum of 12,000 riders.

For interventions where a pre-post design would not be possible (*i.e.,* interventions that are conducted in conjunction with an infrequently-occurring event), the interviews will follow a test-control design where they are administered during the intervention in the program site, and in a control site that did not experience an intervention. The proposed interviews will be anonymous. Participation by respondents will be voluntary.

Need and Use of Information: The National Highway Traffic Safety Administration (NHTSA) was established to reduce the mounting number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of motor vehicle standards and traffic safety programs.

The heavy toll that impaired driving exacts on the Nation in fatalities, injuries, and economic costs is well documented. Impaired motorcycle riding has also been an increasing concern on our Nation's roads. Motorcycle fatalities in the US decreased in 2009 for the first time after steadily increasing for 11 years; however, even with this decline, the number of motorcycle fatalities in 2009 was nearly double that from a decade earlier. Alcohol impairment is a factor that contributes to a substantial proportion of fatal motorcycle crashes. In 2009, 30% of motorcycle riders fatally injured in crashes had a blood alcohol concentration (BAC) at or above .08 g/dL, which is *per se* evidence of impaired riding in all States. Forty-two percent of riders who died in single-vehicle crashes in 2009, and 63% of riders who died in single-vehicle crashes on weekend nights, had a BAC of .08 g/dL or higher.

In 2012, NHTSA anticipates sponsoring demonstration projects in multiple sites to conduct interventions with the purpose of reducing impaired motorcycle riding. NHTSA plans to evaluate these interventions to determine their effectiveness. A key component of this evaluation effort will use brief interviews to assess motorcycle riders' knowledge of the intervention, self-reported drinking and riding behavior, and belief that alcohol-impaired driving laws are enforced for all motorists, including motorcycle riders in the areas in which the interventions will occur.

The findings from this proposed collection of information will assist NHTSA in addressing the problem of alcohol-impaired motorcycle riding. NHTSA will use the findings to help focus current programs and activities to achieve the greatest benefit, to develop new programs to decrease the likelihood of impaired riding, and to provide informational support to States, localities, and law enforcement agencies that will aid them in their efforts to reduce impaired motorcycle crashes.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information): Under this proposed effort, NHTSA intends to conduct up to 12,000 face-to-face interviews with motorcycle riders. Interview length will average 5 minutes, and each member of the sample would complete one interview. Businesses would be ineligible for the sample and would not be interviewed. Interviews will be conducted in a maximum of 4 demonstration sites and 2 control sites, with up to 4 interview administrations occurring in each site (baseline and post-intervention surveys before and after each of 2 program waves). Up to 500 motorcycle riders will be interviewed at each site during each interview administration.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information: NHTSA estimates the respondents in the sample will require an average of 5 minutes to complete the interviews. Thus, for the 12,000 respondents, the estimated reporting burden hours on the general public will be a maximum of 1,000 hours, over one year. The respondents will not incur any record-keeping burden or record-keeping cost from the information collection.

Authority: 44 U.S.C. 3506(c)(2)(A).

Jeffrey Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2011–9130 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2011–0063]

Pipeline Safety: Request for Special Permit

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: Pursuant to the Federal pipeline safety laws, PHMSA is publishing this notice of special permit requests we have received from several pipeline operators, seeking relief from compliance with certain requirements in the Federal pipeline safety regulations. This notice seeks public comments on these requests, including comments on any safety or environmental impacts. At the conclusion of the 30-day comment period, PHMSA will evaluate the requests and determine whether to grant or deny a special permit.

DATES: Submit any comments regarding these special permit requests by May 16, 2011.

ADDRESSES: Comments should reference the docket numbers for the specific special permit request and may be submitted in the following ways:

- *E-Gov Web Site*: *http://www.Regulations.gov*. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov*.

Note: Comments are posted without changes or edits to *http://*

www.Regulations.gov, including any personal information provided. There is a privacy statement published on *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT:

General: Kay McIver by telephone at 202–366–0113, or e-mail at *kay.mciver@dot.gov.*

Technical: Steve Nanney by telephone at 713–628–7479, or e-mail at *Steve.Nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA has received requests for special permits from several pipeline operators who seek relief from compliance with certain pipeline safety regulations. Each request includes a technical analysis provided by the respective operator. Each request has been filed at www.Regulations.gov and assigned a separate docket number. We invite interested persons to participate by reviewing these special permit requests at *http://www.Regulations.gov*, and by submitting written comments, data or other views. Please include any comments on potential environmental impacts that may result if these special permits are granted.

Before acting on these special permit requests, PHMSA will evaluate all comments received on or before the comments closing date. Comments will be evaluated after this date if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment we receive in making our decision to grant or deny a request.

PHMSA has received the following special permit requests:

Docket No.	Requester	Regulation(s)	Nature of special permit
PHMSA–2010–0311 ...	Gulf South Pipeline Company LP (GSPC) (Operated by Boardwalk Pipeline Partners).	49 CFR 192.611	To authorize Gulf South Pipeline LP (GSPC) to engage in an alternative approach to conduct risk control activities based on Integrity Management Program principles rather than lowering the Maximum Allowable Operating Pressure (MAOP) or replacing the subject pipe segments. This application is for two 30-inch segments, segments 3 and 4, of the TPL 330 natural gas pipeline located in St. Landry Parish of Louisiana. These segments have changed from Class 1 and 2 locations to Class 3 locations. Segments 3 and 4 are located at Survey Station 3,673+02 ft. to Survey Station 3,696+13 ft. and Survey Station 3,772+10 ft. to Survey Station 3,806+09 ft., respectively. Both segments have a MAOP of 1,000 psig and a total combined length of 1.08 miles.
PHMSA–2010–0300 ...	Belle Fourche	49 CFR 195.106, 195.112(a)(b), 195.120, 195.200, 195.406(a)(1) and 195.653.	To authorize Belle Fourche an exemption from certain requirements in Subpart A, Subpart C and Subpart H of 49 CFR Part 195. Belle Fourche seeks exception in two general categories; first for permission to allow flexible steel pipe in Federally regulated service, and second to adopt the use of requirements and standards appropriate for flexible steel pipes. Belle Fourche further seeks permission to insert Flexsteel pipe into 32 miles of existing out-of-service 4-inch steel pipelines, for the transport of diesel fuel from Belle Fourche's Hawk Point station to the Arch Coal Mine diesel tank in Campbell County, Wyoming.
PHMSA–2006–26618	El Paso Pipeline Group for Tennessee Gas Pipeline.	49 CFR 192.611	To authorize Tennessee Gas Pipeline to extend previously approved permit for the 30-inch Niagara Spur Loop Line 230B–200, near Lockport, New York by an additional 1,250 feet. The previously issued permit allowed Tennessee Gas Pipeline (TGP) to operate at or below the MAOP of 877 psig.
PHMSA–2011–0056 ...	Exxon Mobil	49 CFR 195.452(h)(4)	To authorize Exxon Mobil Pipeline Company (EMPCo) permission to employ alternative repair criteria to repair reconditioned sections of the South Bend to New Iberia and the New Iberia to Sunset segments of their pipeline. Specifically EMPCo proposes to leave in-situ the anomalous conditions that were previously repaired/addressed during reconditioning activities performed circa 1951, prior to the pipeline installation. This pipeline transports crude production from Louisiana's South Marsh Island Offshore System pipeline (South Bend Station) to New Iberia and Sunset stations for further delivery into Alon's refinery in Krotz Springs or the Anchorage Terminal near Baton Rouge. The segment is 34.5 miles long. Of that portion, the HCA mileage is 32.0 miles. The pipeline runs through the counties of Parish, St. Martin, Lafayette and St. Landy in Louisiana. The pipeline segment is Interstate with original construction dates of 1951, 1952 and 1967. The majority of the 12.75″ OD line was constructed from pipe that was reconditioned post World War II (including puddle welding of pitted and dented areas, double jointing, and new coating).

Authority: 49 U.S.C. 60118 (c)(1) and 49 CFR 1.53.

Issued in Washington, DC, on April 8, 2011.

Jeffrey D. Wiese,

Associate Administrator for Pipeline Safety.

[FR Doc. 2011–9226 Filed 4–14–11; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 1043 (Sub-No. 2X)]

Montreal, Maine & Atlantic Railway, Ltd.—Abandonment Exemption—in Aroostook County, ME

On March 28, 2011, Montreal, Maine & Atlantic Railway, Ltd. (MMA) filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to abandon a .4-mile rail line extending between milepost V 23.72 at Bridge Street and milepost V 24.12 at Main Street, in Van Buren, Aroostook County, Me. The line traverses United States Postal Service Zip Code 04785.

In addition to an exemption from the provisions of 49 U.S.C. 10903, MMA seeks exemption from 49 U.S.C. 10904 (offer of financial assistance (OFA) procedures) and 49 U.S.C. 10905 (public use conditions). MMA also seeks relief from the trail use provisions of the Board's regulations at 49 CFR 1152.29. In support, MMA states that, upon receipt of abandonment authority, it plans to sell the .4-mile rail line and its transloading yard to the United States General Services Administration (GSA). In turn, GSA plans to use the property, together with other property that GSA has acquired, to construct a new land port of entry facility for the U.S. Customs and Border Protection Agency. MMA also seeks expedited action in this proceeding. These requests will be addressed in the final decision.

The line does not contain federally granted rights-of-way. Any documentation in MMA's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad–Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

By issuing this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by July 15, 2011.

Any OFA under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,500 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than May 5, 2011. Each trail use request must be accompanied by a $250 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to Docket No. AB 1043 (Sub-No. 2X), and must be sent to: (1) Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; and (2) James E. Howard, 1 Thompson Square, Suite 201, Charlestown, MA 02129. Replies to MMA's petition are due on or before May 5, 2011.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment or discontinuance regulations at 49 CFR pt. 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis (OEA) at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by OEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact OEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at "*www.stb.dot.gov.*"

Decided: April 8, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–9029 Filed 4–14–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35478]

Rocky Mountain Railcar and Repair, Inc.—Acquisition and Operation Exemption—Line of Railroad in Tooele County, UT

Rocky Mountain Railcar and Repair, Inc. (Rocky Mountain), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire from Utah Industrial Depot and operate 11.5 miles of rail line, located inside an existing industrial facility in Tooele County, Utah.[1] The rail line includes a spur that connects to the Union Pacific Railroad Company main line.

According to Rocky Mountain, the transaction is expected to be consummated on or after September 28, 2011 (180 days after the exemption was filed); this is after the May 1, 2011 effective date of the exemption (30 days after the exemption was filed).

Rocky Mountain certifies that its projected annual revenues as a result of this transaction will not result in Rocky Mountain becoming a Class II or Class I rail carrier. Rocky Mountain further certifies that its projected annual revenues upon becoming a Class III carrier will not exceed $5 million.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions to stay must be filed no later than April 22, 2011 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35478, must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Trent D. Stirling, Rocky Mountain Railcar and Repair, Inc., 1485 W. James Way, Tooele, UT 84074.

Board decisions and notices are available on our Web site at "*www.stb.dot.gov.*"

Decided: April 12, 2011.

[1] Rocky Mountain states that it currently operates a railcar repair facility, but that it seeks to become a common carrier.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–9167 Filed 4–14–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 34554 (Sub-No. 15)]

Union Pacific Railroad Company—Temporary Trackage Rights Exemption—BNSF Railway Company

AGENCY: Surface Transportation Board, DOT.

ACTION: Partial Revocation of Exemption.

SUMMARY: Under 49 U.S.C. 10502, the Board revokes the class exemption as it pertains to the trackage rights described in Docket No. FD 34554 (Sub-No. 14) [1] to permit the trackage rights to expire on or about December 18, 2011, in accordance with the agreement of the parties,[2] subject to the employee protective conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth and Ammon, in Bingham and Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

DATES: This decision is effective on May 15, 2011. Petitions to stay must be filed by April 25, 2011. Petitions for reconsideration must be filed by May 5, 2011.

ADDRESSES: Send an original and 10 copies of all pleadings, referring to Docket No. FD 34554 (Sub-No. 15) to: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on UP's representative: Elisa B. Davies, General Attorney, Union Pacific Railroad Company, 1400 Douglas Street, Mail Stop 1580, Omaha, NE 68179.

FOR FURTHER INFORMATION CONTACT: Julia Farr, (202) 245–0359. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. Board decisions and notices are available on our Web site at "*www.stb.dot.gov.*"

Decided: April 7, 2011.

By the Board, Chairman Elliott and Commissioner Mulvey.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–9057 Filed 4–14–11; 8:45 am]

BILLING CODE 4915–01–P

[1] In that docket, on January 27, 2011, Union Pacific Railroad Company (UP) filed a verified notice of exemption under the Board's class exemption procedures at 49 CFR 1180.2(d)(7). The notice covered the agreement by BNSF Railway Company (BNSF) to extend to December 18, 2011, the expiration date of the local trackage rights granted to UP over BNSF's line of railroad extending from BNSF milepost 579.3 near Mill Creek, Okla., to BNSF milepost 631.1 near Joe Junction, Tex., a distance of approximately 52 miles. UP submits that while the trackage rights are only temporary rights, because they are "local" rather than "overhead" rights, they do not qualify for the Board's class exemption for temporary trackage rights under 49 CFR 1180.2(d)(8). *See Union Pac. R.R.–Temporary Trackage Rights Exemption–BNSF Ry.,* FD 34554 (Sub-No. 14) (STB served February 11, 2011).

[2] The trackage rights were originally granted in *Union Pacific Railroad—Temporary Trackage Rights Exemption—The Burlington Northern and Santa Fe Railway,* FD 34554 (STB served Oct. 7, 2004). Subsequently, the parties filed several notices of exemption based on their agreements to extend expiration dates of the same trackage rights. *See* FD 34554 (Sub-No. 2) (STB served February 11, 2005); FD 34554 (Sub-No. 4) (STB served March 3, 2006); FD 34554 (Sub-No. 6) (STB served January 12, 2007); FD 34554 (Sub-No. 8) (STB served January 4, 2008); FD 34554 (Sub-No. 10) (STB served January 8, 2009); and FD 34554 (Sub-No. 12) (STB served December 31, 2009). Because the original and subsequent trackage rights notices were filed under the class exemption at 49 CFR 1180.2(d)(7), under which trackage rights normally remain effective indefinitely, in each instance the Board granted partial revocation of the class exemption to permit the authorized trackage rights to expire. *See* FD 34554 (Sub-No. 1) (STB served November 24, 2004); FD 34554 (Sub-No. 3) (STB served March 25, 2005); FD 34554 (Sub-No. 5) (STB served March 23, 2006); FD 34554 (Sub-No. 7) (STB served March 13, 2007); FD 34554 (Sub-No. 9) (STB served March 20, 2008); FD 34554 (Sub-No. 11) (STB served March 11, 2009); and FD 34554 (Sub-No. 13) (STB served March 15, 2010). At the time of the extension authorized in Docket No. FD 34554 (Sub-No. 12), the parties anticipated that the authority to allow the rights to expire would be exercised by December 18, 2010. However, the parties filed on January 27, 2011, in Docket No. FD 34554 (Sub-No. 14) their most recent notice of exemption so that the trackage rights could be extended to December 18, 2011, and in Docket No. FD 34554 (Sub-No. 15) their latest petition to partially revoke the class exemption to permit expiration, which we are addressing here.

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Community Development Financial Institutions (CDFI) Fund, Department of the Treasury, is soliciting comments concerning the Capital Magnet Fund (CMF) Environmental Review Notification Report (ERNR).

DATES: Written comments should be received on or before June 14, 2011 to be assured of consideration.

ADDRESSES: Direct all comments to David Dworkin, Program Manager, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, by e-mail to *cdfihelp@cdfi.treas.gov* or by facsimile to (202) 622–7754. This is not a toll free number.

FOR FURTHER INFORMATION CONTACT: The CMF Environmental Review Notification Report may be obtained from the CMF page of the CDFI Fund's Web site at *http://www.cdfifund.gov.* Requests for additional information should be directed to David Dworkin, Program Manager, Community Development Financial Institutions Fund, U.S. Department of the Treasury, 601 13th Street, NW., Suite 200 South, Washington, DC 20005, or call (202) 622–6355. This is not a toll free number.

SUPPLEMENTARY INFORMATION:

Title: Capital Magnet Fund Environmental Review Notification Report.

Abstract: The purpose of the CMF is to competitively award grants to certified CDFIs and qualified nonprofit housing organizations to finance affordable housing and related community development projects. The CMF was authorized in July of 2008 under Section 1339 of the Housing and Economic Recovery Act of 2008 (Pub. L. 110–289), and $80 million was appropriated for this initiative under the Consolidated Appropriations Act of 2010 (Pub. L. 111–117). Successful CMF Applicants who receive awards must enter into assistance agreements with the CDFI Fund. The assistance agreement will set forth certain required terms and conditions of the award, including reporting and data collection requirements. The assistance agreement also requires the awardee to complete and submit the ERNR each time the awardee identifies a new CMF project for which (i) a categorical exclusion does not apply, or (ii) the awardee determines that the proposed project does involve actions that normally require an Environmental Impact Statement; as described in the CDFI

Fund Environmental Quality Regulations (12 CFR part 1815). The ERNR will assist the CDFI Fund in determining whether additional environmental review is necessary for the proposed CMF project, as mandated by 12 CFR Part 1815.

Current Actions: New collection.

Type of Review: Regular Review.

Affected Public: Capital Magnet Fund Awardees.

Estimated Number of Respondents: 20.

Estimated Annual Time per Respondent: 4 hours.

Estimated Total Annual Burden Hours: 80 hours.

Requests For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record and will be published on the CDFI Fund Web site at *http://www.cdfifund.gov.* Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the CDFI Fund, including whether the information shall have practical utility; (b) the accuracy of the CDFI Fund's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Authority: Pub. L. 110–289.

Dated: April 8, 2011.

Donna Gambrell,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2011–9205 Filed 4–14–11; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its effort to reduce paperwork and respondent burden, invites the general public and Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to the treatment of gain from the disposition of interest in certain natural resource recapture property by S corporations and their shareholders.

DATES: Written comments should be received on or before June 14, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be directed to Joel Goldberger, at (202) 927–9368, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet, at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Treatment of Gain From the Disposition of Interest in Certain Natural Resource Recapture Property by S Corporations and Their Shareholders.

OMB Number: 1545–1493.

Regulation Project Number: T.D. 8684.

Abstract: This regulation prescribes rules under Code section 1254 relating to the treatment by S corporations and their shareholders of gain from the disposition of natural resource recapture property and from the sale or exchange of S corporation stock. Section 1.1254–4(c)(2) of the regulation provides that gain recognized on the sale or exchange of S corporation stock is not treated as ordinary income if the shareholder attaches a statement to his or her return containing information establishing that the gain is not attributable to section 1254 costs.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, and individuals.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 1,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 5, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–8756 Filed 4–14–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning information collection requirements related to manufacturers excise taxes on sporting goods and firearms and other administrative provisions of special application to manufacturers and retailers excise taxes.

DATES: Written comments should be received on or before June 14, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to, Yvette B. Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to, Joel Goldberger (202) 927–9368, Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov*.

SUPPLEMENTARY INFORMATION: *Title:* Manufacturers Excise Taxes on Sporting Goods and Firearms and Other Administrative Provisions of Special Application To Manufacturers and Retailers Excise Taxes.

OMB Number: 1545–0723.

Regulation Project Number: T.D. 8043.

Abstract: Chapters 31 and 32 of the Internal Revenue Code impose excise taxes on the sale or use of certain articles. Code section 6416 allows a credit or refund of the tax to manufacturers in certain cases. Code sections 6420, 6421, and 6427 allow credits or refunds of the tax to certain users of the articles. This regulation contains reporting and recordkeeping requirements that enable the IRS and taxpayers to verify that the proper amount of tax is reported or excluded.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, not-for-profit institutions, farms, and state, local, or tribal governments.

Estimated Number of Respondents: 1,500,000.

Estimated Time per Respondent: 19 minutes.

Estimated Total Annual Burden Hours: 475,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility; (b) accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 8, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–8996 Filed 4–14–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to manufacturers excise taxes on sporting goods and firearms and other administrative provisions of special application to manufacturers and retailers excise taxes.

DATES: Written comments should be received on or before June 14, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Joel Goldberger (202) 927–9368, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Manufacturers Excise Taxes on Sporting Goods and Firearms and Other Administrative Provisions of Special Application to Manufacturers and Retailers Excise Taxes.

OMB Number: 1545–0723.

Regulation Project Number: T.D. 8043.

Abstract: Chapters 31 and 32 of the Internal Revenue Code impose excise taxes on the sale or use of certain articles. Code section 6416 allows a credit or refund of the tax to manufacturers in certain cases. Code sections 6420, 6421, and 6427 allow credits or refunds of the tax to certain users of the articles. This regulation contains reporting and recordkeeping requirements that enable the IRS and taxpayers to verify that the proper amount of tax is reported or excluded.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals, business or other for-profit organizations, not-for-profit institutions, farms, and state, local, or tribal governments.

Estimated Number of Respondents: 1,500,000.

Estimated Time per Respondent: 19 minutes.

Estimated Total Annual Burden Hours: 475,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate

of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 5, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–8763 Filed 4–14–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to changes with respect to prizes and awards and employee achievement awards.

DATES: Written comments should be received on or before June 14, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of regulation should be directed to Joel Goldberger, (202) 927–9368, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Joel.P.Goldberger@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Changes With Respect to Prizes and Awards and Employee Achievement Awards.

OMB Number: 1545–1100.

Regulation Project Number: REG–209106–89.

Abstract: This regulation requires recipients of prizes and awards to maintain records to determine whether a qualifying designation has been made in accordance with section 74(b)(3) of the Internal Revenue Code. The affected public is prize and award recipients who seek to exclude the cost of a qualifying prize or award.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 5,100.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 1,275.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 5, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–9018 Filed 4–14–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–New (DBQs—Group 3)]

Proposed Information Collection (Disability Benefits Questionnaires—Group 3) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection and allow 60 days for public comment in response to the notice. This notice solicits comments for information needed to obtain medical evidence to adjudicate a claim for disability benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before June 14, 2011.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail to *nancy.kessinger@va.gov*. Please refer to "OMB Control No. 2900–New (DBQs—Group 3)" in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 461–9769 or FAX (202) 275–5947.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility;

(2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Titles

a. Central Nervous System and Neuromusculo Diseases, Disability Benefits Questionnaire, VA Form 21–0960C–5.

b. Headaches (Including Migraine Headaches), Disability Benefits Questionnaire, VA Form 21–0960C–8.

c. Multiple Sclerosis (MS), Disability Benefits Questionnaire, VA Form 21–0960C–9.

d. Esophageal Disorders (Including GERD), Disability Benefits Questionnaire, VA Form 21–0960G–1.

e. Gallbladder and Pancreas Conditions, Disability Benefits Questionnaire, VA Form 21–0960G–2.

f. Intestinal Disorders (Other Than Surgical or Infectious) (Including Irritable Bowel Syndrome, Crohn's Disease, Ulcerative Colitis, and Diverticulitis) Disability Benefits Questionnaire, VA Form 21–0960G–3.

g. Intestines Surgical and/or Infectious Intestinal Disorders (Bowel Resection, Colostomy, Ileostomy, Bacterial and Parasitic Infections) Disability Benefits Questionnaire, VA Form 21–0960G–4.

h. Hepatitis, Cirrhosis and Other Liver Conditions, Disability Benefits Questionnaire, VA Form 21–0960G–5.

i. Peritoneal Adhesions Disability Benefits Questionnaire, VA Form 21–0960G–6.

j. Stomach and Duodenal Conditions (Not Including GERD or Esophageal Disorders) Disability Benefits Questionnaire, VA Form 21–0960G–7.

k. Rectum and Anus Disability Benefits Questionnaire, VA Form 21–0960H–2.

l. Breast Conditions and Disorders Disability Benefits Questionnaire, VA Form 21–0960K–1.

m. Gynecological Conditions Disability Benefits Questionnaire, VA Form 21–0960K–2.

n. Sleep Apnea Disability Benefits Questionnaire, VA Form 21–0960L–2.

o. Arthritis Disability Benefits Questionnaire, VA Form 21–0960M–3.

p. Osteomyelitis Disability Benefits Questionnaire, VA Form 21–0960M–11.

q. Ear Conditions (Including Vestibular and Infectious) Disability Benefits Questionnaire, VA Form 21–0960N–1.

OMB Control Number: 2900–New (DBQs—Group 3).

Type of Review: New collection.

Abstract: Data collected on VA Form 21–0960 series will be used to obtain information from claimant's treating physician that is necessary to adjudicate a claim for disability benefits.

Affected Public: Individuals or households.

Estimated Annual Burden

a. VA Form 21–0960C–5—5,000.
b. VA Form 21–0960C–8—3,750.
c. VA Form 21–0960C–9—7,500.
d. VA Form 21–0960G–1—10,000.
e. VA Form 21–0960G–2—1,250.
f. VA Form 21–0960G–3—1,250.
g. VA Form 21–0960G–4—1,250.
h. VA Form 21–0960G–5—5,000.
i. VA Form 21–0960G–6—1,250.
j. VA Form 21–0960G–7—2,500.
k. VA Form 21–0960H–2—2,500.
l. VA Form 21–0960K–1—7,500.
m. VA Form 21–0960K–2—10,000.
n. VA Form 21–0960L–2—1,250.
o. VA Form 21–0960M–3—25,000.
p. VA Form 21–0960M–11—10,000.
q. VA Form 21–0960N–1—6,250.

Estimated Average Burden per Respondent

a. VA Form 21–0960C–5—30 minutes.
b. VA Form 21–0960C–8—15 minutes.
c. VA Form 21–0960C–9—45 minutes.
d. VA Form 21–0960G–1—15 minutes.
e. VA Form 21–0960G–2—15 minutes.
f. VA Form 21–0960G–3—15 minutes.
g. VA Form 21–0960G–4—15 minutes.
h. VA Form 21–0960G–5—30 minutes.
i. VA Form 21–0960G–6—15 minutes.
j. VA Form 21–0960G–7—15 minutes.
k. VA Form 21–0960H–2—15 minutes.
l. VA Form 21–0960K–1—15 minutes.
m. VA Form 21–0960K–2—30 minutes.
n. VA Form 21–0960L–2—15 minutes.
o. VA Form 21–0960M–3—15 minutes.
p. VA Form 21–0960M–11—15 minutes.
q. VA Form 21–0960N–1—15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents

a. VA Form 21–0960C–5—10,000.
b. VA Form 21–0960C–8—15,000.
c. VA Form 21–0960C–9—10,000.
d. VA Form 21–0960G–1—40,000.
e. VA Form 21–0960G–2—5,000.
f. VA Form 21–0960G–3—5,000.
g. VA Form 21–0960G–4—5,000.
h. VA Form 21–0960G–5—10,000.
i. VA Form 21–0960G–6—5,000.
j. VA Form 21–0960G–7—10,000.
k. VA Form 21–0960H–2—10,000.
l. VA Form 21–0960K–1—30,000.
m. VA Form 21–0960K–2—20,000.
n. VA Form 21–0960L2—5,000.
o. VA Form 21–0960M–3—100,000.
p. VA Form 21–0960N–11—40,000.
q. VA Form 21–0960N–1—25,000.

Dated: April 8, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–9156 Filed 4–14–11; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 76 Friday,

No. 73 April 15, 2011

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422 and 423

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4144–F]

RIN 0938–AQ00

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule makes revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) to implement provisions specified in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) (ACA) and make other changes to the regulations based on our experience in the administration of the Part C and Part D programs. These latter revisions clarify various program participation requirements; make changes to strengthen beneficiary protections; strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and make other clarifications and technical changes.

DATES: *Effective Dates:* These regulations are effective on June 6, 2011, unless otherwise specified in this final rule. Amendments to 42 CFR 422.564, 422.624, and 422.626 published April 4, 2003 at 68 FR 16652 are effective June 6, 2011.

Applicability Date: In section II.A. of the preamble of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective 60 days after the date of display of this final rule.

FOR FURTHER INFORMATION CONTACT:

Vanessa Duran, (410) 786–8697, Christopher McClintick, (410) 786–4682, and Sabrina Ahmed, (410) 786–7499, General information.

Heather Rudo, (410) 786–7627 and Christopher McClintick, (410) 786–4682, Part C issues.

Deborah Larwood, (410) 786–9500, Part D issues.

Kristy Nishimoto, (410) 786–8517, Part C and Part D enrollment and appeals issues.

Deondra Moseley, (410) 786–4577, Part C payment issues.

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Regulations Text

Acronyms

ACA The Affordable Care Act of 2010 (which is the collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152))
AO Accrediting Organization
ADS Automatic Dispensing System
AEP Annual Enrollment Period
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ Agency for Health Care Research and Quality
ALJ Administrative Law Judge
ANOC Annual Notice of Change
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CCS Certified Coding Specialist
CHIP Children's Health Insurance Programs
CMP Civil Money Penalties or Competitive Medical Plan
CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar year
DOL U.S. Department of Labor
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DUM Drug Utilization Management
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration (HHS)
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FY Fiscal year
GAO Government Accountability Office
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System

ICD–9–CM Internal Classification of Disease, 9th, Clinical Modification Guidelines
ICEP Initial Coverage Enrollment Period
ICL Initial Coverage Limit
ICR Information Collection Requirement
IRMAA Income-Related Monthly Adjustment Amount
IVC Initial Validation Contractor
LEP Late Enrollment Penalty
LIS Low Income Subsidy
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage—Prescription Drug Plans
M+C Medicare +Choice program
MOC Medicare Options Compare
MPDPF Medicare Prescription Drug Plan Finder
MIPPA Medicare Improvements for Patients and Providers Act of 2008
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-coverage
OEP Open Enrollment Period
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
PART C Medicare Advantage
PART D Medicare Prescription Drug Benefit Programs
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POS Point of service
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QIO Quality Improvement Organization
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
RADV Risk Adjustment Data Validation
RAPS Risk Adjustment Payment System
RHIA Registered Health Information Administrator
RHIT Registered Health Information Technician
SEP Special Enrollment Periods
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
TMR Targeted Medication Review
TrOOP True Out-Of-Pocket
U&C Usual and Customary
USP U.S. Pharmacopoeia

I. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new "Part C" in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act) which established the current MA program (known as Medicare+Choice under the BBA). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) established the Part D program and made significant revisions to Part C provisions governing the Medicare Advantage (MA) program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

As we have gained experience with the MA program and the prescription drug benefit program, we periodically have revised the Part C and Part D regulations to continue to improve or clarify existing policies and/or codify current guidance for both programs. In December 2007, we published a final rule with comment on contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors (72 FR 68700). In April 2008, we published a final rule to address policy and technical changes to the Part D program (73 FR 20486). In September 2008 and January 2009, we finalized revisions to both the Medicare Advantage and Medicare prescription drug benefit programs (73 FR 54226 and 74 FR 1494, respectively) to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275), which contained provisions affecting both the Medicare Part C and Part D programs, and to make other policy changes and clarifications based on experience with both programs (73 FR 54208, 73 FR 54226, and 74 FR 2881). We also clarified the MIPPA marketing provisions in a November 2008 interim final rule (73 FR 67407).

Proposed and final rules addressing additional policy clarifications under the Part C and Part D programs appeared in the October 22, 2009 (74 FR 54634) and April 15, 2010 **Federal Register** (75 FR 19678 through 19826), respectively. (These rules are hereinafter referred to as the October 2009 proposed rule and the April 2010 final rule, respectively.) As noted when issuing these rules, we believed that additional programmatic and operational changes were needed in order to further improve our oversight and management of the Part C and Part D programs, and to further improve a beneficiary's experience under MA or Part D plans.

Indeed, one of the primary reasons set forth in support of issuing our April 2010 final rule was to address beneficiary concerns associated with the annual task of selecting a Part C or Part D plan from so many options. We noted that while it was clear that the Medicare Part C and Part D programs have been successful in providing additional health care options for beneficiaries, a significant number of beneficiaries have been confused by the array of choices provided and have found it difficult to make enrollment decisions that are best for them. Moreover, experience had shown that organizations submitting multiple bids under Part C and Part D had not consistently submitted benefit designs significantly different from each other, which we believed added to beneficiary confusion. For this reason, the April 2010 rule required that multiple plan submissions in the same area have significant differences from each other. Other changes set forth in the April 2010 final rule were aimed at strengthening existing beneficiary protections, improving payment rules and processes, enhancing our ability to pursue data collection for oversight and quality assessment, strengthening formulary policy, and finalizing a number of clarifications and technical corrections to existing policy.

On November 22, 2010, a proposed rule (hereinafter referred to as the November 2010 proposed rule) appeared in the **Federal Register** (75 FR 224), in which we proposed to continue our process of implementing improvements in policy consistent with those included in the April 2010 final rule, while also implementing changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health

Care and Education Reconciliation Act (Pub. L. 111–152) are collectively referred to as the Affordable Care Act (ACA). The ACA includes significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the ACA concerning the Part C and Part D programs largely focus on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affect the way we implement our policies concerning beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. Some of the other provisions for which we proposed revisions to the MA and Part D programs, based on the ACA and our experiences in administering the MA and Part D programs, concern MA and Part D marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals and deeming. In general, the proposed rule was intended to strengthen the way we administer the Part C and Part D programs, and to aid beneficiaries in making the best plan choices for their health care needs.

II. Provisions of the Final Regulations and Analysis of and Responses to Public Comments

A. Overview of the Final Changes and Public Comments Received

1. Overview of the Final Changes

In the sections that follow, we discuss the changes made in the final rule to regulations in 42 CFR parts 417, 422, and 423 governing the MA and prescription drug benefit programs. To better frame the discussion of the specific regulatory provisions, we have structured the preamble narrative by topic area rather than in subpart order. Accordingly, we address the following five specific goals:

- Implementing the provisions of the ACA.
- Clarifying various program participation requirements.
- Strengthening beneficiary protections.
- Strengthening our ability to distinguish stronger applicants for Part C and Part D program participation and to remove consistently poor performers.
- Implementing other clarifications and technical changes.

A number of the revisions and clarifications in this final rule affect both the MA and prescription drug programs, and some affect section 1876 cost contracts. Within each section, we have provided a chart listing all subject areas containing provisions affecting the Part C, Part D, and section 1876 cost contract programs, and the associated regulatory citations that are being revised.

We note that these regulations are effective 60 days after the date of display of the final rule. Table 1 lists key changes that have an applicability date other than 60 days after the date of display of this final rule. The applicability dates are discussed in the preamble for each of these items.

We are implementing several changes to the regulations to reflect provisions in the ACA which are already in effect. Table 2 lists the key changes. While these ACA provisions became effective on the statutory effective date, the regulations implementing these provisions will be effective 60 days after the date of display of the final rule.

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Table 1: Applicability Date of Key Provisions Other than 60 Days after the Date of Display of the Final Rule

Preamble Section	Section Title	Applicability Date
II.B.10	Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	01/01/2012
II.B.11	Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	01/01/2013
II.B.12	Complaint System for Medicare Advantage Organizations and PDPs	01/01/2012
II.B.13	Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	01/01/2012
II.B.17	Improvements to Medication Therapy Management Programs	01/01/2013
II.B.20.a through d	Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate	01/01/2012
II.E.4	Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds	01/01/2012
II.F.4	Part D Transition Requirements	01/01/2012

Table 2: Key Statutory Provisions with Statutory Effective Dates Earlier than 60 Days after the Date of Display of the Final Rule

Preamble Section	Section Title	Effective Date of Statutory Requirement As Specified in the ACA
II.B.2	Simplification of Beneficiary Election Periods	01/01/2011
II.B.3.b	Extending SNP Authority	Upon enactment of the ACA
II.B.3.c	Dual Eligible SNP Contracts with State Medicaid Agencies	Upon enactment of the ACA
II.B.4	Section 1876 Cost Contract Plan Competition Requirements	Upon enactment of the ACA
II.B.5	Making Senior Housing Facility Demonstration Plans Permanent	01/01/2010
II.B.6	Authority to Deny Bids	01/01/2011
II.B.7	Determination of Part D Low-Income Benchmark Premium	01/01/2011
II.B.8.a through c	Voluntary De Minimis Policy for Subsidy Eligible Individuals	Plan year 2011
II.B.9.a through c	Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	01/01/2011
II.B.14	Including Costs Incurred by AIDS Drug Assistance Programs and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold	01/01/2011
II.B.18	Changes to Close the Part D Coverage Gap	01/01/2011
II.B.19.a	Authority to Apply Frailty Adjustment under PACE payment rules for Certain Specialized MA Plans for Special Needs Individuals	01/01/2011
II.B.19.b	Application of Coding Adjustment	01/01/2006
II.B.19.c	Improvements to Risk Adjustment for Special Needs Individuals with Chronic Health Conditions	01/01/2011

2. Public Comments Received on the Proposed Rule

We received approximately 261 timely public comments on the November 2010 proposed rule. These public comments addressed issues on multiple topics. Commenters included health and drug plan organizations, insurance industry trade groups, pharmacy associations, pharmaceutical benefit manager (PBM) organizations, provider associations, representatives of hospital and long term care institutions, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, researchers, and others.

In this final rule, we address all comments and concerns on the policies included in the proposed rule. We also reference comments that were outside the scope of the proposals set forth in the proposed rule, in the comment and response sections of this final rule.

We present a summary of the public comments and our responses to them in the applicable subject-matter sections of this final rule.

Comment: A commenter stated that CMS revised the date for the closing of the comment period from January 21, 2011 to January 11, 2011 and requested that CMS provide a rationale for shortening the comment period for the proposed rule.

Response: Our proposed rule was placed on display at the Office of the Federal Register and made available on the CMS Web site on November 10, 2010. Section 1871(b)(1) of the Act requires "notice" of the proposed rule, and a period of 60 days for public comment thereon. Because notice of the provisions of the proposed rule was provided on November 10, 2010 the comment period closed on January 11, 2011, which is 60 days after the date of display of the proposed rule at the Office of the Federal Register and on the CMS Web site.

B. Changes To Implement the Provisions of the Affordable Care Act

The ACA includes significant reforms of both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the ACA that concern the Part C and Part D programs largely focus on beneficiary protections, MA payments, and simplification of MA and Part D program processes. The changes based on provisions in the ACA are detailed in Table 3.

TABLE 3—Changes to Implement the Provisions of the Affordable Care Act

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
Cost Sharing for Specified Services at Original Medicare Levels	Subpart B Subpart C	§417.454 §422.100	N/A	N/A
Simplification of Beneficiary Election Periods	Subpart B	§422.62 §422.68	Subpart B	§423.38 §423.40
Special Needs Plan (SNP) Provisions	Subpart A Subpart C Subpart D	§422.2 §422.4 §422.101,§422.107 §422.152	N/A	N/A
Section 1876 Cost Contractor Competition Requirements	Subpart J	§417.402	N/A	N/A
Making Senior Housing Facility Demonstration Plans Permanent	Subpart A Subpart B	§422.2 §422.53	N/A	N/A
Authority to Deny Bids	Subpart F	§422.254,§422.256	Subpart F	§423.265 §423.272
Determination of Part D Low-Income Benchmark Premium	N/A	N/A	Subpart P	§423.780
Voluntary De Minimis Policy for Subsidy Eligible Individuals	N/A	N/A	Subpart B Subpart P	§423.34 §423.780
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	N/A	N/A	Subpart B Subpart F	§423.44 §423.286 §423.293
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	N/A	N/A	Subpart P	§423.772 §423.782
Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA-PD Plans	N/A	N/A	Subpart D	§423.154
Complaint System for Medicare Advantage Organizations and PDPs	Subpart K	§422.504	Subpart K	§423.505

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	N/A	N/A	Subpart C Subpart M	§423.128 §423.562
Including Costs Incurred by AIDS Drug Assistance Programs and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold	N/A	N/A	Subpart C Subpart J	§423.100 §423.464
Cost Sharing for Medicare-Covered Preventive Services	Subpart B Subpart C	§417.454 §422.100	N/A	N/A
Elimination of the Stabilization Fund	Subpart J	§422.458	N/A	N/A
Improvements to Medication Therapy Management Programs	N/A	N/A	Subpart D	§423.153
Changes to Close the Part D Coverage Gap	N/A	N/A	Subpart C Subpart R	§423.104 §423.884
Payments to Medicare Advantage Organizations	Subpart G	§422.308	N/A	N/A
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate	Subpart F	§422.252,§422.258 §422.266	N/A	N/A
Quality Bonus Payment and Rebate Retention Appeals	Subpart F	§422.260	N/A	N/A

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1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

Section 3202 of the ACA amended section 1852 of the Act to establish new standards for MA plans' cost sharing. Specifically, section 1852(a)(1)(B) of the Act was amended by the addition of a new clause (iii) that limits cost sharing under MA plans so that it cannot exceed the cost sharing imposed under Original Medicare for specific services identified in a new clause (iv). New section 1852(a)(1)(B)(iv) of the Act lists the three service categories for which cost sharing in MA plans may not exceed that required in Original Medicare (chemotherapy administration services, renal dialysis services, skilled nursing care) and section 1852(a)(1)(B)(iv)(IV) of the Act specifies that this limit on cost sharing also applies to such other services that the Secretary determines appropriate, including services that the Secretary determines require a high level of predictability and transparency for beneficiaries. The limits on cost sharing in clause (iii) are "subject to" an exception in clause (v) which provides that, "[i]n the case of services described in clause (iv) for which there is no cost sharing required under Parts A and B, cost sharing may be required for those services" under the clause (i) standard in place prior to the amendments made by section 3202 of the ACA. This section requires that overall cost sharing for Medicare Part A and B services be actuarially equivalent to that imposed under Original Medicare. As noted in the April 2010 final rule (75 FR 19712) and clarified in our April 16, 2010 policy guidance, the provisions of section 3202 of the ACA apply to MA plans offered in CY 2011. To codify these provisions, we proposed to amend § 422.100 by adding new paragraph (j). In addition, under our authority in section 1876(i)(3)(D) of the Act to impose "other terms and conditions" deemed "necessary and appropriate," we proposed to add new paragraph (e) in § 417.101 to extend the requirements in section 3202 of the ACA to section 1876 cost contracts. In this rule we explain that our proposed addition to § 417.101 was technically incorrect and have corrected the regulation citation so that our proposed addition is new paragraph (e) to § 417.454 to extend the requirements in section 3202 of the ACA to section 1876 cost contracts. We believe that this extension is necessary in order to ensure that all Medicare beneficiaries have the benefit of the cost sharing protections enacted in the ACA, regardless of whether they receive their Part A and B benefits through Original Medicare, an MA plan, or under a section 1876 cost contract.

In our April 16, 2010 guidance issued via the Health Plan Management System (HPMS) ("Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low

Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011"), we included clarifying information related to implementation of the required cost sharing for chemotherapy administration services, renal dialysis services, and skilled nursing care for CY 2011 and we defined chemotherapy administration services to include chemotherapy drugs, radiation therapy services and other related chemotherapeutic agents, as well as administration, and skilled nursing care to mean skilled nursing facility services. We also clarified that, since there is no cost sharing under Original Medicare for the first 20 days of skilled nursing services, under section 1852(a)(1)(B)(v) of the Act, the new restrictions in section 3202 of the ACA do not apply to such services during this period.

In our proposed additions to § 417.454 and § 422.100, we proposed to incorporate these definitions for the two service categories. We welcomed comments on these proposed cost sharing standards.

We also proposed to limit cost sharing for home health services under MA plans to that charged under Original Medicare and noted that, although we can generally rely on our authority at 1852(a)(1)(B)(iv)(IV) of the Act to apply Original Medicare cost sharing limits to other services that the Secretary determines appropriate, because there is no cost sharing under Original Medicare for home health services, as in the case of the first 20 days of skilled nursing facility services, the exception in clause (v) of section 1852(a)(1)(B) of the Act would apply, and the limit on cost sharing under section 1852(a)(1)(B)(iii) of the Act would not apply. Thus, in proposing to apply Original Medicare cost sharing amounts to home health services or any other service with zero cost sharing, we instead indicated that we would rely on our authority in section 1856(b)(1) of the Act to establish MA standards by regulation, and in section 1857(e)(1) of the Act to impose additional "terms and conditions" found "necessary and appropriate" to require that cost sharing for these services under MA plans conform to that under Original Medicare, meaning that no cost sharing could be imposed for these services.

We solicited public comment on our proposal to limit cost sharing for home health services to that charged for those services under Original Medicare.

Comment: There were many commenters who opposed our proposal to limit cost sharing for home health services under MA and cost plans at Original Medicare levels. The commenters expressed concern that limiting cost sharing for home health decreases their flexibility in their plan design and limits the plans' tools to ensure appropriate utilization of home health care.

MedPAC strongly opposed our proposal to limit home health cost sharing to $0 for several reasons including: Home health is a less well-defined benefit in Medicare and its appropriate use is more difficult to monitor and the proposed prohibition on cost sharing for home health is unduly restrictive. They also argued that CMS' proposal is based on weak rationale. The comment included a statement of MedPAC's belief that cost sharing should be one of the tools that plans can use at their discretion as a means of ensuring appropriate utilization. The comment informed us that MedPAC was currently considering these kinds of issues as a part of their deliberations on whether or not to recommend that traditional FFS Medicare should have cost sharing for home health services, along with the level of such cost sharing and the circumstances in which the cost sharing would apply.

Response: We find MedPAC's concerns about our proposal, in addition to those expressed by many other commenters to be persuasive and believe we should not finalize, at this time, our proposal to prohibit cost sharing for in-network home health services. MedPAC has recommended to Congress that it should direct the Secretary to establish a per episode copayment for home health episodes of care that are not preceded by a hospitalization or post-acute care use. We believe it is reasonable for us to take time to perform additional analyses of home health service utilization by beneficiaries enrolled in MA plans.

Comment: We received several comments that supported our proposal to limit cost sharing for home health services at Original Medicare levels. Those commenters believe that it will provide beneficiaries with a benefit package that is transparent and easily predictable for out-of-pocket expenses.

Response: We thank the commenters for their support but, as previously discussed at length, we believe that it would be more appropriate not to finalize our proposal. We will continue to evaluate the effectiveness of our current policies to protect beneficiaries from unfair or discriminatory cost sharing, confusing plan choices, and unaffordable care before implementing any additional policy change. Furthermore, under current policy only plans that provide extra beneficiary protection from high cost sharing by adopting a voluntary MOOP are permitted to charge cost sharing for home health services. We will continue to find the most appropriate balance between protecting beneficiaries from excessive out-of-pocket cost sharing and ensuring the financial viability of the MA program.

Comment: One commenter stated that prohibiting cost sharing for home health could lead to further pricing challenges and another stated there are a number of provisions in the ACA that limit a plan's ability to charge cost sharing for specified services and that these provisions are being implemented at the same time that CMS is implementing payment cuts and medical costs are continuing to increase. The commenter stated all plans would be in jeopardy of financial insolvency if they are prohibited from balancing costs, benefits, and payment cuts.

Response: As stated in our proposed rule, we estimated that the cost to the Medicare program of our proposal would not be significant. We also stated that we did not expect a significant financial impact on the relatively few plans that charge cost sharing for home health services. However, given our decision not to move forward with this proposal for other reasons, this issue is moot.

Comment: We received one comment that expressed concern that our proposed codification section 3202 of the ACA could be interpreted and implemented in a manner so as to mandate the cost sharing obligation to be charged, rather than permitting plans to set cost sharing levels at or below that cost sharing limit amount.

Response: We thank the commenter for sharing this concern. We thought we were clear in our proposal that plans would be able to set cost sharing levels at or below those charged under Original Medicare but will make every effort to be clear and consistent in our guidance related to these limits.

Comment: We received two comments that requested that we add Durable Medical Equipment (DME) to the list of service categories for which cost sharing may not exceed the levels required under Original Medicare.

Response: We thank the commenters for their suggestion and we will consider proposing that addition in future rulemaking.

Comment: We received several comments that challenged CMS' decision to allow plans to charge cost sharing during the first 20 days of skilled nursing care. One commenter

stated that charging cost sharing in the first part of the SNF stay makes sense for the plans but does not make sense for the beneficiaries. They stated that they understand CMS' actuarial equivalency rationale and that the law allows MA cost sharing for the services, but believe CMS' policy is contrary to the intent of health care reform. Another commenter stated that prohibiting cost sharing for the first 20 days of skilled nursing care would increase transparency for beneficiaries and could offer better opportunities for frail beneficiaries.

Response: Prior to the ACA, we allowed plans to charge cost sharing during the first 20 days of skilled nursing care so long as the plan's SNF benefit satisfied the actuarial equivalence test. In subregulatory guidance subsequent to enactment of the ACA, we clarified that because there is not cost sharing under Original Medicare for the first 20 days of SNF care, under section 1852(a)(1)(B)(v) of the Act, the new restrictions in section 3202 of the ACA do not apply to such services during this period and that we would continue our policy to allow cost sharing during the first 20 days of SNF care. We do not believe that enrolled beneficiaries are disadvantaged by this policy for at least two reasons. First, plans' cost sharing for SNF care is transparent to beneficiaries as it is reflected in the Summary of Benefits and the Medicare Plan Finder and second, because of the beneficiary protections from unexpected, unmanageable out-of-pocket costs that Medicare requires all MA plans to provide.

CMS limits the cost sharing that may be charged for SNF care so that it does not exceed what the beneficiary would pay under Original Medicare, including the minimal cost sharing we allow during the first 20 days in a covered SNF stay. We believe that minimal cost sharing is more than offset by other savings and protections offered under plans' benefit packages. One very important protection that all plans are required to offer is the maximum out-of-pocket (MOOP) limit on enrolled beneficiaries' out-of-pocket costs for covered in-network services. The maximum amount an enrolled beneficiary can be required to pay for those services is $6,700. In addition, most plans that charge cost sharing in the first 20 days of SNF care, waive the Original Medicare requirement for a 3-day qualifying inpatient hospital stay which saves beneficiaries enrolled in those plans from having to pay the costs for an inpatient stay.

Comment: One commenter requested that CMS establish an employer group waiver excepting MA plans offered through employer/union group health plans from the proposed cost sharing standards.

Response: We thank the commenter for this suggestion but we believe that employer group plans must be subject to the same cost sharing as other MA plans in order to provide the beneficiaries enrolled in those plans the same protections as beneficiaries enrolled in other MA and cost plans.

Comment: Several commenters supported our proposed codification of section 3202 of the ACA to limit cost sharing for chemotherapy administration services, renal dialysis services, skilled nursing care, and such other services as the Secretary determines appropriate to levels not to exceed that charged under Original Medicare and stated that it was welcome news for beneficiaries. One commenter specifically expressed support for the extension of the cost sharing limits to section 1876 cost contracts. Some of the commenters also requested that CMS provide greater clarity that the limits on cost sharing apply only to in-network services.

Response: We thank the commenters for their support and in response to the these comments we will revise our proposed regulation text to clarify in § 422.100 that the cost sharing charged for chemotherapy administration services, renal dialysis services and skilled nursing care provided in-network may not exceed the amount of cost sharing required for those services under Original Medicare. Thus, in part, the final regulation text will be revised to read: "On an annual basis, CMS would evaluate whether there are service categories for which MA plans' *in-network* cost sharing may not exceed that required under Original Medicare and specify in regulation which services are subject to that cost sharing limit."

Comment: A few commenters objected to our codification in the proposed rule of our proposal to extend the cost sharing limits of section 3202 of the ACA to section 1876 cost plans because we proposed to set forth this requirement in a new paragraph (g) to § 417.101, which otherwise does not govern cost plans. The commenters suggested that we instead add a new paragraph to § 417.454, Charges to Medicare enrollees. One commenter also recommended that we change our reference to "MA plans" in the proposed regulation language to "HMO" or "CMP" to be consistent with the standard terminology used in the regulations to refer to the section 1876 contracting entity.

Response: We thank the commenters for their suggestions. Accordingly, in this final rule, we will not include the cost-sharing requirements in § 417.101, but will instead add new paragraph (e) to § 417.454 to require cost sharing charged by section 1876 cost plans for chemotherapy, renal dialysis and skilled nursing care to be limited to that charged under Original Medicare. We also will remove reference to "MA plans" in the new regulatory text language and replace it with "HMO or CMP."

We have considered all of the comments on this proposal and will finalize, as revised, the addition of a new paragraph and (j) to § 422.100 to implement section 3202 of the ACA requiring that MA plans' in-network cost sharing charges for chemotherapy, SNF care and dialysis will be no greater than that charged under Original Medicare, and a new paragraph (e) to § 417.454 to extend these protections to section 1876 cost contracts. However, we will not finalize our proposal to add new paragraph (4) to § 417.454(e) or new paragraph (4) to § 422.100(j) to prohibit plans from charging cost sharing for home health services.

2. Simplification of Beneficiary Election Periods (§ 422.62, § 422.68, § 423.38, and § 423.40)

Section 3204 of the ACA modified section 1851(e)(3)(B) of the Act such that, beginning with plan year 2012, the annual coordinated election period (AEP) under Parts C and D will be held from October 15 to December 7. We proposed to amend 0§ 422.62(a)(2) and § 423.38(b) to codify this change.

Section 3204 of the ACA also revised section 1851(e)(2)(C) of the Act to establish, beginning in 2011, a 45-day period at the beginning of the year (January 1 through February 14) that allows beneficiaries enrolled in MA plans the opportunity to disenroll and join Original Medicare, with the option to enroll in a Medicare prescription drug plan. This 45-day period, also referred to as the Medicare Advantage Disenrollment Period (MADP), replaces the open enrollment period (OEP) that previously occurred annually from January 1st through March 31st. To codify this provision, we proposed the following changes:

- § 422.62(a) was amended to provide for this new disenrollment opportunity and clarify that the OEP ended after 2010;
- § 422.68(f) was amended to specify the effective date for disenrollment

requests submitted during the new 45-day disenrollment period;

• § 423.38(d) was amended to allow individuals who disenrolled from an MA plan between January 1 through February 14th to enroll in a standalone PDP; and

• § 423.40(d) was amended to specify the enrollment effective dates for individuals who enroll in a standalone Medicare prescription drug plan after disenrolling from MA during the 45-day period.

Comment: Commenters requested that CMS conduct beneficiary education on the new AEP timeframe.

Response: We are strongly committed to using all available means for ensuring that beneficiaries are made aware of the new AEP timeframes. Thus, we expect to conduct specific outreach and education on this topic and highlight the change in Medicare & You 2012 which will be mailed to all beneficiaries.

Comment: Commenters recommended that CMS adjust the timing of plan bids and make other important information, such as model notices, available earlier for plan preparation of the AEP. In addition, commenters requested that plan marketing be allowed to start earlier than October 1 for the AEP.

Response: We are considering the timing of our processes and will be making appropriate adjustments as we prepare for a successful implementation of the new AEP timeframe, but we do not plan to change the bid submission or plan marketing dates. The plan bid submission date is set by statute and remains the first week in June, leaving only a narrow timeframe for review and approval of bids and benefits and to ensure that marketing materials align with approved benefits. Accurate marketing materials are key to enabling beneficiaries to make appropriate determinations regarding their health care and prescription drug coverage. Also, we do not believe it is appropriate or necessary to allow plans to market earlier than October 1 given that a beneficiary may not enroll in a plan until October 15th.

Comment: Commenters recommended that CMS create an open enrollment period that would allow beneficiaries to enroll in Medigap products without regard to health status or pre-existing conditions. Another commenter recommended that CMS clarify that beneficiaries who disenroll from an MA plan using the 45-day disenrollment period do not have guaranteed issue rights to prevent underwriting the plan premium if they choose to purchase a Medigap policy.

Response: Section 1882 of the Act does not provide for a Federal annual open enrollment period for Medigap. Further the commenter is correct that using the MADP does not give the beneficiary guaranteed issue rights under Federal law to prevent health-based underwriting of the Medigap policy premium. In some cases, State Medigap laws may offer additional guaranteed issue rights to beneficiaries who are affected by the MADP.

Comment: Some commenters recommended that CMS establish a special election period (SEP) for the first year of the new AEP timeframe to allow individuals to make plan elections through December 31. Additionally, one commenter suggesting allowing plan sponsors to accept and process enrollment requests received from December 8 through December 31.

Response: Again, we will take a number of steps to ensure that beneficiaries are made aware of the new AEP timeframes, and that they have the tools they need to make informed decisions during the new AEP timeframe. We believe that through planned outreach and education efforts directly to beneficiaries and with stakeholders and plans, beneficiaries will have sufficient notification to make their health plan elections by December 7. We believe that the establishment of the suggested SEP would directly conflict with the clear intent of the statute.

Comment: A commenter recommended that individuals using the opportunity afforded by the MADP be allowed to enroll in an MA plan offered by the same parent organization instead of defaulting to Original Medicare. Another commenter recommended CMS find a less expensive alternative to the MADP such as reinstating the open enrollment period or eliminating lock-in.

Response: Again, the new 45-day disenrollment period, as established in the ACA, is clearly designed to permit only moves from MA to Original Medicare. Eliminating or broadening the scope of this election period would contradict the intent of the statute. Similarly, "lock-in" is mandated by the statute and cannot be eliminated by CMS.

Comment: A commenter addressed CMS' plans to establish an SEP to allow beneficiaries in an MA plan with less than five stars to enroll in a plan with five stars outside of the normal enrollment periods. The commenter recommended that, in regions where there are no plans with five stars, individuals be allowed to enroll in plans with 4.5 stars outside of the normal enrollment periods.

Response: We appreciate the suggestion; however the SEP for individuals to enroll in 5-star plans is outside the scope of this regulation. We will consider this suggestion as we finalize guidance concerning the scope of the SEP associated with Plan Ratings later this year. We appreciate the comments that were submitted and will be finalizing these proposals without modification.

3. Special Needs Plan (SNP) Provisions (§ 422.2, § 422.4, § 422.101, § 422.107, and § 422.152)

In our proposed rule, we defined a fully integrated dual eligible special needs plan (SNP) as specified by the ACA, and set forth proposed regulations implementing changes made by the ACA. These changes would extend the authority to offer SNPs, extend provisions permitting existing D–SNPs that are not expanding their service areas to continue operating without contracts with State Medicaid agencies through 2012, and establish a required NCQA quality approval process for SNPs.

a. Adding a Definition of Fully Integrated Dual Eligible SNP (§ 422.2)

Section 3205 of the ACA revised section 1853(a)(1)(B) of the Act to provide authority to apply a frailty payment under PACE payment rules for certain individuals enrolled in fully integrated dual eligible special needs plans described in section 3205(b) of the ACA. In order to implement this provision, we proposed a definition of fully integrated dual eligible special needs plan to § 422.2 that will apply for these purposes. Under our proposed definition, the D–SNP must meet the following criteria in order to be considered a fully integrated dual eligible special needs plan:

• Enroll special needs individuals entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2.

• Provide dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization (MCO).

• Have a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute and long-term care benefits and services, consistent with State policy.

• Coordinate the delivery of covered Medicare and Medicaid health and long-term care services, using aligned care management and specialty care network methods for high-risk beneficiaries.

• Employ policies and procedures approved by CMS and the State to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance.

In this final rule, we adopt our proposed definition of a fully integrated dual eligible special needs plan with some modification. For reasons discussed below, we have in this final rule revised the definition by removing the word "including" and have replaced the word "assurance" with "improvement."

Comment: The majority of commenters supported our proposed definition of a fully integrated dual eligible special needs plan. However, three commenters raised concerns about two potential ambiguities in the part of the proposed definition which requires that a fully integrated dual eligible special needs plan "[e]mploy policies and procedures approved by CMS and the State to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and quality assurance." Specifically, these commenters recommended that we eliminate the word "including" after member materials, because the functions that follow the word "including" in the proposed definition are not all related to member materials. Further, these same commenters suggested that we use the terms "performance measurement" in place of "quality assurance" in the proposed definition, because, as suggested by the commenters, the term "performance measurement" is more consistent with current regulatory language.

Response: We appreciate the commenters' support for the definition we proposed for a fully integrated dual eligible special needs plan. We agree with the commenters that, as written, the final prong of the proposed definition is not sufficiently clear about what policies and procedures must be approved by CMS and the State to ensure integration and coordination. Accordingly, in response to these comments, we have revised this part of the proposed definition in § 422.2 of the MA program regulations by eliminating the word "including" after member materials because, as the commenters suggest, the functions that follow the word "including" are not all related to member materials. We believe this word deletion makes this prong of the definition more clear, and also more accurately reflects our intention that a fully integrated dual eligible special needs plan coordinate or integrate Medicaid and Medicare member materials, enrollment, communications, grievance and appeals, and quality improvement. In addition, we revised this part of the proposed definition by substituting the terms "quality improvement" for "quality assurance" (or "performance measurement" as suggested by three commenters). "Quality improvement" is most consistent with existing MA terminology. We believe the term "performance measurement" does not sufficiently specify our intention to ensure that this portion of the definition requires coordinated or integrated policies regarding quality. Further, the use of the term "quality improvement" intentionally demonstrates our intention that a fully integrated dual eligible special needs plan integrate or coordinate the full spectrum of programs and tools utilized to ensure quality.

Comment: Several commenters suggested that we broadly or flexibly interpret the definition of a fully integrated dual eligible special needs plan to allow for the broad variety of dual eligible special needs plan contracting arrangements in place in different States. Additionally, one commenter that submitted a comment with this suggestion also requested that under the third prong of the definition, we allow for some combination of specified primary, acute and long-term care benefits and services because States need flexibility to design the details of their programs in response to their stakeholders' needs and concerns. In contrast, another commenter urged us to use caution when approving plans as fully integrated dual eligible special needs plans, and recommended that we specify that any fully integrated dual eligible special needs plan purporting to offer long-term supports and services must offer the full range available in a given State.

Response: We believe that there is a great deal of flexibility in our proposed definition of a fully integrated dual eligible special needs plan, as written in the proposed rule and this final rule, to account for the variability in State integration efforts. For example, the terms "consistent with State policy" in the definition recognizes the variability in the degree and extent to which Medicaid services are covered from one State to the next. Additionally, as highlighted by another commenter, use of the word "specified" in the definition ("coverage of *specified* primary, acute, and long term care benefits and services, consistent with State policy") also acknowledges that States vary in the degree to which Medicaid services are covered by the State by only requiring the plan to cover those services specified by the State Medicaid Agency. Moreover, fully integrated dual eligible special needs plans and States have the flexibility to choose to contract to serve certain subsets of the sState's overall dual eligible population, provided that the MIPPA compliant State contract between the State and the fully integrated dual eligible special needs plan supports this arrangement. Therefore, in order to meet this definition a plan will be required to provide all covered Medicaid primary, acute and long-term care services and benefits to beneficiaries, and not some combination thereof.

Comment: One commenter recommended that we include in the definition of a fully integrated dual eligible special needs plan the reference to PACE frailty levels from the statutory definition of a fully integrated dual eligible special needs plan found in section 3205 of the ACA. This commenter suggested that this reference to PACE frailty levels should be included in the definition of a fully integrated dual eligible special needs plan, as well as where it now appears in § 422.308.

Response: While section 3205 of the ACA provides us with the authority to apply a frailty adjustment payment to a fully integrated dual eligible special needs plan with a similar average level of frailty as the PACE program, the statute does not limit our ability to use the definition of a fully integrated dual eligible special needs plan for only this purpose. Therefore, we will not include this requested reference in the final definition so we are able use this definition for other purposes in the future.

Comment: One commenter asked us to clarify what is meant by "aligned care management and specialty care network methods for high-risk beneficiaries," and also provided brief recommendations on how to implement this requirement. Further, the commenter recommended that any clarification on the "aligned care management" requirement specify that a fully integrated dual eligible special needs plan is responsible for managing care that is covered by Medicare or Medicaid in such a way that the individual beneficiary gets full access to all services covered by both programs.

Response: Section 164(d) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) requires that special needs plans "have in place an evidenced-based model of care with appropriate networks of providers and specialists * * * and use[s] an interdisciplinary team in the

management of care." The terms "aligned care management and specialty care network methods for high-risk beneficiaries" derive from this requirement in MIPPA. In the September 18, 2008 **Federal Register**, we issued an interim final rule with comment on this MIPPA provision. We have received several comments on this provision and will finalize the provision later this year. As such, the final rule will provide additional clarification on what is required to "coordinates the delivery of covered Medicare and Medicaid health and long-term care services, using aligned care management and specialty care network methods for high-risk beneficiaries" as required by the definition for a fully integrated dual eligible special needs plan.

Comment: One commenter asked us to clarify the requirement that a plan designated as a fully integrated dual eligible special needs plan must provide notices specific to the dual-eligible population it is serving as opposed to generic notices designed for non-dual beneficiaries that do not correctly identify their rights and obligations.

Response: We appreciate this concern and currently require certain communications be developed specific to a beneficiary's eligibility. For example, we have created an Annual Notice of Change/Evidence of Coverage standard template specifically for dual eligible special needs plans for use starting with contract year 2012. The template was developed through several rounds of consumer testing and listening sessions with SNP representatives and consumer advocates. Other CMS models may be customized to meet the needs of dual eligible members. Furthermore, fully integrated and dual eligible special needs plans are required to coordinate and integrate member materials to contain information specific to both the Medicare and Medicaid benefits. We are committed to ensuring beneficiaries receive appropriate and helpful marketing materials and will continue to explore opportunities to improve beneficiary experience in this regard.

Comment: One commenter recommends that we approve and allow both fully integrated dual eligible special needs plans and non-fully integrated dual eligible special needs plans to operate so that a larger population of duals may be served by these plans.

Response: We agree with this commenter's recommendation. We will continue to approve and allow both fully integrated dual eligible special needs plans and non-fully integrated dual eligible special needs plan to operate so a larger population of duals may be served by these plans.

Comment: One commenter seeks clarification in the requirement that a fully integrated dual eligible special needs plan have a "capitated" contract with the State Medicaid agency.

Response: In response to this comment to clarify the meaning of the term "capitated" in the third prong of the definition, a capitated contract is a contract that provides for a fixed payment from the State Medicaid Agency to the fully integrated dual eligible special needs plan that does not vary based on services provided in exchange for the plan's provision of the covered Medicaid benefits to the beneficiaries.

b. Extending SNP Authority

Based on section 3205(a) of the ACA, which revised section 1859(f)(1) of the Act, we proposed in our November 2010 proposed rule (75 FR 71198) to extend the authority for SNPs to restrict enrollment to special needs individuals, thereby permitting SNPs to continue to limit enrollment to special needs individuals through the 2013 contract year. This extension applies to all SNP categories defined at § 422.2, with the exception of dual eligible SNPs (D–SNPs) that do not have a contract with the State in which they operate in contract year 2013, as described in section II.B.3.c of this final rule.

This provision was effective upon enactment of the ACA. However, we proposed that the regulations implementing this provision would be effective 60 days after the publication of this final rule.

After considering comments, we are finalizing this provision without modification.

Comment: Several commenters believed that delaying the proposed provision's effective date until 60 days after publication of the final rule was unnecessary.

Response: We disagree with the commenters' claim that it is unnecessary to delay implementation of this provision until 60-days following publication of this final rule. While section 3205(a) of the ACA was effective upon enactment, the regulations codifying this provision can be effective no earlier than 60 days following publication of this final rule, as provided under the Administrative Procedure Act for economically significant regulations.

Comment: One commenter suggested that extending the SNP program for longer than 1 year would provide SNPs with more operational certainty.

Response: Our proposed provision extended all SNPs, with the exception of D–SNPs that do not have a State contract in the State in which they operate, until contract year 2013, consistent with the statutory language at section 1859(f)(1) of the Act. We do not have the statutory authority to extend the SNP authority beyond the length of time Congress specified in the ACA. Therefore, we are finalizing this provision without modification.

c. Dual-Eligible SNP Contracts With State Medicaid Agencies (§ 422.107)

Section 164(c)(2) of MIPPA required all new D–SNPs and all existing D–SNPs that are seeking to expand their service areas to have contracts with the State Medicaid agencies in the States in which they operate. The provision allowed existing D–SNPs that were not seeking to expand their service areas to continue to operate without a State contract through the 2010 contract year as long as they met all other statutory requirements. Section 3205 of the ACA, which revised section 164(c)(2) of MIPPA, extends the date that D–SNPs not seeking to expand their service areas can continue to operate without a State contract to December 31, 2012. In order to implement this provision, we proposed to revise § 422.107(d)(ii) to specify the new deadline.

This provision was effective upon enactment of the ACA. However, we proposed that the regulations implementing this provision would be effective 60 days after the publication of the final rule.

Comment: Many commenters supported this proposed provision. However, the majority of the comments we received on this provision centered on the operational issues related to the State contracting requirement. Several commenters indicated that variation in State contracting and procurement processes has caused some D–SNPs to experience delays in obtaining contracts with State Medicaid agencies and they requested that CMS give D–SNPs additional flexibility to meet these contracting deadlines. A few commenters suggested that CMS incentivize States to engage with D–SNPs that are seeking to contract with the State(s) in their service areas, while another commenter proposed that CMS hold plans harmless if States either refuse to contract with them or require them to meet contract requirements that are beyond the minimum CMS-required contract elements. Other commenters recommended that CMS provide further regulatory and operational guidance on the State contracting process. Several commenters expressed concern that

States were receiving conflicting information from CMS central and regional offices (ROs), and asked CMS to develop a model State contract for dissemination to D–SNPs, States, and the CMS ROs. Some commenters recommended that CMS establish a system of review and oversight of D–SNP State contracts through rulemaking.

Response: The proposed rule neither codified the D–SNP State contracting requirement nor specified specific contract requirements; it only amended § 422.107 to conform to the statutory extension of the State contracting deadline for existing, non-expanding D–SNPs. Comments about operationalizing the State contracting requirement were not strictly within the scope of this rule. We note that, although we are not addressing these specific operational concerns in this final rule, we intend to provide additional operational guidance on the D–SNP State contracting requirements in future operational guidance well in advance of the State contracting deadline of December 31, 2012.

d. Approval of Special Needs Plans by the National Committee for Quality Assurance (§ 422.4, § 422.101, and § 422.152)

The ACA amended section 1859(f) of the Act to require that all SNPs, existing, new, and those wishing to expand their service areas, be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. Section 1859(f) of the Act further specified that the NCQA approval process shall be based on the standards established by the Secretary.

In our November 2010 proposed rule (75 FR 71199), we stated that both the quality improvement (QI) program plan description and the model of care (MOC) are critical clinical elements that represent the potential for the SNP to provide integrated care for Medicare enrollees. We proposed that NCQA review both the QI program plan description and the MOC submitted during the application process for all SNPs using standards developed by CMS. Specifically, we proposed to add a new paragraph (iv) to § 422.4(a) to require MA plans wishing to offer a SNP, whether new or current, to be approved by NCQA, effective January 1, 2012, by submitting their quality QI program plan and MOC to CMS for NCQA evaluation and approval, per CMS guidance. We also proposed to codify the new requirement at § 422.101(f), which specifies MOC requirements, by adding a new paragraph (vi). Finally, we proposed to codify the new requirement by revising § 422.152(g), which specifies QI program requirements.

In the proposed rule, we also clarified that CMS would not participate in the scoring and review of the MOC and QI program plans. We also stated in our proposed rule that we would release specific instructions and guidance to organizations, including the specific criteria that NCQA would use to evaluate the QI program plan description and MOC, information about technical assistance training that would be available to the SNPs as they prepared their QI program plan and MOC submissions, as well as details on the frequency of the SNP approval process. We also expressed concern that an annual approval process could be burdensome for plans and solicited comments on how to determine the appropriate frequency for the SNP approval process.

Based on the comments we received on the proposed rule, we are modifying § 422.4(a)(iv), § 422.101(f), and § 422.152(g), as described below.

Comment: Several commenters expressed concern with our proposed SNP approval process and the components that comprise that process. Specifically, these commenters noted that both the 2012 application cycle and the 2011 SNP structure and process measure submissions were due in February 2011. The commenters requested that CMS clarify any relationship between the two processes. Other commenters requested that CMS link the SNP approval process to the work NCQA currently performs around QI, MOC and HEDIS® requirements.

Response: In our proposed rule, we proposed that NCQA would review the QI program plan and MOC submitted by all SNPs during the application cycle using standards developed by CMS. Our basis for this proposal was that the description of the plan's QI program plan and the MOC contained critical elements representing the potential for a SNP to provide integrated care for Medicare enrollees. Some commenters appear to have confused our proposed requirements for the SNP approval process with other quality requirements, such as, the quality improvement projects (QIPs), chronic care improvement programs (CCIPs) and the NCQA structure and process measures. As a result of this confusion, the majority of these comments did not support using evaluation of either the QI program plan or MOC as part of this process. Other commenters recommended that CMS ensure that there is consistency between the requirements for the SNP approval process and those of the other, unrelated NCQA quality assessment process.

Response: We agree with commenters that the QI program plan may not be the most appropriate basis for approval of SNPs. Therefore, we have modified our original proposal by removing evaluation of the QI program plan from the NCQA SNP approval process described in § 422.4(a)(iv), § 422.101(f), and § 422.152(g). As a result, the SNP approval process will be based only on evaluation of the MOC, which will allow the NCQA to focus purely on a component of quality that is primarily clinical in nature and is also unique to SNPs. Removing evaluation of the QI program plan from the SNP approval process may also help reduce the confusion and concern plans expressed about alignment of the SNP approval process with other QI assessment measures and activities. All MA plans will still be required to submit their QI program plan; however, we will retain responsibility for review and assessment of this component as part of our larger QI efforts.

Comment: Several commenters urged CMS to ensure that there is consistency between the QI program and MOC documents submitted during the application process and NCQA structure and process measures submissions.

Response: The submission of structure and process measures is an ongoing annual QI assessment activity for all SNPs. The SNP approval process is a separate process for ensuring that SNPs comprehend the unique requirements of the SNP program and are capable of implementing these requirements. We believe commenters may be confusing submission of structure and process measures and the SNP approval process given NCQA's involvement in both processes, even though there is no relationship between the two. Therefore, we clarify that there is no relationship between the documents required to be submitted during the application process and the information required for the structure and process measures submissions.

Comment: Two commenters requested that CMS address the relationship between the requirements for D–SNPs to contract with States, the SNP application, and the new SNP approval process. They further requested that CMS clarify that if a D–SNP were approved by NCQA for longer than one year but lost its State contract, CMS would not approve the D–SNP and would terminate the plan.

Response: The D–SNP State contracting requirement is separate from the SNP approval and SNP application

processes and is described elsewhere in this final rule.

Comment: Several commenters recommended that CMS consider incorporating the SNP approval process into the existing NCQA accreditation process. One of the commenters requested that CMS replace specific Medicare requirements, such as QI program requirements that may be part of the NCQA accreditation process, in lieu of more appropriate and relevant MOC and SNP-specific measures.

Response: Section 1859(f) of the Act specifies that the SNP approval process "shall be based on the standards established by the Secretary." While CMS has broad discretion regarding the development of the SNP approval process, our goal is to develop a process that is equitable for all SNPs. We do not believe that substituting NCQA accreditation for explicit SNP approval is appropriate because accreditation is voluntary, and not all plans are accredited, nor is NCQA the only accreditation organization recognized by CMS. CMS also has agreements with URAC (formerly the Utilization Review Accreditation Committee) and the Accreditation Association for Ambulatory Healthcare (AAAHC) to be deeming accreditation organizations. Each accreditation organization defines its fully accredited status level differently.

Comment: Several commenters supported our proposal to consider implementing a multi-year approval period for high scoring plans. These commenters recommended a 3-to-5-year approval cycle to limit the administrative burden on plans that demonstrate their ability to meet the needs of special needs populations. These commenters stated that implementing an extended approval cycle would also allow CMS the opportunity to provide additional oversight of low performing plans. Two commenters recommended that CMS structure the approval process in a manner similar to that of the NCQA structure and process measures review cycle.

Response: We agree with the commenters' position that a multi-year approval period would limit MA organizations' administrative burden. To that end, we intend to implement a multi-year approval process that will allow plans that receive a higher score on NCQA's evaluation of their MOC to be granted a longer approval period, meaning they would not be required to be reapproved for 1 or more years, unlike plans that score at the lower end of the scoring spectrum and which will be granted a shorter approval period. Specific guidance regarding the standards for multiyear approvals will be provided in separate guidance such as HPMS memoranda and annual call letters.

Comment: One commenter supported a multi-year approval cycle but recommended that, rather than develop new measures, CMS should use QI measures that SNPs currently collect, such as annual QI audit results.

Response: We are conducting a review of the MOCs from a sample of the SNPs. While data are not yet available from these audits, we expect that the audits will be completed by the end of calendar year 2011. We will use these data to revise and improve the MOC requirements in the future, as well as to refine the required evaluation criteria for the SNP approval process over time. We will also continue to research additional and appropriate QI measures to use as part of this process.

Comment: To avoid introducing additional complexity into the transition to NCQA approval of SNPs, one commenter recommended that CMS not introduce new criteria for evaluation of SNPs at this time. This commenter also recommended that, once our approval standards are finalized, CMS leave them intact for several years in order to give NCQA and plans time to assess operational impacts and to fine-tune their systems.

Response: We intend to continue using criteria for evaluation of SNPs that are familiar to plans. However, we will continue researching the feasibility of revising the criteria for future approval cycles. We will communicate changes to these criteria and provide opportunities for public review and comment.

Comment: Several commenters expressed concern that CMS is proposing to delegate full authority of the SNP approval process to NCQA. These commenters did not favor giving so much authority to a private entity whose processes and activities are not subject to public scrutiny. These commenters recommended that CMS periodically audit NCQA's work to ensure that the work it is tasked with performing is serving the best interests of the beneficiaries.

Response: Section 1859(f) of the Act requires that NCQA approve SNPs based on standards established by the Secretary. We will maintain oversight of this process via its contract with NCQA, as well as by establishing appropriate standards for NCQA approval, as described elsewhere in this preamble.

Comment: One commenter requested that CMS clarify that it will continue its own review of SNP applications rather than allow NCQA approvals of two documents to serve as deemed compliance with all regulatory requirements.

Response: We confirm that we will retain responsibility of the MA and SNP application review process, and the SNP approval process is one component of this process. We believe this commenter may have confused the NCQA approval process with the annual application process, since both have the same timeline.

Comment: Several commenters recommended that CMS remove the SNP approval process from the annual SNP application timeframe.

Response: We disagree with these commenters' recommendation. While we proposed to link the SNP approval process to the MA application process, the SNP approval process is only one component of the overall process for determining whether a SNP may operate in contract year 2012. SNPs must still complete other components of the SNP proposal and other CMS requirements to be fully operational in contract year 2012. We believe we are minimizing MA organizations' administrative burden by linking the SNP approval process to the annual application cycle. Synchronizing the timelines for these two processes will allow SNPs to follow timelines and procedures with which they are familiar and allow for SNP approvals to be completed prior to the bid submission deadline.

Comment: One commenter recommended that CMS work with SNPs to identify a list of SNP-specific clinical and non-clinical QIP topics that are relevant to target populations served by SNPs, as well as a list of topics for dual-eligible SNPs (D–SNPs) that could be coordinated with State Medicaid agencies so that they can meet both Federal and State requirements.

Response: A major element in the design of the QIPs and CCIPs continues to be that they must address a target population that is appropriate for that plan. We intend to review the non-clinical and clinical QIPs and CCIPs that MA organizations have submitted to identify gaps in topics that plans should be addressing. We intend to issue further guidance on the submission of QIPs and CCIPs, through HPMS memoranda or the annual call letter process.

Comment: Several commenters requested the opportunity to review and comment on the new QI program plan and MOC instructional guidance.

Response: We are currently in the process of conducting a review of MOCs from a sample of SNPs. Information received from the review will be used to assist us in revising and improving the

MOC. In addition, we intend to use the information to modify and refine the required evaluation criteria over time to improve the QI program and the MOC. Updates or changes to the QI program plan and MOC instructional guidance will be made available in advance for public review and comment.

Comment: One commenter recommended that the CMS Federal Coordinated Health Care Office work with NCQA and States to align MOC and QI program requirements established by CMS for the SNP approval process for D–SNPs.

Response: We appreciate the recommendation and note that we are already working closely with the Federal Coordinated Health Care Office on a myriad of SNP issues.

Comment: One commenter believed it was not clear when plans that are not requesting a service area expansion (SAE) would be evaluated. This commenter also requested that CMS clarify whether the January 1, 2012 effective date means that the approval process begins in 2012 or that the approvals must be completed for all existing SNPs prior to January 1, 2012 (thus beginning in 2011).

Response: We approve potential applicants for contract the year prior to the date the contract becomes operational. Therefore, any requirements that must be in effect as of January 1, 2012 will be addressed as part of the 2012 SNP application cycle for contract year 2012. The deadline for submitting applications for consideration during the 2012 application cycle was February 24, 2011.

4. Section 1876 Cost Contractor Competition Requirements (§ 417.402)

In accordance with section 3206 of the ACA, which revised section 1876(h)(5)(C) of the Act, we proposed in our November 2010 proposed rule (FR 75 71199) to extend implementation of the section 1876 cost contract competition provisions until January 1, 2013. Previously, MIPPA had specified that section 1876 cost contractors operating in service areas or portions of service areas with two or more local or two or more regional Medicare coordinated care plans meeting minimum enrollment requirements (5,000 enrollees for urban areas and 1,500 enrollees for non urban areas) would be non-renewed beginning in 2010.

In implementing the new contract non-renewal date, we specified in our November 2010 proposed rule that we would evaluate enrollment of competing MA coordinated care plans beginning in 2012, send out non-renewal notices to affected section 1876 cost contracts in 2013, and that affected section 1876 cost contractors would first be unable to offer a plan beginning contract year 2014. We proposed to codify the statutory change in § 417.402(c).

We received no comments on this provision and are finalizing the provision as proposed.

5. Making Senior Housing Facility Demonstration Plans Permanent (§ 422.2 and § 422.53)

Section 3208 of the ACA established (at section 1859(g) of the Act) that as of January 1, 2010, senior housing facility plans participating as of December 31, 2009 "in a demonstration project established by the Secretary under which such a plan was offered for not less than 1 year" may continue participation as Medicare Advantage senior housing facility plans. In implementing this provision of the ACA, we proposed in our November 2010 proposed rule (75 FR 71199 and 71200) to amend the definitions at § 422.2 to include "senior housing facility plan" as a new coordinated care plan type. Our proposed definition of the term was consistent with the statutory requirements for such plans at section 1859(g) of the Act: that such a plan restrict enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2); provide primary care services onsite and have a ratio of accessible physicians to beneficiaries that we determine is adequate consistent with prevailing patterns of community health care as provided under § 422.112(a)(10); provide transportation services for beneficiaries to specialty providers outside of the facility; and was participating as of December 31, 2009 in a demonstration established by us for not less than 1 year. We also noted that a senior housing facility plan must otherwise meet all requirements applicable to MA organizations under this part.

In addition, we proposed to add a new § 422.53 to subpart B of Part 422 to address the eligibility and enrollment policies applicable to senior housing facility plans. We proposed specifying at § 422.53 that MA senior housing facility plans must restrict enrollment in these plans to residents of continuing care retirement communities, and that individuals enrolled in such plans must meet all other MA eligibility requirements in order to be eligible to enroll. In addition, we proposed specifying at § 422.53(c) that an MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS-approved process. We proposed that the regulations implementing this provision would be effective 60 days after the publication of the final rule.

We are finalizing our proposed provisions regarding senior housing facility plans without modification.

Comment: One commenter requested that our regulations make clear that, if a beneficiary who is enrolled in a senior housing facility plan moves out of the senior housing facility, he/she would be eligible for a special election period and, therefore, able to enroll in another MA plan or PDP outside of the annual election period.

Response: We agree with this commenter that a special election period should apply in this situation; however, it is not necessary to codify a new special election period for this situation. Current guidance in Chapter 2 of the Medicare Managed Care Manual *http://www.cms.gov/MedicareMangCareEligEnrol/Downloads/FINALMAEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf,* entitled "Medicare Advantage Enrollment and Disenrollment," provides that an MA enrollee is eligible for the SEP for changes in residence if he/she moves out of the plan's service area. Since a senior housing facility plan's service area is comprised of only the senior housing facility, an enrollee who moves out of the senior housing facility may use this existing SEP to enroll in any MA or Part D plan for which he/she is eligible in his/her new place of residence and is eligible for Medigap guaranteed issue rights if he/she disenrolls to Original Medicare.

6. Authority to Deny Bids (§ 422.254, § 422.256, § 423.265, and § 423.272)

Section 3209 of the ACA amends section 1854(a)(5) of the Act by adding subsection (C) (ii) to stipulate and expressly provide that the Secretary may deny a bid submitted by an MA organization for an MA plan if it proposes significant increases in cost sharing or decreases in benefits offered under the plan. Section 3209 of the ACA also extends this provision to apply to the review of bids from Part D sponsors by amending section 1860D–11(d) of the Act to add a new paragraph (3). This statutory authority applies to bids submitted for contract years beginning on or after January 1, 2011. However, as indicated in section II.A. of this final rule, the regulations codifying this provision will be effective 60 days after the date of display of the final rule.

In the proposed rule, we stated that we believe these amendments clarify the Secretary's authority to deny bids

submitted by MA organizations and PDP sponsors and provide support for our current policies as specified in our final rule, "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19678 through 19826). These policies include imposing limits on cost sharing and denying bids submitted by plans with sustained low enrollment or bids for multiple plans offered by the same MA organization or PDP sponsors in a service area that are not meaningfully different with respect to benefits or costs. These policies were further discussed in a memorandum sent on April 16, 2010 via the Health Plan Management System (HPMS) titled "Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011."

Because these policies have been implemented so recently, we concluded that it was premature to propose additional regulatory restrictions limiting MA organizations' or PDP sponsors' flexibility in developing plan bids until we are able to evaluate the effectiveness and impact on the market of those current policies. However, in the preamble to the proposed rule, we requested comments on the criteria outlined in our April 16, 2010 guidance issued via HPMS and whether we should establish additional requirements to limit plan offerings in a service area and whether there are other measures we should consider as part of future rulemaking that may help us in our efforts to protect beneficiaries and promote the provision of high quality, affordable health plans. We also invited comments on whether we should adopt other substantive criteria for exercising our authority under 3209 of the ACA by implementing caps or limits on the number of plans offered in a region, or on the number of sponsors participating in the program. Finally, we solicited comments on the best way to ensure fair notice and equal treatment for all plan bids in the absence of specific non-acceptance and denial policies. While we indicated that we would not propose additional specific regulatory criteria for CY 2012, we noted that our decision should not be interpreted as an indication that we would not adopt specific policies in future rulemaking. We will consider the suggestions and comments we received from the public on the proposed rule to guide our future policy.

We proposed to codify the amendments made to sections 1854(a)(5) and 1860D–11(d) of the Act by adding paragraph (a)(5) to § 422.254, revising § 422.256(a), adding paragraph (b)(3) to § 423.265 and by adding paragraph (b)(4) to § 423.272.

Comment: We received several recommendations in response to our request for comments on our current meaningful differences policies. Commenters recommended that CMS issue clear and comprehensive guidance containing the CMS criteria for evaluating and accepting or denying MA and Part D plan bids well in advance of the bid deadline. Moreover, commenters recommended that CMS provide specific information to MA organizations and Part D sponsors that is sufficiently detailed to allow sponsors the ability to replicate the methodologies applied in the tools that CMS uses in its bid evaluations. This information should be sufficient for plan actuaries to test their assumptions against CMS assumptions prior to their bid submission.

Response: We appreciate your comments regarding our current meaningful differences policies. We have released, via the Final Rate Announcement and Call Letter for CY 2012 released on April 4, 2011, a detailed discussion of the methods and tools that CMS intends to use to evaluate bids and ensure beneficiaries enjoy meaningful choices among MA and Part D plans. Specifically, in the final CY 2012 Call Letter, we announce that we will make an out-of-pocket cost (OOPC) model available that will allow plans to calculate OOPC estimates for each of their benefit offerings to prepare for negotiations with us. Standalone PDPs, MA, and MA–PD sponsors and organizations are encouraged to run their plan benefit structures through the OOPC model to ensure meaningful differences between their plan offerings as required by CMS regulations (see § 423.272(b)(3)(i) and § 423.265(b)(2)). Plans will be asked to complete this analysis prior to submitting their bids for the CY 2012.

A detailed discussion regarding the thresholds that CMS will be using for CY 2012 meaningful differences policies are included in the Final Rate Announcement and Call Letter for CY 2012.

Comment: We received several comments regarding the bid evaluation tools used by CMS and as specified in the April 16, 2010 guidance. Specifically, commenters indicated that if the total beneficiary cost (TBC) metric is used in future bidding cycles, CMS will need to take into account plan-specific variations such as plan consolidation, new plan service areas, pairing of plans to meet target margins and other payment policy issues such as the lagged sustainable growth rate (SGR) fix.

A few commenters indicated that CMS did not provide sufficiently detailed information as to how plan benefits as part of the OOPC calculation were projected and estimated for 2011. A number of sponsors discovered during bid negotiations that estimates they had produced to guide their benefit designs were significantly different than CMS recommendations. Commenters recommended CMS reevaluate use of the tool to analyze plan bids and engage in detailed discussion with MA and Part D plan sponsors to identify alternatives.

One commenter believes the OOPC tool, which is used by CMS to provide out-of-pocket costs information through the *http://www.Medicare.gov* Web site, is inappropriate and the estimates produced by the tool are not linked to the projections of MA and Part D plan-specific enrollee utilization of healthcare services and the revenue needed to fund them that are at the core of plan bids. Instead, these estimates reflect utilization under the Medicare fee-for-service program for a sample of beneficiaries that is somewhat out of date.

Response: We appreciate the commenters' suggestions and critique of our current bid evaluation tools. Based on the comments we have received in response to this rule and from the industry following bid negotiations for CY 2011, we have committed to providing additional information regarding the OOPC calculation and an OOPC tool to address the industry's specific concerns and to support their development of plan bids for CY 2012. We have also provided additional guidance and proposed policies for bid review in the Final Rate Announcement and Call Letter for CY 2012.

Comment: A few commenters recommend that star quality ratings either should, or should not, be used when evaluating plan bids. One commenter indicated that quality ratings, such as low star ratings, should be used as bid evaluation criteria since lower star ratings would result in decreased enrollment causing the plan to eventually fail meeting our low-enrollment thresholds. Other commenters support the use of star ratings and recommended that CMS only reassign beneficiaries to plans with a star rating of four stars or higher ensuring beneficiaries are offered plans that have a track record of quality service. One commenter indicated that they support the use of the star rating system; however, CMS would need to

consider the different changes faced by plans in geographic areas.

Response: We appreciate the comments we received regarding the potential use of quality ratings in determining whether to deny or decline bids under our new authority. While we will not be codifying specific criteria under this rule at this time, in the future we may explore the use of our authority to deny bids based on quality ratings, such as the star ratings.

Comment: Several commenters indicate that CMS should not impose limits on the number of plans in a service area, nor limit the number of MA organizations or Part D sponsors participating in the program, as this would be inconsistent with the competitive framework of the MA and Part D programs. One commenter indicated that limiting the number of plans in a specific service area would limit competition and potentially lead to higher prices and program costs in the long run. Another commenter suggests that CMS defer further consideration of initiatives to limit the number of plans offered until the impact of existing policies and statutory program changes can be fully evaluated.

Response: We appreciate the comments we received regarding limiting the number of plans in a service area and limiting the organizations that participate in the program using the new authority to not accept bids. We will not be codifying such limits under this rule. We will consider these comments if we propose additional rulemaking limiting plans in a service area, or, limiting organizations participating in the program.

Comment: One commenter requests that we continue the waiver of our meaningful differences policy for employer group waiver plans (EGWPs).

Response: We announced in the Final Rate Announcement and Call Letter for CY 2012, released on April 4, 2011, that this waiver will continue to apply to EGWPs for CY 2012 and future contract years.

Comment: Many commenters indicated either their support for, or opposition to, a premium increase threshold when determining whether to deny or decline bids under our new authority. In particular, one commenter indicated that CMS be permitted to deny a bid if such premium increases or benefit changes are unsubstantiated. An exception to an unsubstantiated change would be if actuarially the benefit design requires that benefits be decreased if premiums increased. Another commenter indicated that denying bids based upon changes to premiums assumes all sponsors have gravitated to the same level of maturity and that individual plan differences should be accounted for when applying a cap on premium increases.

Response: We appreciate the comments we received regarding the use of strict limits on premium increases or benefit decreases when evaluating bids. While we will not be codifying into regulation strict limitations on premium increases or benefit decreases as part of this final rule, we will take these comments into consideration as our policies regarding our authority to deny bids evolve.

Comment: One commenter urged that CMS consider a plan's proposed profit margin in order to assure consistent and fair treatment across health plans. This commenter believed that plans with higher profit margins have a greater capacity to implement member cost reductions requested by CMS, and plans that have losses, or very small profit margins, should be allowed to increase their profit to allow for risk reserves.

Response: We appreciate the recommendation provided by this commenter. As our meaningful differences policies and the impact of such policies on plan bids evolve, we will consider the possibility of examining plan profit margins as part of our bid evaluation criteria.

Comment: A few commenters believed it was important for us to develop an appeals process for plans that face bid denials and that such processes should allow for the timely reconsideration of our decision.

Response: We will not be adopting specific bid denial criteria or processes in this final rule. We will continue to work with plans prior to, and during, the bidding process to ensure the meaningful differences policies and bid evaluation criteria, as set forth in our CY 2012 Final Rate Announcement and Call Letter, take into account the individual plan's population, service area, and level of maturity. We will ensure this information is provided in a timely manner so that plans will know, prospectively, our expectations regarding the plans that will be made available to our Medicare population.

Comment: We received many comments requesting that CMS disclose, prior to bid development, all criteria that will be used to review bids each contract year. The commenters asserted that without definitions of what CMS identifies as "significant increases" in cost sharing or "decreases in benefits" offered and all other criteria by which plan bids will be evaluated and possibly denied, MAOs and Part D sponsors could be subject to inconsistent and potentially unfair bid denials. Commenters overwhelmingly requested that CMS make available in this final rule, its annual Call Letter or other appropriate published guidance, no later than mid-April, the specific standards plan bids will be required to meet as well as, the tools and methodologies that would be necessary for plans to replicate CMS' bid review results. They asserted that if plans are provided the appropriate tools and information they will be able to develop and submit initial plan bids that meet all CMS requirements.

Response: We agree with commenters that plan bids based on guidance we provide prior to or during bid development are more likely to satisfy our requirements. The final CY 2012 Call Letter, released on April 4, 2011, provides the tools and information necessary for sponsors to develop and submit complete initial bids that will meet our requirements.

Comment: Some of the comments we received requested that CMS not deny bids based on increases in beneficiary costs or on decreases in benefits offered because plans may need to increase costs or decrease benefit offerings to cover the growing gap between costs for providing services and revenue. Commenters expressed concern that continued application of the Total Beneficiary Cost (TBC) review criterion that CMS used for review of CY 2011 bids has the potential to undermine the financial integrity of plan bids and to adversely affect enrolled beneficiaries. Some stated their beliefs that the constraint on increases in plans' revenue required to meet the TBC measure is likely below a reasonable cost trend and could result in negative margins for some plan bids, putting them in conflict with other CMS bid guidance. Finally, commenters asserted that CMS criteria that limit premium and other beneficiary cost increases or decreases in benefits offered are not consistent with competitive bidding, the fundamental principal that bids should satisfy actuarial soundness requirements that anticipated revenue is sufficient to cover plan costs, or the requirement that bids be certified by actuaries.

Response: We understand that MAOs and Part D plan sponsors may be facing a number of challenges as they develop plan bids for CY 2012, including those related to meeting our standards for meaningfully different plan offerings, out-of-pocket maximums and cost sharing standards. We develop bid requirements with input from our Office of the Actuary (OACT), which takes into consideration the potential impact of its own guidance regarding negative margins. Together, we have developed a

TBC requirement that will not restrict a plan's ability to meet any additional bid guidance (for example, OACT's negative margin requirement) and considers environmental changes, as well as changes in Medicare payment and their impact on plan bids. In our final CY 2012 Call Letter, we describe the methodology we will use to limit significant increases in TBC to ensure that plans offered for CY 2012 are affordable and offer good value for enrollees. As described previously, we have provided a detailed discussion of the methods and tools we intend to use to evaluate plan bids in our CY 2012 Call Letter. We evaluate this guidance annually, and make refinements as necessary, taking into consideration comments we receive from industry following the end of bid review season. For CY 2012, we also are providing additional information about the OOPC calculation and will make an OOPC model available so that plans will be able to calculate OOPC estimates for their target benefit offerings in advance of submitting their bids to CMS. We believe that this increased transparency will support plans in their work to develop their benefit designs.

Comment: Many commenters indicated that if CMS does maintain its policy to approve only plan bids that do not propose significant increases in beneficiary costs or decreases in benefits offered using the TBC measure then the measure will need to take into account the large effects of CMS payment changes, plan-specific variations such as plan consolidation, new plan service areas, whether the plan is a SNP, pairing of plans to meet target margin and other payment policy issues. One commenter urged that MAOs be able to adjust for mistakes made in prior years' bids, such as to revise benefit amounts to curb demonstrated adverse selection into the plan.

Response: We thank the commenters for their suggestions for enhancing the development of the TBC criterion. We have considered these issues and worked with OACT to incorporate several of these factors, to the extent possible, into the TBC measure for CY 2012. However, we wish to point out that CMS does not support the notion that a plan should be able to adjust their pricing year to year to account for "mistakes" in a prior year's bid. Plans are responsible for submitting bids that reflect accurate and actuarially reasonable bid projections and assumptions for the coming year, which should not include amounts attributable to making up for errors in a past year. Therefore, our TBC measure will not account for errors in a plan's previous year's bid. To the extent practicable, we will consider relevant and appropriate factors and circumstances in order to develop and publish in a timely manner measures that we will use to evaluate bids consistently across plans.

Comment: Commenters expressed their concern that any single threshold established by CMS for review of significant increases in beneficiary costs or decreases in benefits offered would fail to address the many circumstances that vary across plans such as, geographic location, plan size, plan experience, plan type, and their belief that CMS must ensure that plans have some "due process" rights related to the upcoming contract year bid review. In addition to receiving full and timely disclosure of the criteria to be used for evaluating plan bids, commenters would like an opportunity to question, or comment on, CMS' methodologies prior to their implementation, and request assurance from CMS that bids will be reviewed using only published criteria. The commenters believe that CMS owes them a meaningful opportunity to challenge the application of CMS' criteria to their bids, using actuarial analysis, and to modify a bid that does not satisfy the criteria or where CMS choose not to accept the organization's rationale for the bid. As another example, commenters requested that CMS permit bid approvals in cases in which the plan can demonstrate actuarial justification for decreases in benefits offered and/or increases in beneficiary costs that exceed CMS' threshold.

Response: We thank the commenters for sharing these concerns. As in past years, our goal is to ensure that the MA and Part D programs remain healthy and that there are meaningful, high value choices available to beneficiaries We note that during CY 2011 bid reviews, the vast majority of outlier plans came into compliance with CMS guidance or submitted acceptable justifications to CMS for their plan bid. In an effort to reduce confusion, and the need for resubmissions, CMS is providing comprehensive guidance and tools in advance of the bid submission deadline so that organizations can develop initial submissions that meet all bid requirements. Organizations had an opportunity to comment on our guidance and methodology through the draft CY 2012 Call Letter and we considered such comments in preparing the final CY 2012 Call Letter, released on April 4, 201l.

Comment: One commenter recommended that CMS, as it implements its authority deny bids, continue to examine the impact of cost sharing for specialty tier drugs in a plan's formulary which may reduce patient access to needed medications.

Response: This comment is not relevant to the discussion in the proposed rule concerning our authority to deny bids; rather, it is a comment on CMS' formulary review process. We have in place a rigorous formulary review process that ensures cost-sharing imposed by plans on drugs found on specialty tiers will not impede a beneficiary's access to medications.

7. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

The ACA amends the statute governing the calculation of the LIS benchmark premium amount (see section 3302 of the ACA, as amended by section 1102 of HCERA). As amended, section 1860D–14(b)(3)(B)(iii) of the Act requires us to calculate the LIS benchmarks using MA–PD basic Part D premiums before the application of Part C rebates each year, beginning with 2011. We proposed to update the regulations at § 423.780(b)(2)(ii)(C) to incorporate this change. We also proposed that the regulations implementing this provision would be effective 60 days after the publication of the final rule.

Comment: We received several comments in support of the proposed change.

Response: We agree that LIS benchmarks should be calculated using basic Part D premiums before the application of Part C rebates and we are finalizing this provision without modification.

8. Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

Section 3303(a) of the ACA modifies section 1860D–14(a) of the Act by creating a new subsection (5) that permits PDPs and MA–PD plans to waive a *de minimis* monthly beneficiary premium for low income subsidy (LIS) eligible individuals who are enrolled in the plan. The provision also prohibits the Secretary from reassigning LIS individuals enrolled in a plan with a premium greater than the LIS benchmark premium amount, so long as the amount of the premium that exceeds the LIS benchmark is *de minimis* and the plan volunteers to waive that *de minimis* amount.

Section 3303(b) of the ACA modifies section 1860D–1(b)(1) of the Act by inserting new language in subparagraph (C) and adding a new subparagraph (D) that permits the Secretary to include PDPs and MA–PD plans that waive the *de minimis* amount in the auto-

enrollment process that we use to enroll those LIS-Eligible individuals who fail to enroll in a Part D plan. If these plans are included in the process, and more than one such plan exists within the respective PDP region, the statute requires that enrollees be randomly assigned among all such plans in the PDP region. We proposed to amend § 423.34 and § 423.780(f) to codify the new statutory requirements. The statutory provision is effective January 1, 2011; however, as indicated in section II.A. of this final rule, the regulations implementing these provisions are effective 60 days after the date of display of this final rule.

a. Reassigning LIS Individuals (§ 423.34)

Section 423.34(c) specifies that CMS may reassign certain LIS-eligible individuals if CMS determines that further enrollment is warranted. We have used this authority to reassign LIS-eligible individuals annually when a PDP's monthly beneficiary premium amount will exceed the low income benchmark, as calculated in § 423.780(b)(2). As noted previously, the ACA prohibits the Secretary from reassigning a plan's LIS eligible enrollees based on the fact that the plan's monthly beneficiary premium exceeds the LIS benchmark premium amount, so long as the amount of premium that exceeds the LIS benchmark is *de minimis* and the plan volunteers to waive that *de minimis* amount. Thus, plans that would otherwise have lost enrollees because of a *de minimis* monthly beneficiary premium can retain such membership. We proposed to amend § 423.34(c) regarding reassignment of LIS beneficiaries to reflect section 1860D–14(a)(5) of the Act.

Comment: All commenters supported our proposal to amend section § 423.34(c) to reflect newly added section 1860–14(a)(5) of the Act. These commenters noted that the primary benefits of such a *de minimis* policy are to minimize the need for reassignments, and the associated disruptions of an individual's continuity of care. One commenter recommended that we provide additional language in § 423.34(c)(1) to describe the circumstances under which reassignment occurs and the individuals affected by reassignment, in order to provide meaningful context for the exception described in § 423.34(c)(2).

Response: We agree with commenters that the *de minimis* policy supports the desirable goal of minimizing disruptions of an individual's continuity of care potentially associated with reassignment, while simultaneously ensuring a zero-premium Part D benefit to certain LIS-eligible individuals unlikely to have the financial means to pay the *de minimis* amount. Also, we appreciate the suggestion that additional context be added in § 423.34(c)(1) to describe the circumstances under which reassignment occurs and the individuals affected by reassignment. However, we believe that it is more appropriate to provide the level of detail the commenters request through subregulatory guidance. Therefore, we are finalizing our proposal to amend § 423.34(c) without modification. We will update Chapter 3 of the Medicare Prescription Drug Benefit Manual, ("Eligibility, Enrollment, and Disenrollment"—available at the following link: *http://www.cms.gov/MedicarePresDrugEligEnrol*) to provide the additional context requested by commenters.

b. Enrollment of LIS-Eligible Individuals (§ 423.34)

Section 423.34(d) specifies that CMS will automatically enroll LIS-eligible individuals who fail to enroll in a PDP. The pool of PDPs into which we auto-enroll these individuals includes those plans with monthly beneficiary premiums for LIS-eligible individuals that do not exceed the low income benchmark as calculated in § 423.780(b)(2). We proposed to amend § 423.34(d) regarding auto-enrollment of LIS-eligible individuals to be consistent with section 1860D–1(b)(1) of the Act, as modified by section 3303(b) of the ACA, which expands the Secretary's discretionary authority to include PDPs or MA–PD plans that voluntarily waive the de minimis amount in the pool of Part D plans qualified to receive auto-enrollees and reassignees, if the Secretary determines that such inclusion is warranted.

Comment: The majority of commenters supported our proposal to amend § 423.34(d) to be consistent with section 1860D–1(b)(1) of the Act, as modified by section 3303(b) of the ACA. However, a few commenters urged that CMS not codify such discretionary authority with respect to including MA–PD plans that voluntarily waive the *de minimis* amount in the pool of qualified plans to receive auto-enrollees and reassignees. Among the reasons they cited for not including the provisions concerning MA–PD plans in the regulations were that: (1) Random auto-enrollment and reassignment of such beneficiaries into MA–PD plans could have deleterious consequences on an individual's access to his or her Part A and Part B benefits; and (2) the public policy goal of eliminating premium cost-sharing for such LIS-eligible beneficiaries would not be accomplished for those individuals enrolled into an MA–PD plan with a Part D beneficiary premium within the *de minimis* amount but a Part C beneficiary premium of an amount for which the LIS recipient would incur liability.

Response: We agree with the concerns raised by these commenters, particularly with respect to the potential disruption of an individual's access to his or her Part A and Part B benefits (for example, by imposing network restrictions) by including MA–PD plans that voluntarily waive the *de minimis* amount in the pool of Part D plans qualified to receive auto-enrollees and reassignees. Since the inception of the auto-enrollment and reassignment processes, this concern has served as an underlying basis for inclusion of only PDPs in the pool of Part D plans that receive auto-enrollees and reassignees. We also agree that auto-enrollment and reassignment of such LIS-eligible individuals into MA–PD plans, in some cases, would fall short of our public policy goal of ensuring zero premium cost-sharing for these beneficiaries to access their Part D benefit.

For the reasons stated previously, we are amending § 423.34(d) to codify the Secretary's authority only with respect to including PDPs that voluntarily waive the *de minimis* amount in the pool of plans qualified to receive auto-enrollees and reassignees. At this time, we do not intend to exercise such authority to auto-enroll or reassign LIS-eligible beneficiaries into PDPs that voluntarily waive the *de minimis,* except under limited instances, such as to allow beneficiaries to remain within the same parent organization or to ensure that LIS-eligible beneficiaries in all PDP regions have access to a plan with zero beneficiary premium liability. However, the regulations will retain the flexibility to permit future reassignments to PDPs above the LIS benchmark that waive the *de minimis amount,* should the Secretary determine such reassignments to be warranted.

Comment: One commenter suggested that CMS examine the impact on enrollment stability if the Agency were to apply the *de minimis* policy to partial premium subsidy recipients.

Response: The underlying goal of the *de minimis* policy is to minimize unexpected disruptions of care that may result from reassignment. The proposed application of the *de minimis* policy to full-benefit subsidy beneficiaries supports this policy goal, as we do not reassign partial premium subsidy recipients enrolled in a Part D plan with

a beneficiary premium amount that exceeds the LIS benchmark amount. Since partial premium subsidy recipients pay a partial premium, they are more likely to be accustomed to proactively selecting a plan with a premium amount within their financial means to avoid disruption of care. Finally, application of the *de minimis* policy to partial premium subsidy recipients would partially undermine the downward pressure on Part D bids by decreasing the incentive for plans to bid lower in order to retain such beneficiaries. Therefore, we are making no modifications to our *de minimis* proposal with respect to its application to only full-benefit subsidy recipients.

Comment: One commenter urged CMS to permit plan sponsors to reassign LIS beneficiaries enrolled in its "enhanced plan" into the plan sponsor's "basic plan." The commenter noted that such a change would minimize disruption of care as the beneficiary would remain within the same parent organization, which typically has the same formularies and many similar benefits and services across plans. The commenter further noted that such a policy would prevent potential future terminations of members due to non-payment of premium, since their premium in the new plan should be much less than in the enhanced plan.

Response: In accordance with our long-standing public policy of honoring a beneficiary's plan choice by excluding from the reassignment process those beneficiaries who have proactively enrolled in a plan, we will continue our like-minded policy that prohibits plans from passively and selectively reassigning LIS-eligible beneficiaries who have proactively enrolled in the sponsor's enhanced plan. In the rare instance of plan consolidations, such reassignments may be permitted at our discretion, as they would not dishonor the beneficiary's plan choice, since the chosen plan no longer exists under such circumstances. Such situations would generally involve the elimination of the enhanced plan for all enrollees, and thus would not result in the selective reassignment of LIS-eligible beneficiaries.

c. Premium Subsidy (§ 423.780)

We also proposed to amend § 423.780(f) to reflect section 1860D–14(a)(5) of the Act, permitting a Part D plan to waive a *de minimis* amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the *de minimis* amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2). In addition, because section 1860D–14(a)(5) of the Act refers to waivers of *de minimis* premium that exceeds the low-income benchmark, which accounts only for the basic benefit, we limit the waiver of the *de minimis* amount to the premium applicable to the basic benefit.

Comment: We received one comment strongly encouraging CMS to increase the *de minimis* amount beyond $2.00 for full-benefit dual-eligible beneficiaries enrolled in special needs plans to help meet the needs of this more vulnerable population.

Response: We determine the *de minimis* amount based on the outcome of the plan bidding process. We consider the impacts of setting the *de minimis* amount at varying levels each year, including the impact on the number of zero premium plans and the number of reassignments. At this time, however, we do not believe that it is necessary to apply different *de minimis* amounts for various plan types, because we believe that a uniform *de minimis* amount ensures that impacted beneficiaries are treated equitably in terms of their premium assistance regardless of plan type. Thus, we plan to continue establishing a uniform *de minimis* amount applicable to all plan types each year.

Comment: Some commenters recommended that CMS release the LIS benchmarks and the *de minimis* amount earlier than August to allow adequate time for Part D sponsors to modify systems and member communications given the statutory change to the AEP.

Response: While we appreciate concerns about providing sufficient time for Part D sponsors to modify their systems and member communications, we cannot determine the regional LIS benchmarks until August when the Part D bids have been received and reviewed. In order for Part D sponsors to modify systems and member communications, they would need both the regional LIS benchmarks and the *de minimis* amount. Additionally, we release the *de minimis* amount in August to ensure that it does not influence bid submissions inappropriately. Therefore, we will not be modifying the release date of the regional LIS benchmarks or *de minimis* amount and are finalizing our proposal without modification.

9. Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D—IRMAA) (§ 423.44, § 423.286, and § 423.293)

Section 3308 of the ACA amended section 1860D–13(a) of the Act by establishing an income related monthly adjustment amount (hereafter referred to as Part D—IRMAA) that is added to the monthly Part D premium for individuals whose modified adjusted gross income exceeds the same income threshold amounts established under section 1839(i) of the Act with respect to the Medicare Part B income related monthly adjustment amount (Part B—IRMAA).

In CY 2007, the income ranges set forth in section 1839(i) of the Act required that individual and joint tax filers enrolled in Part B whose modified adjusted gross income exceeded $80,000 and $160,000, respectively, would be assessed the Part B—IRMAA on a sliding scale. As specified in section 1839(i)(5) of the Act, since the implementation of the Part B—IRMAA, each dollar amount within the income threshold tiers has been adjusted annually based on the Consumer Price Index. As a result of the annual adjustment, for calendar year 2010, the income threshold amounts were increased to reflect the four income threshold amount tiers shown below:

Individual tax filers with income:	Joint tax filers with income:	Premium Percentage
Equal to or less than $85,000	Equal to or less than $170,000	0—No IRMAA
Greater than $85,000 and less than or equal to 107,000	Greater than $170,000 and less than or equal to $214,000	35 percent
Greater than $107,000 and less than or equal to $160,000	Greater than $214,000 and less than or equal to $320,000	50 percent
Greater than $160,000 and less than or equal to $214,000	Greater than $320,000 and less than or equal to $428,000	65 percent
Greater than $214,000	Greater than $428,000	80 percent

We note that section 3402 of the ACA freezes the income thresholds at the above 2010 levels through 2019.

In accordance with section 3308 of the ACA, effective January 1, 2011, any individual enrolled in the Medicare prescription drug program whose modified adjusted gross income exceeds the same income threshold amount tiers established under Part B will have an income related increase to his/her Part D monthly premium. Section 3308 of the ACA provides that the Part D—IRMAA will be calculated using the Part D national base beneficiary premium and the premium percentages in the above chart as follows: BBP × [(P percent − 25.5 percent)/25.5 percent]. The BBP is the base beneficiary premium and P is the applicable premium percentage (35 percent, 50 percent, 65 percent, or 80 percent). The premium percentage used in the calculation will depend on the level of the Part D enrollee's modified adjusted gross income.

Section 3308 of the ACA requires CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D—IRMAA no later than September 15 of every year, beginning in 2010. Beginning in 2010, we must also provide SSA, no later than October 15 of each year, with: (1) The modified adjusted gross income threshold ranges; (2) the applicable percentages established for Part D—IRMAA in accordance with section 1839(i) of the Act; (3) the corresponding monthly adjustment amounts; and (4) any other information SSA deems necessary to carry out the Part D—IRMAA. With respect to the final item, we previously provided SSA with an initial list of all individuals enrolled in the Part D program.

In accordance with section 3308 of the ACA and the interim final rule with request for comments entitled "Regulations Regarding Income-Related Monthly Adjustment Amounts to Medicare Beneficiaries' Prescription Drug Coverage Premiums" (75 FR 75884), SSA used this initial list of Part D enrollees to request beneficiary-specific tax payer information from the Internal Revenue Service in order to determine: (1) Which Part D enrollees exceed the income threshold amounts established under section 1839(i) of the Act; and (2) the income related monthly adjustment amount that these enrollees must pay. This exchange of information between CMS and SSA occurred in 2010 so that individuals identified were billed the correct Part D—IRMAA beginning January 1, 2011. Following this initial data exchange with SSA, CMS will routinely provide SSA with the names of all individuals newly enrolling in the Part D program so that SSA can repeat the process of identifying individuals who must pay the Part D—IRMAA and the specific income-related amount. We will also routinely provide the names of individuals who have disenrolled from the Part D program so that such individuals will no longer be assessed the Part D—IRMAA. In cases where an individual disagrees with a determination that he/she is subject to the Part D—IRMAA, such individual may appeal as provided in the SSA regulations under 20 CFR part 418.

Section 3308 of the ACA also stipulates that the Part D—IRMAA must be withheld from benefit payments in accordance with section 1840 of the Act. Therefore, in cases where an individual is receiving benefit payments from SSA, the Railroad Retirement Board (RRB), or the Office of Personnel Management (OPM), the Part D—IRMAA must be withheld from such benefit payments. However, if the benefit payment is insufficient to allow the Part D—IRMAA withholding, or an individual is not receiving benefit payments as described in section 1840 of the Act, section 3308 of the ACA requires SSA to enter into agreements with CMS, RRB, and OPM, as necessary, in order to allow the Part D—IRMAA to be collected directly from these beneficiaries.

To implement section 3308 of the ACA, we proposed to revise § 423.286 (rules regarding premiums), § 423.293 (collection of monthly beneficiary premium), and § 423.44 (involuntary disenrollment by PDP).

a. Rules Regarding Premiums (§ 423.286)

Currently, § 423.286(a) provides that the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D-eligible individuals enrolled in the plan with the exception of employer group waivers, the assessment of the Part D late enrollment penalty, or an enrollee receiving low-income assistance. We proposed to revise the following:

- Section 423.286(a) to include the assessment of the income related monthly adjustment amount as another exception to the requirement for a uniform monthly beneficiary premium for a Part D plan in a PDP region;
- Section 423.286(d)(4) to define the increase for the income related monthly adjustment amount for Part D;
- Section 423.286(d)(4)(i) to specify that SSA would determine the individuals that are subject to the Part D—IRMAA and the amount of the adjustment;
- Section 423.286(d)(4)(ii) to provide the formula used to calculate the monthly adjustment amount; and
- Section 423.286(d)(4) to provide appeals rights to individuals who disagree with SSA's determination that they are subject to the Part D—IRMAA or the threshold amount of the adjustment they must pay.

Comment: Commenters wanted to know if there was any plan responsibility in tracking or collecting the Part D—IRMAA. One commenter believed the Part D—IRMAA would

cause beneficiary confusion and that plans would have little recourse to address beneficiary concerns. A few commenters requested that CMS provide information to plans, including copies of communications released to the IRMAA population and individuals' Part D—IRMAA billing information, potentially through the Medicare Advantage Prescription Drug (MARx) System via a transaction reply response (TRR). This information would enable plans to address both general and specific beneficiary concerns and provide proactive communications to improve the beneficiary experience. Lastly, a commenter encouraged CMS to provide plans with guidance regarding how plans' customer service agents can best handle beneficiary inquiries regarding income related adjustments to their premium.

Response: Part D plan sponsors do not have responsibility for tracking or collecting the Part D—IRMAA. Section 3308 of the ACA clearly states that the additional amount is to be withheld from a beneficiary's Social Security benefit check. In cases where the benefit check is not sufficient to allow the withholding, the beneficiary will be directly billed the amount by CMS. However, as discussed below, Part D plan sponsors will be responsible for providing beneficiaries with the disenrollment notice after we notify plans that the beneficiary's Part D coverage has been terminated for failure to pay his/her Part D—IRMAA.

On December 10, 2010, we released to Part D plan sponsors a memorandum entitled, "Part D—Income Related Monthly Adjustment Amount—Frequently Asked Questions & Answers," which included plain-language, beneficiary-friendly questions and answers specifically addressing inquiries plans may receive from beneficiaries. These FAQs include information such as how the Part D—IRMAA is collected, the responsible entity for determining who should be assessed the amount, as well as the appropriate government agency a beneficiary should contact with additional questions.

We have provided clear instructions to plans regarding the appropriate referral agency for specific questions regarding an individual's Part D—IRMAA determination and billing. We will continue to work with Part D plan sponsors to determine what specific additional guidance they need in answering beneficiary inquiries related to the Part D—IRMAA.

Comment: A commenter asserted that there will be an increase in premium-related complaints submitted to 1–800–MEDICARE due to the Part D—IRMAA noting that plans are unable to influence or control members' experiences related to the premium increase and should not be penalized for these complaints. The commenter requested that CMS exclude complaints specific to the Part D—IRMAA premiums in plan quality metrics.

Response: While there may be an increase in the number of beneficiary complaints related to the Part D—IRMAA, we believe our developed scripts and FAQs will address most concerns. We agree beneficiary complaints related to these types of issues should not be part of Medicare Part D plan sponsors' quality metrics.

Comment: Commenters requested that we clarify how a Part D sponsor would operationalize the Part D—IRMAA and whether the Part D—IRMAA affects the Part D bid or the base beneficiary premium.

Response: Currently, Part D sponsors are not expected to implement any operational changes with regards to the collection of the Part D—IRMAA. Unlike the normal Part D plan premiums, applicable beneficiaries will not pay the Part D—IRMAA to Part D sponsors. Instead, as noted previously, the Part D—IRMAA will be collected by the Federal government via a withholding from beneficiaries' SSA, RRB, or OPM benefit payments or collected by us directly. As stated previously, though, Part D plan sponsors will be responsible for providing beneficiaries with the disenrollment notice if we involuntarily disenroll an individual for failure to pay his/her Part D—IRMAA, just as they would for any other disenrollment action initiated via a CMS transaction file, such as those disenrollments that result from choosing another plan.

Consistent with section 1860D–15(a)(1) of the Act, we will not apply Part D—IRMAA to the base beneficiary premium used to calculate the Part D direct subsidy payments. In addition, no other Part D—IRMAA related adjustments will be made to the Part D payments received by Part D sponsors. As a result, the Part D—IRMAA is expected to have no impact on the Part D bids or Federal payments received by Part D sponsors.

Comment: One commenter conveyed that it did not support the imposition of the Part D—IRMAA because of the "potentially adverse effect" of this provision, referencing our estimate that approximately 220,000 beneficiaries may disenroll from the Part D program as a result of the Part D—IRMAA (see 75 FR 71256). Another commenter suggested that CMS monitor the impact of this policy on enrollment in Part D plans and the potential for adverse selection. More specifically, this commenter was concerned that the most healthy, affluent seniors may elect to delay enrollment in a Part D plan as it may be financially advantageous to pay the late enrollment penalty for delaying enrollment rather than paying the Part D—IRMAA for many years when expected drug expenditures are minimal. Despite one of the commenters' dislike for this statutory requirement, the commenter applauded CMS for developing timely regulations to implement this new requirement.

Response: We have no discretionary authority to waive the Part D—IRMAA, which is clearly required by the ACA. We are dedicated to ensuring a timely and thorough implementation and appreciate acknowledgement of our efforts to develop regulations to implement this new requirement. We will monitor all aspects of Part D—IRMAA implementation, including the impact of this policy has on future Part D disenrollments and enrollments.

Comment: One commenter asserted that the introduction of the IRMAA for Part B and Part D premiums through Social Security deductions is not understood by many beneficiaries. Consequently, the commenter encouraged consideration of some notification from SSA or CMS of each individual's premiums under each Part prior to the upcoming year.

Response: Each year, SSA will determine who will be assessed an IRMAA in both the Part B and Part D programs. In November, SSA will send the beneficiary an annual letter that indicates the amount of any IRMAA the individual may owe. Further, CMS and SSA developed beneficiary-friendly publications and FAQs to assist beneficiaries and our partners with understanding this new requirement. We believe that more outreach and education will assist beneficiaries in understanding the IRMAA and which government Agency (CMS or SSA) should be contacted with further questions. Plans may refer beneficiaries to SSA with questions regarding the content of their annual letter from SSA regarding the IRMAA.

We would also like to note that in the preamble of the proposed rule we inadvertently referenced the wrong citation in describing our proposal to add provisions regarding a beneficiary's right to file an appeal of SSA's Part D—IRMAA determination. We referenced § 423.286(d)(4)(iii) and (iv), but should have referred to § 423.286(d)(4)(i) which is where these provisions were

proposed and where they are being finalized in this rule.

b. Collection of Monthly Beneficiary Premium (§ 423.293)

We proposed establishing a new § 423.293(d)(1) to describe how the Part D—IRMAA would be collected. First, we addressed the process for collecting the Part D—IRMAA from SSA, RRB, or OPM benefit payments. In cases where SSA determines that a Part D enrollee must pay a Part D—IRMAA, such amount must be paid through withholding from the enrollee's Social Security benefit payments, or benefit payments by the RRB or OPM in the manner that the Part B premium is withheld. Additionally, we proposed at § 423.293(d)(2) that in cases where premium withholding is not possible because the monthly benefit check is insufficient to allow the withholding, or the enrollee is not receiving any monthly benefit payment, the individual must be directly billed for the Part D—IRMAA through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or according to other means that we may specify.

Section 3308 of the ACA provides that the Part D—IRMAA is an increase to the monthly beneficiary premium for certain individuals. Section 1851(g)(B)(i) of the Act, as incorporated by section 1860D–1(b)(5) of the Act, establishes that a beneficiary may be terminated for failing to pay his/her Part D premiums. At § 423.293(d)(3), we proposed that CMS will terminate Part D coverage for any individual who fails to pay the income related monthly adjustment amount in accordance with proposed § 423.44 (see discussion below).

Comment: Several commenters conveyed that they understood that implementation of the Part D—IRMAA requires coordination among CMS, Part D plan sponsors, and SSA, with SSA having primary responsibility for an individual's IRMAA determination. They suggested that the final regulations address the need for the timely exchange of beneficiary information and any updates in order to facilitate coordination amongst these entities. As an example, commenters contended that in cases where a higher income beneficiary is no longer enrolled in a Part D plan, the Part D sponsor should send this information immediately to CMS and SSA so that the Part D—IRMAA is no longer deducted from the beneficiary's benefit check or billed to the beneficiary.

Response: We appreciate the recommendation that CMS and SSA maintain close and timely coordination related to Part D enrollment and the Part D—IRMAA. As noted in the proposed rule "* * * CMS will routinely provide SSA with the names of all individuals newly enrolling in the Part D program * * * and will also routinely provide the names of individuals who have disenrolled from the Part D program so that such individuals will no longer be assessed the Part D—IRMAA." Furthermore, as stated in § 423.36 and in our guidance, Part D plan sponsors must submit the disenrollment transactions to CMS within 7 calendar days of receipt of the beneficiary's completed disenrollment request in order to ensure the correct effective date. (See Chapter 3, § 50.4.1 "Voluntary Disenrollments" of the *Medicare Prescription Drug Benefit Manual* published August 17, 2010). We believe that through this existing process, all involved entities will receive timely notification to address changes to either Part D enrollment or Part D—IRMAA.

Comment: One commenter asserted that they foresaw enrollment "glitches" similar to those of LIS-eligible beneficiaries who were inadvertently dropped from one plan but not correctly auto-enrolled in the next. This commenter further stated that, undoubtedly, some high-income beneficiaries would face disenrollment because of miscommunications that result because prescription drug plan premiums are paid to their chosen plan and the Part D—IRMAA is paid to CMS. Based on this assertion, the commenter encouraged CMS to develop an expeditious, straight-forward process for resolving such problems and to publicize that process on Medicare.gov.

Response: We appreciate the commenter's concern about possible problems or beneficiary confusion regarding payments for the Part D—IRMAA to the Federal government and plan premiums. The vast majority of individuals required to pay the Part D—IRMAA will have the IRMAA amount deducted from their monthly benefit check, which will eliminate the possibility of involuntary disenrollment for failure to pay the Part D—IRMAA. For those individuals who will be billed by CMS directly, we will notify them via monthly billing notices. Further, we have developed FAQs for use by plans, partners, and 1–800–MEDICARE to educate beneficiaries on the proper means to make payments for their Part D—IRMAA. However, we will consider outlining the process for Part D—IRMAA payment and possible disenrollment on Medicare.gov to assist in beneficiary understanding.

c. Involuntary Disenrollment by CMS (§ 423.44)

Section 3308 of the ACA provides that the Part D—IRMAA increases the monthly beneficiary premium for individuals who are subject to the assessment. Therefore, we proposed to apply provisions similar to the existing Part D premium rules to terminate Part D coverage (provided for by Section 1860D–13(c) of the Act) for any individual who fails to pay the Part D—IRMAA. Specifically, we proposed the following:

- Section 423.44(e)(1) provides that CMS will disenroll individuals who do not pay their Part D—IRMAA.
- Section 423.44(e)(2) provides individuals a 3-month grace period to pay outstanding Part D—IRMAA amounts before they are involuntarily disenrolled.
- Section 423.44(e)(3) provides an opportunity for a disenrolled beneficiary to establish "good cause" for failure to pay their Part D—IRMAA and have their plan enrollment reinstated if Part D—IRMAA arrearages are paid.
- Section 423.44(e)(4) requires PDPs, after notification by CMS, to notify enrollees of the termination of their enrollment in the Part D plan in a form and manner determined by CMS.
- Section 423.44(e)(5) establishes that the effective date of disenrollment is the first day following the initial grace period.
- Finally, we proposed modifying the title of § 423.44 from "Involuntary Disenrollment by the PDP" to "Involuntary Disenrollment from Part D Coverage."

Comment: We received several comments on the length of the proposed grace period applicable to Part D—IRMAA premiums. While several commenters commended CMS for proposing a longer grace period to pay the Part D—IRMAA, other commenters suggested that CMS synchronize the 3-month grace period for payment of the Part D—IRMAA with the plans' minimum 2-month grace period already established by CMS regulations and guidance. Commenters asserted that having different grace periods could cause potential conflict and confusion if the enrollee failed to pay both the Part D premium and the Part D—IRMAA and was provided a grace period by both the PDP and CMS, but on differing timelines (for example, a 2-month grace period under the PDP and a 3-month grace period under CMS).

Commenters also requested that we take into consideration the potential

overlap, conflicts, and/or confusion that could occur for beneficiaries receiving notices for non-payment of their plan premium and non-payment of the Part D—IRMAA and any conflicting grace periods. The commenter requested that CMS revise the approach to better coordinate the timing of the plan beneficiary disenrollment notices with the plan and the Part D—IRMAA grace periods and that we should do our best to prevent the potential problems. Another commenter asked us to clarify that a Part D beneficiary could be disenrolled from a Part D plan for failure to pay the plan premium after the plan's two-month grace period regardless of whether the enrollee has paid their Part D—IRMAA or has not exhausted the 3-month grace period for the D—IRMAA.

In addition, one commenter recommended that CMS delay implementation of the grace period specific to the Part D—IRMAA in light of the other CMS provisions that require process and system changes. According to this commenter, CMS should consider this recommendation since the Part D—IRMAA affects only a small percentage of the total Part D population.

Response: Under the Original Medicare program, beneficiaries assessed the Part B–IRMAA are afforded an initial 3-month grace period to pay their Part B premiums before they are terminated. As individuals may be subject to both the Part B and the Part D—IRMAA, we believe that the grace period for both programs should be consistent.

With respect to synchronizing the Part D—IRMAA with plan premium grace periods, our regulations at § 423.44(d)(1)(iii) stipulate that plans choosing to implement a policy of involuntary disenrollment for failure to pay the Part D plan premium must provide a minimum 2-month grace period. A Part D plan sponsor with an established 2-month minimum grace period may disenroll a beneficiary for failing to pay the plan's premium, if such grace period ends prior to the 3-month grace period allotted for payment of the Part D—IRMAA. Current guidance (Medicare Prescription Drug Benefit Manual, Chapter 3, § 50.3.1) allows plans to implement a longer grace period or forgo involuntary disenrollments for failure to pay premiums entirely. Therefore, plans already have the ability to modify their respective grace periods and are encouraged to do so if they believe the existence of two different grace periods will create conflict or confusion.

As noted previously, the vast majority of individuals subject to the Part D—IRMAA are paying the income-based amount through a deduction from their Social Security checks, and thus the grace period associated specifically with payment of the Part D—IRMAA is not a factor. However, to the extent that individuals fail to pay only the Part D—IRMAA, we believe it is appropriate to use the same procedures and time frames that apply to the Part B–IRMAA. Note that individuals who fail to pay the Part D premium that is owed to a plan may be disenrolled by the plan after the expiration of the 2-month grace period, regardless of the payment status of their Part D—IRMAA.

If a plan chooses to retain a grace period that is shorter than the one specific to the Part D—IRMAA, once the beneficiary is disenrolled from the plan, the assessment of the Part D—IRMAA will cease. Therefore, the beneficiary will receive the disenrollment notice as a result of not paying the plan's premium and there will be no need to issue the involuntary notice for failing to pay the Part D—IRMAA. For example, if the beneficiary fails to pay the plan premium within the plan's grace period but the grace period specific to the Part D—IRMAA has not lapsed, the Part D plan sponsor will, in accordance with CMS rules, send us a plan transaction to disenroll the beneficiary. Following confirmation from us that the disenrollment transaction has been accepted, the Part D plan sponsor must send the beneficiary the disenrollment notice no later than 3 business days following the last day of the grace period. (See Chapter 3, Section 50.3.1 of the Medicare Prescription Drug Benefit Manual.) Once the beneficiary has been disenrolled from the plan, the withholding and/or billing of the Part D—IRMAA will cease. Lastly, in those cases where the Part D—IRMAA and the plan premium grace periods are different, but end on the same date, the beneficiary will receive two disenrollment notifications—Notice of Failure to Pay Plan Premiums and the Notification of Involuntary Disenrollment by the Centers for Medicare and Medicaid Services for Failure to Pay the Part D—IRMAA since the former conveys information about requesting the plan to reconsider its decision and the latter provides information about requesting a "good cause" determination.

For these reasons, we are finalizing the regulatory provisions as proposed. However, we will carefully consider these comments and potential system impacts as it develops its program instructions to plans regarding the procedures for disenrolling beneficiaries who fail to pay their Part D—IRMAA and the timing of when plans will convey the notice. In addition, we will closely monitor the disenrollment process and make adjustments to the process to ensure optimum coordination between the timing of the grace period and the issuance of the beneficiary disenrollment notice.

Comment: One commenter recommended that CMS make attempts to collect the Part D—IRMAA before terminating the enrollee, and encourages CMS to publish, with opportunity for public comment, the proposed process for doing so.

Response: As explained previously, for individuals that do not have their Part D—IRMAA deducted from their Social Security checks, we are following the same process we use in collecting the Part B–IRMAA. This process involves repeated monthly statements (initial bill, second notice and a delinquent notice) to the beneficiary to solicit the payment and to notify the individual of the potential consequences of failure to make a payment prior to disenrollment at the end of the initial 3-month grace period. In addition, if payment is not made, the beneficiary will have an additional 3 months to establish "good cause" for failure to pay their Part D—IRMAA and remit payment for any arrearages to be reinstated into their Part D plan. We believe this process provides sufficient notification to the beneficiary and opportunity to pay their Part D—IRMAA prior to disenrollment for failure to pay.

Comment: Several commenters expressed concern with the proposed requirement that plans issue the disenrollment notice to enrollees involuntarily disenrolled for failure to pay their Part D—IRMAA. Commenters believed that CMS was in the best position to send these notices in a timely manner since we, not the plan, are aware of the member's Part D—IRMAA amount and any possible arrearages. Commenters were concerned that if plans served as an intermediary in this process, they would inevitably be contacted with complaints or subject to grievances. It was suggested that a CMS-generated notice would reduce the burden on plans and would more clearly communicate to enrollees that CMS should be contacted regarding questions on the Part D—IRMAA.

Response: As described previously, individuals who are subject to disenrollment based on their failure to pay the Part D—IRMAA will have first received a series of monthly billing statements from CMS informing them of

their obligation to pay the Part D—IRMAA, and the consequences of their failure to do so. If and when disenrollments do become necessary, we believe affected individuals should be afforded the same notices that other individuals would receive from their plans. Thus, we disagree that plans should not be responsible for sending a disenrollment notice. Such notices are part of a plan's daily business operations. This process is consistent with existing requirements for disenrollment of a beneficiary who is no longer eligible to remain in a Medicare prescription drug plan due to loss of Medicare Part A and/or B. In this situation, we involuntarily disenroll the beneficiary, and the beneficiary's Part D plan sponsor is required to provide the individual with the Disenrollment Due to Loss of Medicare Part A and/or Part B Notice (See Chapter 3, Section 50.2.2 of the Medicare Prescription Drug Benefit Manual).

We recognize that Part D plan sponsors may receive questions from their members regarding the disenrollment. As such, the notification used by Part D plan sponsors will explicitly state that the disenrollment is being effectuated by the plan at CMS' direction. This notice further instructs the beneficiary to contact us, not the plan, about questions pertaining to the notice. As noted previously, the December 10, 2010 CMS memorandum mentioned previously provides plans with language they can use in responding to members' Part D—IRMAA inquiries. We will continually develop and release information to Part D plan sponsors, partners, and beneficiaries via the CMS information channels (1–800–MEDICARE, *http://www.medicare.gov*) that will assist beneficiaries with questions about their Part D—IRMAA and direct them to the appropriate entity for assistance. Thus, we will retain the proposed provision that Part D plan sponsors will provide a beneficiary with the notice when he/she is disenrolled for failing to pay the Part D—IRMAA.

Comment: A commenter contended that it was not clear from our proposal if CMS intended to tell Part D plan sponsors to disenroll the non-paying member before or after the end of the grace period. The commenter concluded that if timing for notification is the latter, this could result in a retroactive disenrollment from the plan, with possible complications in terms of bills for non-covered services and medications retroactive to the effective date of the disenrollment.

Response: We recognize this concern and will keep this issue in mind as we develop operational guidance on the disenrollment process.

Comment: Two commenters disagreed with the proposed policy of an additional 3-month grace period for individuals to establish "good cause" after the disenrollment date, allowing for no disruption in coverage if reinstated. Another commenter suggested that plans be informed if a disenrolled member requests a "good cause" determination for failure to pay their Part D—IRMAA.

Response: We believe that beneficiaries should be afforded the opportunity to establish "good cause" for not paying the Part D—IRMAA amount and the ability to be reinstated in their Part D coverage without interruption. We appreciate the comment regarding plan notification of requests for good cause and will take this into consideration as we develop the process for good cause" determinations. (See section II.C.8 of this preamble for a further discussion of this issue.)

Comment: A few commenters expressed concern about what would happen to individuals involuntarily disenrolled from their plan for failure to pay their Part D—IRMAA. Some commenters requested that we clarify that a disenrollment for failure to pay the Part D—IRMAA would result in a loss of health coverage if the individual is enrolled in an MA plan, cost plan, or employer group health plan with prescription drug coverage. Another commenter asked whether a beneficiary who is disenrolled for failure to pay the Part D—IRMAA would be subject to the Part D late enrollment penalty (LEP) upon reenrollment in a Part D plan. In addition, commenters made the following suggestions:

- Establish a special enrollment period (SEP) for disenrolled individuals to re-enroll into another MA-only (or a cost plan).
- Allow for passive enrollment into an MA-only plan within the same organization if an individual is disenrolled from their MA–PD plan for failure to pay Part D—IRMAA.
- Grant employer group waiver plans a waiver from the disenrollment process.

Response: An individual in an MA–PD who fails to pay the Part D—IRMAA within the 3-month grace period will be disenrolled to Original Medicare. Because this policy ensures that beneficiaries will not lose health care coverage, we believe an SEP is unwarranted and unnecessary. Furthermore, a beneficiary's Part D coverage may be reinstated without interruption if within 3 months after disenrollment, the enrollee demonstrates "good cause" for failure to pay the Part D—IRMAA and pays all Part D—IRMAA and plan premium arrearages. The SEP policy at § 423.38(c)(8)(ii) permits CMS to address exceptional enrollment cases for individuals on a case-by-case basis. To the extent that individuals believe they have exceptional situations that warrant consideration to enroll in a MA-only (or other plan that does not offer Part D coverage), they should call 1–800–MEDICARE and ask to be put in touch with a CMS regional caseworker. In addition, the policies for the Part D LEP remain unchanged by the implementation of Part D—IRMAA. An individual who is disenrolled for failure to pay the Part D—IRMAA may be subject to the Part D LEP if he or she goes without creditable prescription drug coverage for 63 days or more. If an individual would like to restart prescription drug coverage, he or she would have to pay any arrearages and make an election during a valid enrollment period.

Individuals in employer group waiver plans and employer group health plans will also be disenrolled for failure to pay Part D—IRMAA. Employer groups that want to assure that their members retain coverage are not prohibited from informing their retirees that they will be reimbursed by their employer group for any Part D—IRMAA they are required to pay.

We appreciate the comments on our proposals and, for the reasons contained in the discussion previously, are finalizing these provisions as proposed. We have, however, made technical revisions to § 423.286(d)(4) and§ 423.293(d) to incorporate references to the new SSA regulations regarding the Part D IRMAA, which were published after the issuance of our proposed rule.

10. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

The MMA, as reflected in § 423.782, established that full-benefit dual eligible institutionalized individuals have no cost-sharing for covered Part D drugs under their PDP or MA–PD plan. Section 3309 of the ACA eliminates cost-sharing for full-benefit dual eligible individuals who are receiving home and community-based services (HCBS) under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 of the Act, or under a State Plan Amendment under section 1915(i) of the Act, or if such services are

provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) or 1932 of the Act. These services are targeted to frail, elderly individuals who, without the delivery in their home of services such as personal care services, would be at risk of institutionalization. We proposed to amend § 423.772 to establish the definition of "individual receiving home and community-based services" and § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. The Best Available Evidence (BAE) policy set forth in § 423.800—which requires plans to charge a lower copayment if certain evidence is provided—is written broadly enough that it will apply to this new copayment category; therefore, we proposed to make no regulatory changes to § 423.800. We proposed to update our guidance to plans to provide additional detail on how the BAE rules apply to this population.

Section 3309 of the ACA provides the Secretary with discretion regarding the effective date of this provision, with the stipulation that it shall be effective no earlier than January 1, 2012. We proposed that this provision would take effect on January 1, 2012, because we believed it was important to provide this benefit at the earliest possible date to an estimated 600,000 beneficiaries a year.

Comment: Commenters supported our proposal to amend § 423.772 to establish the definition of an "individual receiving home and community-based services" and § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. One commenter urged the inclusion of individuals residing in assisted living facilities in the definition of an "individual receiving home and community-based services" in § 423.772.

Response: The commenter that urged the inclusion of individuals residing in assisted living facilities in the definition of an "individual receiving home and community-based services" raises an important distinction warranting the following clarification in our guidance to plans and States. Individuals residing in an assisted living facility will be included in the definition of an "individual receiving home and community-based services" only to the extent that they satisfy the inclusion criteria set forth in section 3309 of the ACA. Specifically, the assisted living facility resident must be a full-benefit dual eligible individual receiving HCBS under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 of the Act, or under a State Plan Amendment under section 1915(i) of the Act, or if such services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) or 1932 of the Act.

We appreciate the strong support we received from commenters for our proposal to amend § 423.772 to establish the definition of an "individual receiving home and community-based services" and § 423.782(a)(2)(ii) to reflect that these individuals will have no cost-sharing. We are finalizing these regulations as proposed.

Comment: Many commenters urged us to provide explicit guidance on the types of BAE that would be deemed acceptable to establish HCBS status, along with clear reporting requirements for plans receiving such evidence to report it to us. Several of these commenters recommended that we categorize these individuals on the Transaction Reply Report (TRR) as low-income subsidy level 3 (institutionalized—$0 cost share), as opposed to developing a new low-income subsidy level for the HCBS status. One commenter requested guidance on whether the PDE value will be unique for these individuals.

Response: We agree with commenters that successful implementation of this provision will require us to update its guidance to plans to provide additional detail on how BAE rules apply to this population. In such guidance, we intend to address key concerns raised by commenters, including at a minimum how such beneficiaries will appear on the TRR, their low-income subsidy level, and the correct PDE value to be reported.

Comment: Several commenters urged CMS to provide explicit guidance to State Medicaid Agencies regarding the new zero copayment group, and develop data transfer protocols to ensure that States accurately identify HCBS eligible individuals and transmit such data to CMS in a timely fashion.

Response: We look forward to partnering closely with States to facilitate the identification of all such HCBS eligible individuals and to ensure timely and accurate transmission of the necessary data to CMS. We will provide customized guidance to states to ensure that they have a clear understanding of this new category of individuals qualified for the zero copayment status. We will require State Medicaid Agencies to submit data at least monthly identifying these individuals by leveraging the existing data exchange currently used by States to identify their dual eligible individuals to CMS. We will add a new value for the existing institutional status field, which will prompt CMS to set a zero copayment liability for full-benefit dual eligible beneficiaries who qualify for HCBS zero cost-sharing, as set forth under section 3309 of the ACA.

Comment: One commenter recommended that CMS provide model notifications to Part D plans to send to affected beneficiaries to ensure that such beneficiaries are provided maximal opportunities to understand their new zero copayment Part D status. Another commenter suggested that CMS develop a form for Medicaid Managed Care plans to provide to beneficiaries, attesting to their use of HCBS services.

Response: We thank the commenters for these suggestions. We will determine later in 2011 whether the existing Part D model notifications that provide such beneficiaries with their copayment status are adequate or whether a new Part D model notice customized to this population might be beneficial. We will also consider the latter suggested notice as we update our BAE guidance to plans to ensure the most efficient procedures for accurately identifying this population.

Comment: Two commenters noted that individuals who receive HCBS under a home and community-based waiver under section 1115 and State plan participants under section 1915 of the Act generally receive letters informing them that they have qualified. These commenters described such letters as varying significantly among States and programs, and urged that CMS work with plans to help them identify such letters to serve as BAE.

Response: We will work with States to identify the most common forms of such letters provided to participants, and we intend to share best practices with plans to more effectively identify full-benefit subsidy eligible individuals who qualify for zero cost-sharing under this HCBS provision.

Comment: One commenter urged CMS to clarify that an effective date of January 1, 2012, for the HBCS provision does not permit retroactive application of the zero cost-sharing benefit to extend prior to January 1, 2012, notwithstanding that the effective date of LIS eligibility in many cases is retroactive and extends prior to January 1, 2012.

Response: In accordance with section 3309 of the ACA, the Secretary's discretionary authority to establish the effective date of the HCBS provision is limited by the stipulation that the effective date shall be no earlier than January 1, 2012. This effective date does not allow for retroactive application of

the zero cost-sharing benefit to extend prior to January 1, 2012, even for beneficiaries whose effective date of LIS eligibility extends prior to January 1, 2012. We appreciate the commenter bringing to our attention the need for such clarification and we will provide such clarification in our guidance to plans.

Comment: A commenter urged that CMS require Part D sponsors to appropriately reimburse long term care (LTC) pharmacies for the additional value that those pharmacies must provide to beneficiaries receiving pharmacy services in assisted living facilities, such as special unit dose medication packaging, medication delivery, and medication reviews by pharmacists.

Response: Any such reimbursements are a matter of negotiation between the plan sponsor and the LTC pharmacy.

Comment: Two commenters recommended that CMS adopt the same procedural approach for determining the deeming period for HCBS eligibility that CMS uses for individuals who qualify for the full-benefit subsidy based on Medicaid enrollment. Specifically, if an individual appears on State files as eligible for HCBS at any point during the year, that individual would qualify for the HCBS zero cost-sharing for the remainder of the year. If an individual shows as eligible in the month of July or any later month in the year, the HCBS zero cost-sharing would continue through the next plan year.

Response: We thank the commenters for raising this issue, as it warrants the following noteworthy clarification in our guidance to plans and States. To ensure procedural consistency and operational efficiency, we will apply the same procedural approach for determining the deeming period for HCBS eligibility that we apply for individuals who qualify for the full benefit subsidy based on Medicaid enrollment, as set forth under § 423.773(c)(2), to the extent that an individual's HCBS deemed period does not exceed the individual's full-benefit dual deemed period. Specifically, if an individual is deemed eligible for HCBS zero cost-sharing at any point during the year, that individual will qualify for HCBS zero cost-sharing for the remainder of the year. If an individual is deemed eligible for HCBS zero cost-sharing in the month of July or any later month in the year, the individual's HCBS zero cost-sharing will continue through the next plan year so long as the individual was also deemed in the month of July or any later month in the year for the full-benefit subsidy based on Medicaid enrollment. In other words, an individual's ongoing HCBS deemed status is dependent on concurrent deemed full-benefit dual eligibility. We believe that this policy will promote effective administration of the HCBS cost-sharing benefit and decrease the administrative burden on CMS and State Medicaid Agencies, as well as on HCBS eligible individuals. We note that it also is consistent with how we determine the deeming period for institutionalized full benefit dual eligible individuals.

We appreciate the comments that were submitted on these provisions and will be finalizing these proposals.

11. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154)

In our proposed rule, we proposed to implement section 3310 of the ACA by adding a new regulation at § 423.154 to govern how plan sponsors (all organizations and sponsors offering Part D including stand-alone Part D plans, MA organizations, EGWP contracts, and PACE plans) direct network pharmacy dispensing of covered Part D drugs in LTC facilities. Under § 423.154 (a)(1)(i) of the proposed rule, we require all sponsors to contract with network pharmacies servicing LTC facilities, as defined in § 423.100, to dispense brand medications, as defined in § 423.4, to enrollees in such facilities in no greater than 7-day increments at a time. In an effort to target the drugs resulting in the most financial waste and to lessen the burden for facilities transitioning from 30-day supplies to 7-day-or-less supplies, we proposed initially limiting the requirement for 7-day-or-less dispensing to brand drugs as defined in § 423.4. We noted in the proposed rule that as a result of consultation with industry representatives, a transitional approach would ease the initial burden on nursing and pharmacist staff by reducing the number of products for which a pharmacy would have to transition from dispensing one 30-day supply per month to dispensing at least four 7-day supplies per month. We also acknowledged that we are not aware of any objective data that demonstrate the cost effectiveness of full versus partial implementation, but welcomed comments from the public presenting such data and also solicited comments on how soon the industry can transition to include generic drugs in the 7-day-or-less requirement.

Under § 423.154(a)(1)(ii) of the proposed rule, we require Part D sponsors to permit the use of uniform dispensing techniques defined by each of the LTC facilities being serviced. We proposed to define uniform techniques to mean that dispensing methodologies will be uniform with respect to the type of packaging used to dispense Part D drugs within a LTC facility, but may vary by the quantity of medication (days' supply) dispensed at a time. We explained that it is the LTC facilities that are in the best position to identify uniform dispensing techniques to be used throughout their LTC facility. Therefore, we proposed that Part D sponsors must permit their contracted pharmacies to implement the uniform dispensing techniques selected by each LTC facility, and may not require the use of a different packaging system or technology than that selected by the facility through its contracted LTC pharmacy.

We noted in the proposed rule that we do not expect pharmacy delivery schedules to change as a result of the 7-day-or-less dispensing requirement since deliveries are generally made daily to accommodate new admissions and first doses. We do recognize, however, that there may be changes in the way some pharmacies make deliveries. We stated in the preamble of the proposed rule that, subject to State restrictions, pharmacies, and LTC facilities may agree to use a common carrier for some deliveries to LTC facilities. We would not consider a contractual agreement for a pharmacy to deliver a portion of Part D drugs to Part D enrollees residing in LTC facilities via common carrier as causing the pharmacy to be considered a mail order pharmacy. We solicited comments on our interpretation.

We proposed to exclude from the requirements of § 423.154(a), those drugs that are difficult to dispense in a 7-day-or-less supply and those drugs that are dispensed for acute illnesses. We expressed our belief that requiring these types of drugs to be dispensed in 7-day-or-less increments could result in safety or efficacy concerns or could have the counterproductive effect of increasing drug waste. For medications that we proposed to exclude from the requirement, we encouraged use of smaller size containers, when available, to reduce the potential for waste. We proposed to codify these exclusions at § 423.154(b) and solicited comments on the types of dosage forms and drugs that should be excluded from the requirements under § 423.154(a).

We explained that we considered "return for credit and reuse" as a possible solution to reduce waste in LTC facilities. Although "return for credit and reuse" is not prohibited by CMS, we recognized limitations to this approach since "return for credit and

reuse" is not permitted in all states, often excludes lower cost generic drugs, is frequently limited to a subset of drugs in unused or specially approved packaging, does not address issues regarding diversion, and is subject to Drug Enforcement Agency (DEA) limitations with respect to controlled substances. Upon consideration of these facts, we decided that "return for credit and reuse" would not be the optimal solution to address the issue of unused drugs in LTC facilities under Part D.

Although we did not propose "return for credit and reuse" as an alternative to 7-day-or-less dispensing, we understand that it may be a supplement to reduce the minimal pharmaceutical waste associated with 7-day-or-less dispensing, particularly in circumstances where a Part D drug can be safely returned to stock for reuse. We proposed to explicitly allow "return for credit and reuse" in LTC pharmacies, when "return for credit and reuse" is permitted under the State law and is explicitly allowed under the contract between the Part D sponsor and the pharmacy. In addition, when permitted or required contractually, we noted that pharmacy dispensing fees paid to pharmacies may take into account restocking fees consistent with the modification to dispensing fees under § 423.100, "Dispensing Fees" discussed in section II. F. of this final rule (Other Clarifications and Technical Changes).

We explained in our proposed rule that only when data has been systematically collected will the extent of waste of Part D drugs be quantifiable on other than an anecdotal basis. Therefore, we proposed to add a provision at § 423.154(f) to require that Part D sponsors include terms in their LTC pharmacy contracts that require any unused drugs originally dispensed to the Part D sponsor's enrollees to be returned to the pharmacy (not necessarily for reuse) and reported to the sponsor. Such contracts would also address contractual obligations for disposal in accordance with Federal and State regulations. We solicited comments on whether there are DEA or state technical issues that may be barriers to the implementation of this provision.

We noted that options for billing to accommodate 7-day-or-less dispensing are being discussed in a National Council for Prescription Drug Programs (NCPDP) workgroup, and unless the industry voluntarily adopts a single billing standard, we believe that Part D sponsors should generally allow pharmacies to use be currently accepted transactions to minimize burden in transitioning to more frequent dispensing of smaller amounts.

Pursuant to our authority under section 1860D–12(b)(3)(D) of the Act, which incorporates by reference section 1857(e)(1) of the Act, we proposed a new requirement under § 423.154(a)(2) in which Part D sponsors must collect and report to CMS the dispensing methodology used for each dispensing event described by § 423.154(a)(1)(i) and (ii) and on the nature and quantity of unused drugs returned to the pharmacy. This data collection would be done in an effort to help us estimate the relative efficiencies of dispensing methodologies and determine the residual waste to estimate additional savings.

We stated in the proposed rule that this provision would likely lead to a change in copayment methodology. We noted that we anticipate the implementation of particular copayment methodologies will be dependent on the billing and dispensing methodologies used, and as a result, we acknowledged that copayment methodologies within the same plan may vary depending on the LTC facility where the beneficiary resides. Copayment may be collected at the first dispensing event in a month, the last dispensing event in a month, or prorated based on the number of days a Part D drug was dispensed in a month. However, due to the relatively small copayments for low-income subsidy (LIS) beneficiaries, copayments for LIS beneficiaries should be billed with the first or last dispensing event of the month.

Under § 423.154(c) of the proposed rule, we would waive the requirements under paragraph (a) for pharmacies when they dispense brand Part D drugs to Part D enrollees residing in intermediate care facilities for the mentally retarded (ICFMR) and institutes for mental disease (IMDs) due to specific problems with medication delivery and dispensing to closed (and often locked) facilities. We explained that waiving the requirements in this instance would be consistent with the statute when done on a uniform basis (that is, all similarly situated LTC facilities) and when there is a demonstration that applying the dispensing requirements to pharmacies servicing enrollees residing in that type of LTC facility would not serve to reduce waste. We solicited comments on whether other types of facilities (such as LTC facilities utilizing Indian Health Service (IHS) facilities to provide Part D drugs or utilizing Tribal facilities providing pharmacy services for the IHS under Pub. L. 93–638 compacts or contracts) should also be waived from the requirement and on the specific reasons as to why those facilities should be waived from the requirement. In addition, we solicited specific comments on the waiver criteria for LTC pharmacies.

Under § 423.154(d) of the proposed rule and pursuant to section 3310 of the ACA, the requirements of this section would be effective January 1, 2012. However, under § 423.154(e) of the proposed rule, we proposed to allow an independent community pharmacy (such as, not a closed door pharmacy dedicated to servicing LTC facilities only) that is the primary provider of the Part D drugs to a small LTC facility (less than 80 beds) located in a rural community (as defined by the Bureau of the Census) to dispense no more than a 14-day supply through December 31, 2012, assuming that the pharmacy is not already dispensing a 7-day supply to any patient population in the LTC facility. We explained that we expected that Part D sponsors contracting with these pharmacies would find solutions to their significant challenges and work toward full compliance with § 423.154(a) during this extension. Under the proposed rule, these pharmacies would be required to come into full compliance with § 423.154(a) by January 1, 2013. We solicited comments on this matter.

Based on the preceding, we proposed revising § 423.150 by renumbering paragraphs (b) through (g) as paragraphs (c) through (h) and adding a new paragraph (b) to address appropriate dispensing of covered Part D drugs to enrollees in LTC facilities. We proposed adding new requirements, as discussed previously, at § 423.154 to require Part D sponsors to ensure that all pharmacies servicing LTC facilities dispense no more than a 7-day supply of brand medications and use uniform dispensing methodologies as defined by each of the LTC facilities being serviced. In addition, under § 423.154(a)(2), we proposed requiring Part D sponsors to collect and report, as CMS specifies, the dispensing methodology used for each dispensing event described by paragraphs (a)(1)(i) and (ii) of § 423.154. We proposed identifying exceptions to this requirement at § 423.154(b)(1) and (2) relative to specific drugs and waivers of this requirement for specific pharmacies under § 423.154(c). Pursuant to section 3310 of the ACA, we proposed an effective date of January 1, 2012 for these requirements at § 423.154(d), with a limited extension through December 31, 2012 for pharmacies meeting the requirements under § 423.154(e). We also proposed that Part D sponsors require any unused Part D drugs originally dispensed to

their enrollees to be returned to the pharmacy and reported to the sponsor and address whether "return for credit and reuse" is permitted under their contracts with pharmacies servicing LTC facilities at § 423.154(f).

Comment: We received several comments regarding the term "waste." Commenters requested that we clarify the term. Some commenters recommended that we not use the term "waste" but rather "unused drugs" because the "waste" description in the proposed rule does not harmonize with definitions of waste in other State and Federal regulations applicable to unused pharmaceuticals.

Response: We agree with the commenters that the use of the term "waste" may cause confusion because "waste" as discussed in the proposed rule may not be consistent with other agencies' definitions. Further, we believe that in using the term "waste" in section 3310 of the ACA, Congress intended to refer to unused drugs. Therefore, in this final rule we will use the term "unused drugs" instead of "waste."

Comment: A few commenters requested that we allow for 14-day-or-less dispensing instead of 7-day-or-less dispensing. Commenters stated that a 14-day dispensing cycle would balance CMS's goal of reducing drug waste with the administrative, technological, and financial burdens placed on Part D sponsors, pharmacies, and beneficiaries. Commenters urged CMS to consider implementing a 14-day-or-less dispensing cycle because it is a more reasonable and realistic goal that will minimize the burden on pharmacies, beneficiaries, and plans. Some commenters stated that the statute does not mandate 7-day dispensing and that the dispensing techniques may (but need not) include weekly dispensing.

Response: We initially proposed limiting these techniques to 7-days-or-less methodologies. We continue to believe that 7-day-or-less dispensing more effectively minimizes the volume of unused drugs and the resulting financial waste paid for under the Part D program. However, the majority of comments we received in response to our request for information on the impact of our proposed provision suggested that costs might increase significantly. While this point of view conflicts with other opinions we heard during the consultation period with the industry, we did not receive detailed comments that supported more moderate cost increases. We also received little additional information during the comment period on the amount of unused drugs in LTC facilities paid for under the Part D program, and none that could be considered as thorough, unbiased, or authoritative. As a result, the information we have to work with in projecting potential savings reflects widely divergent estimates. The variation in savings estimates range from as low as approximately 3 percent to as high as 17 percent for 7-day supplies, and as high as 20 to 25 percent for automated dose dispensing. Given the divergence in estimates and the uncertainty in the rate of conversion to the more efficient methodologies, we have elected to be conservative in estimating savings and costs in order to finalize a policy we estimate will result in savings. Therefore, we are finalizing the requirement to dispense in 14-day-or-less increments. Nothing about this change, however, precludes facilities and pharmacies from selecting 7-day-or-less methodologies or Part D sponsors from incentivizing the adoption of more efficient dispensing techniques.

We agree with the commenters that the statute does not mandate 7-day-or-less dispensing. Section 3310 of ACA, which is implemented by § 423.154, states "[t]he Secretary shall require PDP sponsors of prescription drug plans to utilize specific uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders, * * * such as weekly, daily, or automated dose dispensing * * *" Because the dispensing frequencies are illustrative examples (as indicated by the use of the phrase "such as"), we interpret this language as an indicator of Congress' preference to give the Secretary flexibility in determining the dispensing increments based on information received from the relevant stakeholders. Based on comments, we believe that 14-day-or-less dispensing is a more prudent approach to initially implementing section 3310 of ACA. A 14-day-or-less dispensing requirement will place less of a burden on pharmacies and LTC facilities than a 7-day-or-less dispensing requirement while allowing CMS to collect data to determine the impact of 14-day-or-less dispensing on unused drugs in LTC facilities.

For purposes of scoring this final rule, we project that the current aggregate level of dispensing fees will double. Obviously, the negotiations between LTC pharmacies and Part D sponsors or PBMs that would determine any changes in dispensing fees have not yet taken place and the actual level of dispensing fees is not knowable. Historically, we believe dispensing fees on LTC claims have been relatively low and not directly related to pharmacy costs, reflecting the economies of scale and dominant competitive strategy of long-term care pharmacies in a highly concentrated industry and the negotiating leverage of large PBMs. Therefore, pharmacy costs have not been recovered solely through dispensing fees, but also through other revenue sources, such as mark-up of negotiated prices for drug sales over acquisition costs and receipt of rebates from drug manufacturers. Since these other revenue sources are expected to remain, it is not at all clear that negotiated dispensing fees must or will increase directly in proportion to the number of dispensing events per month as some, but not all, commenters assert. Although the way we are finalizing this rule will result in only minimal additional costs (for example, only one additional dispensing event per month with 14-day dispensing and a substantial reduction in burden associated with the reporting requirements as compared to the proposed rule), we believe that there will be some upward pressure on dispensing fees to incentivize the use of more efficient and cost effective systems in some pharmacies. Therefore, in order to be as conservative as possible in projecting cost increases, we have assumed a doubling of the current aggregate level of dispensing fees.

The comments that follow refer to the 7-day-or-less dispensing requirement reflecting our requirement in the proposed rule. We believe that the comments also apply to 14-day-or-less dispensing, as it is a shorter dispensing increment than traditional 30-day dispensing used in LTC facilities today. Although all of the comments apply to 14-day-or-less dispensing, we believe that some of the burden and costs described in the comments are decreased as a result of less frequent dispensing events per month associated with 14-day-dispensing versus 7-day-dispensing.

Comment: We received few comments related to concerns about patient care. Some commenters believe that that the confusion resulting from two different dispensing methodologies will lead to medication errors and patient safety issues. Another commenter was concerned about delays in treatment, in particular related to protected class drugs, resulting from, for example, delivery delays due to bad weather. Another commenter recommended that we implement 7-day-or-less dispensing only when the requirement is not likely to interfere with patient care.

Response: Based on our conversations with the industry, we know that most facilities have experience utilizing

multiple dispensing methodologies today. For example, most pharmacies dispense using one technique for their Part D patients and another for their Part A patients. We understand that many pharmacies already dispense in less-than-30-day increments for their Part A patients because it is more efficient for the LTC facilities to do so. This is because the LTC facilities must pay for Part A drugs out of their per diem payments. These LTC facilities already require their LTC pharmacists to employ 7- or 14-day dispensing methodologies to limit exposure to unnecessary costs associated with unused drugs when they are the payor. Thus, it is clear that LTC facilities and their contracted pharmacies have been able to manage dispensing to patients using multiple dispensing methodologies. Consequently, we do not see any evidence that multiple dispensing methodologies per se in a LTC facility necessarily results in medication errors, and we received no comment that provided any specific information to support this assertion.

In fact, we believe that the original 7-day-or-less dispensing requirement, and to a somewhat lesser extent, the new 14-day-or-less dispensing requirement, incentivizes the use of the most effective and efficient dispensing technologies, such as automated dose dispensing, which we believe based on conversations with LTC facility and pharmacy staff who have implemented such systems, will actually result in fewer medication errors. We learned from multiple industry representatives that automated dose dispensing systems reduce medication errors by ensuring the accuracy of the medication dispensed to the patient by eliminating many manual steps involved in removing doses from multiple blister packs and collecting them in paper cups prior to the medication pass. In addition, these systems free up nursing time allowing nursing staff to focus more on patient care.

We believe that facilities and pharmacies evaluating the optimal systems to employ in meeting the required change from 30-day dispensing will seriously consider all alternatives, and many will find that the confluence of improvements in dispensing equipment technology and developments in health information technology standards, combined with changes in dispensing fees represent an excellent opportunity to upgrade their dispensing systems to the most efficient methodologies to further both cost-effective operations and competitive advantage.

As stated in the proposed rule, we have learned from many industry representatives that delivery schedules will not be expected to change significantly to accommodate 14-day-or-less dispensing. We received a few comments on the proposed rule asserting that there might be delays in therapy as a result of changes to delivery schedules to accommodate shorter dispensing increments. However, no commenters provided details that contradict what we heard from most industry representatives during consultation. In most LTC facilities deliveries are already made on a daily basis to accommodate new admissions and first doses. We did not receive any comments with substantiating detail that lead us to believe delivery schedules will have to significantly change as a result of this requirement. Nor do we believe that bad weather will impact deliveries to any greater extent than it does today. We did, however, state in the proposed rule that the way in which some deliveries are made may have to change. We stated that, when allowed by State law, common carriers may be used to make some deliveries from the pharmacy to the LTC facility. So in rare circumstances when a delivery cannot be made by the pharmacy, deliveries by common carrier may supplement the delivery schedule. In summary, the comments we received did not persuade us that the information we received during our pre-rulemaking consultation with the industry was incorrect or insufficient, and for this reason, we continue to believe that the parties are capable of handling various dispensing methodologies and frequent deliveries, and thus the 14-day-or-less dispensing requirement will not interfere with patient care.

Comment: Several commenters supported the proposal that a pharmacy should not be considered a mail order pharmacy because the pharmacy delivers some of the drugs using a common carrier.

Response: We received only supportive comments on this issue, and we intend to issue guidance in manual chapters to document this policy.

Comment: We received a couple of comments regarding the identification of brand name versus generic drugs. A commenter questioned whether the brand name status would be based on the NDA/ANDA status.

Response: As indicated in the proposed rule, "brand name drug" is defined at § 423.4. "Brand name drug" means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b)(2)). Thus, the definition specifically refers to a drug approved under an NDA. In response to this comment, however, and to avoid confusion, we are making a technical change to the regulation to refer to "brand name drug" instead of "brand name medication."

Comment: We received many comments in support of our proposal to limit the 7-day-or-less dispensing requirement to brand name drugs only to minimize any transition issues. Commenters agreed that the majority of the financial waste is associated with brand name drugs. Commenters also stated that limiting the requirement to brand name drugs was a practical approach. We also received a smaller number of comments from certain pharmacies and from environmental groups that did not support our proposal to limit the requirements to brand name drugs. Environmental groups urged us to include generics in the requirement because generic drugs account for majority of the unused drugs (in terms of quantity).

Response: We proposed to limit the requirement to brand name drugs because, after consultation with the industry, we were persuaded by its arguments that by targeting brand name drugs, we would target a majority of the financial waste but minimize the initial burden on LTC facilities and pharmacies converting from a 30-day dispensing increment to a shorter dispensing increment. Once we are able to collect data on unused drugs and negotiated prices in the Part D market, we will be in a better position to evaluate the implications of extending the requirement to generics. As we stated in our proposed rule, however, nothing in the requirement prevents LTC facilities and pharmacies from extending the practice to generic drugs, and we encourage Part D sponsors to facilitate that practice. Given that pharmacies and facilities have that flexibility, we continue to believe that imposing this requirement initially only for brand name drugs is the appropriate policy.

We agree with the environmental groups that extending the requirement to generic drugs would result in fewer unused drugs. However, we must weigh the effect of our proposal against the costs to the Part D program that may arise and the burden on LTC pharmacies and facilities. As such, we believe that the phased-in approach—which focuses first on reducing the amount of unused

drugs in terms of monetary waste—is appropriate.

Comment: Some commenters requested that we conduct a pilot program or conduct studies prior to implementing the 7-day-or-less dispensing requirement. We received some comments recommending that we limit the 7-day-or-less requirement to the most expensive brand name drugs and add drugs to the requirement after studying the impact of the 7-day-or-less requirement. Some commenters urged us to conduct studies prior to extending the 7-day-dispensng requirement beyond brand name drugs and, in particular, measure the increase in dispensing fees relative to the average cost of generic drugs not wasted, to determine whether the requirement should be extended beyond brand-name drugs.

Response: We disagree with the commenters that believe studies or pilots must be conducted prior to any 14-day-or-less requirements. First, section 3310 of the ACA does not contemplate that we conduct a study prior to implementing the provision. Second, we do not believe a pilot program is necessary. Shorter dispensing cycles have already been successfully implemented in many LTC facilities and thus, are not a new approach that warrants a pilot program. Moreover, as noted previously, we already are proceeding with implementation on an incremental basis by applying the requirement only to brand name drugs and taking other steps to facilitate information gathering. In this way, we already are further mitigating any burden associated with this transition by initially focusing on only a portion (20 percent of the drugs dispensed) of drugs dispensed. As discussed elsewhere in this final rule, we will be requiring pharmacies to report dispensing methodologies and report unused drugs to Part D sponsors. Our reporting requirements will provide us with data we can use to evaluate the implications of extending the requirement to generic drugs. Finally, we decline to limit the 14-day-or-less dispensing requirement to the most expensive brand name drugs. Pharmacy reimbursement varies from pharmacy to pharmacy and plan to plan, and therefore the most expensive brand name drugs similarly may vary. We do not believe it would be useful or prudent for us to attempt to identify and maintain a list of such drugs, particularly given that we are prohibited from interfering with price negotiations.

Comment: We received a number of comments in support of our acknowledgment that it is not possible or practical for CMS or Part D sponsors to identify the uniform dispensing techniques that must be used in all pharmacies. We also received comments asking us to clarify "dispensing methodology." Commenters wanted us to clarify whether "dispensing methodology" refers to only the technique used or also the number of days. We received one comment that CMS should require all plan sponsors utilize "7-day" dispensing rather than "7-day-or-less" dispensing. The commenter argues: (1) "7-day-or-less" dispensing is neither uniform nor specific as mandated by the statute; (2) less than 7-days will increase dispensing fee-related costs; and (3) it is impractical because each LTC facility and LTC pharmacy would have to ascertain the requirements imposed by each resident's plan and then manage those requirements.

Response: For the purposes of this provision, the term "dispensing methodology" refers to both the packaging system (for example, single or multidose packing systems such as punch cards, envelopes, or strip packaging) and the dispensing increment (such as 14-day, 7-day, "2–2–3" day, "4–3" day, daily, or automated dose dispensing). "Uniform dispensing techniques" refers to the dispensing methodology or methodologies used in a particular LTC facility. As stated in the proposed rule, the days' supply dispensed to enrollees may vary depending on the drug. Under this provision, it is the LTC facilities that select the dispensing methodology or methodologies used in the LTC facility, obviously in concert with their contracted LTC pharmacy. We disagree with the commenter that our requirements are neither uniform nor specific. We also disagree with the commenter's third point and believe it indicates a misunderstanding of our proposal. The dispensing methodology (or methodologies) will be uniform with respect to each LTC facility, and these uniform requirements will apply to all Part D sponsors and pharmacies dispensing to enrollees in that facility. Thus, a LTC facility may choose to have one dispensing methodology for brand name Part D drugs, and another for generic Part D drugs, and a third for drugs dispensed to non-Part D enrollees. As long as the facility, not the Part D sponsor, chooses the methodologies, such methodologies will be uniform throughout that facility. Conversations with the industry lead us to believe that the facilities will elect to standardize around the 14-day-or-less dispensing methodologies because these methodologies will minimize waste-related costs across the board. Further, the LTC facility will identify the specific type (or types) of packaging to be used to dispense Part D drugs within the LTC facility. Although the days' supply dispensed at a time may vary (up to 14 days' worth), we believe the 14-day maximum is sufficiently uniform, particularly given that LTC facilities may vary widely in terms of their resources, physical plant, and enrollee population. Given these disparities, we continue to believe that it is the LTC facilities that are in the best position to identify the uniform dispensing technique or techniques to be used throughout the facility. That is, we look to the facility to define the technique or combination of techniques that meet the facilities' business needs in concert with their contracted LTC pharmacies and require that the Part D sponsors defer to that decision rather than impose their own requirements. Therefore, the LTC facility will not need to ascertain Part D sponsors' requirements for the LTC facility's residents—indeed, our requirement is precisely the opposite.

However, we agree with the commenter that dispensing fees will likely increase with 14-day-or-less dispensing. Although we are prohibited from intervening between negotiations between Part D plans and pharmacies, we do expect that dispensing fees will increase with the increased number of dispensing events in a billing cycle up to a point. Consistent with feedback from the LTC industry and comments on the proposed rule, we believe that drugs dispensed in shorter dispensing increments will result in fewer unused drugs. We also believe that appropriate dispensing fees that differentiate among the various dispensing methodologies could incentivize more rapid adoption of the most cost-effective technologies and effectively align facility, plan sponsor, and public interest in minimizing costs associated with unused drugs.

Comment: Several commenters asserted that leaving uniform dispensing techniques to the discretion of the LTC facility would lead to undue expense upon pharmacies. One commenter stated that the proposal would lead to more concentration in the LTC pharmacy business which would potentially increase costs.

Response: We believe this comment is based on a misunderstanding of what is meant by "uniform." The commenter may believe that we intended to impose a requirement for a single dispensing methodology throughout each LTC facility and that such regimentation would present a barrier to entry in the

market to pharmacies that specialize in innovative systems. Decreased competition could be expected to result in higher prices. However, as explained previously, we define "uniform" by the dispensing methodologies chosen by the facility because the facility will choose the set of dispensing methodologies that best suits its needs and effectively minimize costs. We expect pharmacies will work with the LTC facilities they contract with to determine the 14-day-or-less dispensing methodology or methodologies that will work best for the LTC facility, taking into account not only physical plant and labor considerations, but also the overall cost effectiveness and waste reduction potential. Again, we have no intent to limit the range of methodologies selected by the LTC facilities to meet the facilities' needs; rather we mean to prohibit Part D sponsors requirements from imposing different requirements than those selected by the facility.

Comment: We received comments stating that CMS should be indifferent to dispensing, shipping and other operational methods employed by a pharmacy as long the billing for the medication is not in excess of 7-days of usage.

Response: We disagree. Section 3310 of the Act directs us to impose requirements aimed at reducing the amount of unused drugs in LTC facilities. For that reason, we do not believe it is enough for us to merely limit billing to no greater than 14-day increments. If we were to focus only on billing, nothing would preclude a pharmacy from dispensing a full 30-day supply of drugs and bill for all of them in 14-day increments regardless of whether they had been used. Such a practice would not prevent the accumulation of unused drugs in LTC facilities and certainly would not reduce financial waste associated with unused drugs. Thus, the commenter's suggested approach would, in our view, run counter to the purpose of the statute.

Comment: Some commenters supported CMS' decision not to require the use of automated dose dispensing. The commenters agreed that such systems are not practical for all facilities. We also received many comments that generally supported the use of automated dose dispensing systems. Commenters believe that these systems are the most efficient and cost effective way to reduce the volume of unused drugs and increase patient safety. We received comments that CMS should promote the rapid adoption of this technology by ensuring appropriate dispensing fees, providing incentive programs similar to the electronic prescribing incentive program, and establishing a Federal program that makes capital more readily available to LTC pharmacies and facilities that are investing in technologies aimed at reducing waste.

Response: We agree that automated dose dispensing systems appear to be the most efficient and effective way to reduce waste. However, as stated in the proposed rule, we recognize there are significant limitations to the rapid industry-wide adoption of automated dose dispensing systems, including capital acquisition costs, state pharmacy board restrictions, lack of final automated medical record to pharmacy system interface standards, and inventory considerations. Additionally, automated dose dispensing may not be considered practical by some LTC facilities due to physical size and plant limitations. However, given our proposed changes to the definition of "dispensing fee" in § 423.100 and the prohibition on our ability to interfere with negotiations between pharmacies and Part D sponsors, we do not believe it is necessary or appropriate for us to provide financial incentives or support of the type the commenters suggest. With respect to incentive programs, we understand the value of the incentive programs; however, we do not believe that the implementation of section 3310 of ACA is predicated on those programs.

Comment: We received comments in support of our proposal to limit the 7-day-or-less dispensing requirement to LTC facilities as defined in § 423.100. This definition excludes assisted living facilities. We also received several comments requesting that we extend the requirements to include assisted living facilities. One commenter stated that including assisted living facilities in the requirements would reduce the pharmacy burden of having to manage multiple dispensing systems. Another commenter suggested that including assisted living facilities in the requirements would be the only way to ensure the Part D sponsors would reimburse pharmacies for services provided.

Response: We decline to revise the regulation to include assisted living facilities. Section 3310 of the ACA refers to LTC facilities, which we believe indicates Congress's intent that the requirements apply to LTC facilities as defined in our regulations that predate the ACA. Therefore, terms and conditions pertaining to services to residents in assisted living facilities, including any differential in dispensing fees is a matter of negotiation between the parties. Moreover, we are aware that the medication packaging requirements needed for beneficiaries residing in assisted living facilities may be different from the medication packaging needs of beneficiaries residing in LTC facilities due to the different levels of independence of the residents of the facilities. Therefore, extending the requirements to assisted living facilities may not reduce the burden associated with multiple systems. However, nothing in the provision precludes pharmacies from extending 14-day-or-less dispensing to assisted living facilities if the assisted living facilities and pharmacies decide that is the best option for their operations. Pharmacies and facilities believing that it is a burden to manage multiple dispensing systems may want to consider extending 14-day-or-less dispensing to assisted living facilities. Pharmacies choosing to extend 14-day-or-less dispensing to assisted living facilities are free to negotiate dispensing fees to reflect that service. However, dispensing fees for those services remain a matter of contract negotiations between the pharmacy and the Part D sponsor.

Comment: We received support for our proposal that the requirements would apply to all pharmacies, including closed-door LTC pharmacies, retail pharmacies, and mail order pharmacies that dispense to Part D enrollees residing in LTC facilities. We received a couple of comments requesting that we limit the requirements to those pharmacies contracted to the LTC pharmacy network, in part, because most retail and mail order pharmacies have no means to identify enrollees residing in LTC facilities.

Response: We disagree that the requirements should be limited to pharmacies dedicated to dispensing medications to patients residing in LTC facilities because we do not believe section 3310 of the ACA is intended to apply only to those pharmacies. We further believe that to accomplish that the purpose of section 3310 of the ACA, which is to reduce the amount of unused drugs in LTC facilities, it is necessary for all pharmacies that dispense Part D drugs to enrollees in LTC facilities to dispense brand name drugs in no greater than 14-day increments. We note that Part D sponsors receive a long-term care institutionalized resident report twice a year from CMS. This report provides information to Part D sponsors on which of their enrollees are institutionalized, as well as the names and addresses of the particular LTC facilities in which those beneficiaries reside. Therefore, Part D sponsors' pharmacies providing services to LTC facilities do have a way

to identify enrollees residing in LTC facilities. Moreover, sponsors generally become aware of their enrollees' institutionalized status much sooner when they get a claim from the LTC pharmacy including the "place of service" code. Upon receipt of that claim, the Part D sponsor is required to contract with that LTC pharmacy. Part D sponsors manage the care of their enrollees, not merely process claims for prescription drugs. Part D sponsors' LTC pharmacies must be capable of meeting certain performance and service criteria, as specified under 50.5.2 of Chapter 5 of the Medicare Prescription Drug Benefit Manual. These performance criteria must be incorporated into an addendum to a Part D sponsor's standard network contract for those pharmacies that would like to be designated as a network long-term care pharmacy. In order to comply with these criteria, sponsors must be able to identify beneficiaries residing in LTC facilities. For these reasons, we believe sponsors will have sufficient information to determine to which enrollees these dispensing requirements apply and can therefore appropriately monitor pharmacy compliance with these requirements.

Comment: We received many comments requesting that we extend the 7-day-or-less dispensing requirement to pharmacies other than those that dispense to LTC facilities. Many commenters requested that we investigate the potential to reduce the volume of unused drugs in other non-institutionalized settings including retail pharmacy and mail order pharmacy.

Response: We appreciate these comments and will consider them as appropriate for future rulemaking; however, we decline to extend these requirements at this time—our proposal was intended to implement section 3310 of the ACA, which is specific to reducing unused Part D drugs in LTC facilities. However, we again reiterate that pharmacies, facilities and Part D sponsors are free to implement measures intended to reduce the amount of unused drugs dispensed, and we believe our revised definition of "dispensing fees" in § 423.100 makes it clear that costs associated with such measures can appropriately be included in pharmacy dispensing fees.

Comment: Many commenters supported our proposal to exclude certain drugs from the 7-day-or-less dispensing requirement. In addition to the list of excluded drugs suggested in the proposed rule, some organizations specifically recommended that we exclude all antibiotics, insulin and diabetic supplies, all controlled substances, contraceptives, liquids, patches, limited distribution drugs, kits, Boniva monthly, vaginal rings, Prephase and Prempro, steroid bursts, weekly medications, Fosamax, powdered medications, total parenteral nutrition (TPNs), and compounded medications. Many commenters requested that we exclude liquids from the 7-day-or-less requirement for practical and patient-safety-related reasons. Some commenters thought it may be difficult to interpret and operationalize the "drugs difficult to dispense in supply increments of 7-day-or-less" exclusion. We also received comments requesting that we clarify the definition of "acute illness." Finally, many commenters requested that CMS should maintain a list of excluded drugs to promote consistency across the industry.

Response: We agree with the commenters who believe the "drugs difficult to dispense" standard may be difficult to interpret and operationalize and, as a result, we are modifying this standard. We will require 14-day-or-less dispensing specifically for solid oral doses of brand name drugs. We also will eliminate the reference to "acute illnesses" and "drugs difficult to dispense." Based on the comments, we will specifically exclude antibiotics and drugs that must be dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information and drugs that are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives). We believe that with this simplification of the rule, a list of Part D drugs by NDC is not necessary; therefore, we decline to maintain such a list.

We disagree with commenters that requested that we exclude controlled drugs. As stated in the proposed rule, the Drug Enforcement Agency rules do not preclude dispensing controlled drugs in 14-day-or-less increments. Further, we believe that 14-day-or-less dispensing of controlled drugs will result in less unused controlled drugs in the LTC facilities, and therefore, will be less of a disposal burden on LTC facilities or a diversion risk. But unlike antibiotics and drugs that must be dispensed in their original packaging, we do not find a similar basis for excluding controlled substances from the dispensing requirements (unless they are excluded for another reason) because there is no clinical or patient safety reason to do so.

Comment: We received some comments requesting an exemption from the dispensing requirement in cases where a prescriber determines that it is medically necessary for the enrollee to receive more than a 7-day supply at a time and in cases where patients are stabilized on a medication. One commenter stated that some drugs and biologicals may require a longer time period in order to gauge tolerance or efficacy, and in those circumstances a partial fill may not be medically appropriate.

Response: We disagree with these comments. First, we believe an exclusion from the dispensing requirements for "medical necessity" is unnecessary. As we stated in the proposed rule, the dispensing requirements have no bearing on the quantity prescribed. A prescriber is free to prescribe any quantity of medication that he or she believes is medically appropriate for the patient. Our requirements merely would govern the increment in which such medication is dispensed to the facility at a time. Further, we are not persuaded that there should be an exception for patients who are stabilized on a medication—we believe it would be more burdensome for pharmacies, Part D sponsors, and LTC facilities to apply beneficiary-specific, drug-specific dispensing requirements without any benefit in the form of reduced financial waste associated with unused drugs. In fact, such an approach could both increase the amount of unused drugs and increase costs. Moreover, while we agree that some drugs and biologicals require a longer time to gauge tolerance or efficacy, we disagree that the answer is to exempt these drugs from the dispensing requirements. To the contrary, it makes more sense to dispense those drugs in 14-day-or-less increments. If the patient does not tolerate the drug or the drug is ineffective and has to be discontinued, fewer unused drugs will result when a 14-or-less day's supply, as opposed to a 30-day supply, is discontinued.

Comment: Some commenters agreed that return and reuse was not an optimal method to reduce the amount of unused drugs in LTC facilities. Others commented that we should allow either return and reuse or a 7-day-or-less dispensing requirement, but not both. Others commented that we should prohibit "return for credit and reuse" for Part D drugs that are subject to the 7-day-or-less dispensing requirement. Some commenters requested that we exempt from the requirement those pharmacies that already utilize low-waste practices or "return for credit and reuse".

Response: As stated in the proposed rule, we considered "return for credit

and reuse" as a way to reduce waste in LTC facilities. We explained that there are limitations to this approach, especially that fact that not all states allow "return for credit and reuse," and reuse of controlled substances is limited by the DEA. Because of these limitations, we believe financial waste will be more effectively reduced by preventing the accumulation of unused drugs in the first place rather than addressing handling of unused drugs after they have accumulated in the LTC facilities. That said, we do not prohibit the "return for credit and reuse" of drugs, and under this provision require Part D sponsors' pharmacy contracts to explicitly address whether return and reuse is authorized where permitted by State law. As stated in the proposed rule, we recognize that "return for credit and reuse" can be effective in certain situations (for example, where there is an onsite pharmacy at the LTC facility); however, we believe that "return for credit and reuse," where allowed by State law, should be used in conjunction with 14-day-or-less dispensing to further reduce the volume of unused drugs over and above that of 14-day-or-less dispensing. We decline to provide an exception from the requirements for those pharmacies already practicing techniques that limit the volume of unused Part D drugs. Part D sponsors' pharmacies that already utilize 14-day-or-less dispensing will be compliant with the requirements. Therefore, pharmacies utilizing "other low waste practices" will not be exempt from the 14-day-or-less dispensing requirements.

Comment: A few organizations commented that the dispensing methodology would not be apparent from the claim making it difficult to comply with the proposed reporting requirement that the Part D sponsor collect and report information on the dispensing methodology used for each dispensing event. We also received comments requesting that we not apply the reporting requirement absent compelling justification of how we will use the information to evaluate efficiencies. Some commenters questioned our authority to collect data on dispensing methodologies and unused Part D drugs. We received a comment that the National Council for Prescription Drug Programs (NCPDP) has developed codes for dispensing methodology that are compatible with the HIPAA billing transactions and that will facilitate CMS's and Part D sponsors' ability to track the dispensing.

Response: We will collect the data from sponsors through Part D reporting requirements. Under section 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e)(1) of the Act, we are authorized to require Part D sponsors to provide such information as we find necessary or appropriate. We are concurrently issuing further guidance on this reporting requirement in a revision to the Part D Reporting Requirements (currently approved under OMB Control No. 0938–0992). We intend to use this data to determine the extent to which the dispensing requirements reduce the amount of unused drugs and determine the cost effectiveness of expanding the requirement beyond brand name drugs. We note that billing transactions are handled through regulatory processes associated with HIPAA transactions. We appreciate the comment from NCPDP that they have developed codes for dispensing methodologies that will facilitate CMS's and Part D sponsors' ability to track the dispensing using information available on version D.0 claim transactions.

Comment: Some commenters supported our proposal to have unused drugs returned to the pharmacy and also supported data collection of the quantity and types of drugs that go unused in LTC facilities. We also received several comments from organizations requesting that CMS delay the requirement that unused drugs be returned to the pharmacy and reported to the Part D sponsor until such time when NCPDP has developed an electronic transaction to capture the nature and quantity of unused drugs. Commenters stated that manual reporting of unused drugs would create a burden on the pharmacy and sponsor and require additional staffing to accommodate the increased workload. Some organizations recommended that we require all solid oral doses (brand and generic drugs) to be dispensed in 7-day-or-less increments and eliminate the "return and report" requirement at least until an NCPDP transaction is developed. Some commenters wanted us to clarify the "return and report" provision. Commenters requested that we clarify whether the provision applies to Part D drugs dispensed prior to the implementation date of the requirement and whether drugs to which the requirements do not apply were exempt from the "return and report" requirement. Many commenters believed that the Controlled Substance Act, hazardous waste laws, and State laws would be a barrier to LTC facilities returning unused drugs to pharmacies. One commenter requested that we add an option for the LTC facilities to report the unused drugs. Another commented that since Part D sponsors do not directly contract with LTC facilities, the Part D sponsors will not have the authority to require LTC facilities to return unused medications to LTC pharmacies. Some commenters stated that there may be more effective ways to gather data than to require all unused drugs be returned to the pharmacies.

Response: As a result of comments, we better understand the existing State and Federal requirements on LTC facilities to manage waste. In response to the comments, we will eliminate the requirement that unused drugs be transferred to the pharmacy and instead retain only the requirement that Part D sponsors collect information from the network LTC pharmacies to determine the amount of unused brand and generic drugs, as defined in § 423.4. We understand that pharmacies routinely receive a date of discontinuation or other information that can be used to calculate such a date (for example, the start date of the new "substitute" prescription may be used as the discontinuation date of the previous prescription) from the LTC facility whenever a medication is discontinued for any reason. Therefore, we believe pharmacies have the data in their own systems to calculate the difference between the quantity dispensed and the quantity consumed, which can be used to calculate the amount of unused medication and which plan sponsors can audit and validate reported amounts. We are revising the PRA package for the Part D Reporting Requirements (currently approved under OMB Control No. 0938–0992) to reflect this approach and will be able to confirm our understanding in the next comment period for the Reporting Requirements.

However, for pharmacies that voluntarily adopt 7-day-or-less dispensing for all solid oral doses (that is, both brand name drugs and generic drugs), we will waive the requirement that Part D sponsors report on the unused drugs. All other pharmacies must report on the amount of unused brand and generic drugs as of implementation of this provision, January 1, 2013. We continue to believe that reporting is essential in order to acquire data from which to evaluate the potential savings from extending the dispensing requirement to generic drugs. Only when data has been systematically collected will the extent of the volume of unused Part D drugs be quantifiable. However, we will eliminate the reporting requirement for those pharmacies that immediately adopt 7-day-or-less dispensing for *both* brand name and generic drugs given

that doing so will almost eliminate unused drugs.

Comment: We received a comment requesting that CMS prohibit plan sponsors from seeking credits for unused drugs that are returned to LTC pharmacies but not reused. We also received a comment requesting that CMS ensure that the final regulations expressly state that beneficiaries are to share in any refund resulting from the return in proportion to the amount of the total cost for the returned drugs covered by their cost sharing contribution.

Response: We believe that the commenter is concerned that sponsors will demand credit for unused drugs associated with the reporting requirement. We stress that this is not the requirement under the rule and expect that sponsors will pay pharmacies for drugs dispensed under this rule, subject to any contractual provisions in the contract between the Part D sponsor and LTC pharmacy. Whether or not Part D plans receive credits and the affect on beneficiaries will be determined by the contract between the sponsor and the pharmacy and the terms of the benefit package. With respect to return and reuse, that is a practice governed by State law and the provisions of the contract between the Part D sponsor and the pharmacy. We do not believe it is necessary or desirable for CMS to preempt State laws on this issue. For these reasons, we decline to adopt the commenters' suggestions. If a pharmacy processes unused drugs and redispenses the drugs, then the pharmacy must abide with any conditions in its contract with the Part D sponsor regarding providing credit and the Part D sponsor must adjust the prescription drug event data and TrOOP accordingly for the original dispensing event.

Comment: We received comments that Part D sponsors should generally allow pharmacies to use currently accepted transactions unless the industry voluntarily adopts a single billing standard. Others recommended that we implement a specific billing standard. Some commenters recommended that we implement "post-consumption billing" as a standard billing methodology because there would be minimal need for drug returns, claim reversal, and TrOOP and drug spend adjustments. Some also stated that a post-consumption-billing method would reduce the potential for fraud.

Response: We defer to the appropriate industry standard-setting organizations and the HIPAA-mandated rulemaking process to determine billing standards and for this reason, decline to amend our regulations for this purpose at this time.

Comment: We received several comments concerned about copayment methodologies. Some commenters recommended that the copayment method not be linked to the dispensing methodology. Several commenters expressed concern over charging beneficiaries additional copays. Many recommended that the beneficiary only be charged one copayment per month. Other commenters believed that the beneficiaries' copayments should be prorated based on the number of days a Part D drug was dispensed in a month.

Response: As stated in the proposed rule, we expect that copayments will be billed on the first dispensing event of the month, the last dispensing event of the month, or prorated with each dispensing event. We leave the decision of which copayment collection methodology to use up to the parties involved in these transactions; however, in response to these comments, we will add a provision to the regulation to clarify our interest that regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the 14-day-or-less dispensing requirements apply shall be no greater than the total cost sharing that would be imposed for such Part D drug if the 14-day-or-less requirements did not apply. This requirement applies for all beneficiaries including low-income subsidy eligible beneficiaries. (We note that, for CY 2013, we are considering collection of daily copayment information in the PBP tool, and that such information would facilitate copayment proration.)

Comment: Some organizations expressed concern over "refill too soon" edits and utilization management requirements that may be placed on drugs dispensed in 7-day-or-less supplies. A majority of the organizations that commented on "refill too soon" edits requested that we issue guidance to Part D sponsors requiring them to turn off the "refill too soon" edit. These organizations were concerned that "refill too soon" edits on drugs dispensed in 7-day-or-less supplies would result in an increase in missed doses due to medication unavailability. Some commenters recommended that Part D sponsors would need to allow for all medications to receive a one-time prior authorization. We also received a comment recommending that prior authorization and step edits be eliminated for drugs dispensed in 7-day-or-less increments and arguing that the rationale behind these utilization management edits is to reduce costs and therefore, they would not be necessary under 7-day-or-less dispensing.

Response: We agree that customary "refill too soon" edits for traditional 30-days supplies will be inappropriate for 14-day-or-less supplies and could result in access issues. We do not agree that PA and step-therapy should be eliminated as they allow savings through use of less costly alternatives with potentially equivalent therapeutic value. We expect that the industry will modify utilization management edits, including refill too soon edits to prevent discriminatory practices that could result in Part D drug access issues.

Comment: We received comments that there may be penalties associated with billing Medicaid for quantities less than a 30-day supply. We also received comments that even the minimal Medicaid co-payment on a prescription becomes a financial burden on such patients if the states are allowed to impose the copayment obligations currently in effect on each 7-day fill.

Response: By statute, Medicaid cannot be billed for Part D drug claims. Therefore, this comment is beyond the scope of the rule because our final rule with respect to dispensing to LTC residents applies only to Medicare Part D.

Comment: We received many comments that did not support our proposal to grant a limited extension to independent community pharmacies servicing small LTC facilities in rural communities. Many commenters believe that it would be difficult to determine which pharmacies meet our proposed extension criteria. Some commenters requested that CMS keep a list of pharmacies that qualify for the extension to eliminate any confusion regarding those pharmacies that qualify for the extension.

Response: As discussed further below, we intend to delay the effective date of the dispensing and reporting requirements set forth in § 423.154 until January 1, 2013. For this reason, an extension for pharmacies servicing small LTC facilities in rural communities is no longer necessary. Instead, the delay in the implementation date will allow all pharmacies and LTC facilities time to evaluate dispensing methodologies and allow them to make a decision regarding the most effective and efficient systems for their facilities. We are amending the final regulation to eliminate the extension for certain pharmacies.

Comment: We received many comments in support of our proposal to waive the dispensing requirements when pharmacies are dispensing to Part D enrollees residing in intermediate care

facilities for the mentally retarded (ICF/MRs) and Institutes for Mental Diseases (IMDs). We also received comments that supported waiving the requirements when pharmacies dispense to similar facilities that meet and demonstrate the same criteria outlined in the proposed rule. We received specific requests to waive I/T/U pharmacies and Indian Health Service or tribal facilities from the requirement. We also received a request to waive this requirement for pharmacies when dispensing to PACE programs. Other commenters opposed any waivers. These commenters argued that the lack of data on unused Part D drugs in these facilities justifies the opposition to the waiver.

Response: We were persuaded by the comments that under certain circumstances, waivers should be granted. The requirements under § 423.154(a) will not apply to I/T/U pharmacies defined in § 423.100. We understand that the I/T/U system is understaffed. As a result, unlike in most LTC pharmacies, which have dedicated clinical pharmacy staff, pharmacists in the I/T/U system are often called upon to perform multiple non-dispensing tasks including providing patient care that would otherwise be provided by a physician. These pharmacists make medication deliveries to LTC facilities only on days when they provide consultant services. In addition, some of these pharmacists provide translation services and/or provide information in a culturally appropriate manner and protocol for the Indian population they serve. Further stressing the system, these pharmacies are called upon to support very remote health stations that are often accessible, in some cases, only on foot, by horseback, airplane, or via helicopter. The majority of the clinics and health stations serviced by I/T/U pharmacists are in remote areas where deliveries cannot be made on a daily basis. For these reasons, we believe that requiring the 14-day-or-less requirement is not feasible for I/T/U pharmacies and could increase rather than decrease costs associated with 30-day dispensing.

The 14-day-or-less dispensing requirements will generally not apply to PACE organizations because PACE programs provide community-based care. When PACE enrollees are in SNFs, we would expect that pharmacies servicing those facilities adhere to the 14-day-or-less dispensing requirement. Therefore, we are waiving these requirements for I/T/U pharmacies, but not for pharmacies when they serve PACE programs.

Comment: We received some comments requesting the CMS maintain a list of facilities for which the dispensing requirements have been waived along with the NCPDP patient resident code so that pharmacies could inform the Part D sponsors that the pharmacy is dispensing to an enrollee residing in a facility that has been waived.

Response: We will consider whether this is a practice that CMS should maintain. However, we currently believe Part D sponsors can adequately identify ICF/MRs, IMDs, and I/T/U pharmacies as these entities generally contract with and bill Part D sponsors directly.

Comment: We received many comments from organizations recommending that we delay the implementation of the requirements described under § 423.154. Many commenters requested a 1-year delay, but some commenters requested a 2-year delay. Most commenters argued that an implementation date of January 1, 2012 would not give sufficient time to renegotiate contracts between the Part D sponsors and the pharmacies or make necessary systems and operational modifications to comply with the requirements. Some commenters argued that maintaining the January 1, 2012 implementation date would lead to inaccurate bids for the 2012 contract year, since planning for systems changes and renegotiation of appropriate dispensing fees incorporating related costs would be expected to extend beyond the CMS bid submission deadline. One commenter indicated that without a delay to permit appropriate negotiation of pharmacy reimbursement, pharmacies would likely just convert existing 30-day punch card systems to 7-day punch card systems rather than make capital investment in more efficient and cost-effective methods for complying with the dispensing requirement. Commenters stated that conversely, the delay until at least January 1, 2013 would ensure that nursing facilities have sufficient time to evaluate dispensing system options (such as automated dose dispensing systems) with their contracted pharmacies and make clear capital investment decisions. A commenter expressed concern that without the delay, hasty business decisions made under pressure could put an otherwise stable pharmacy business at unnecessary risk for failure, particularly given that these decisions would involve capital investments that cannot easily be reversed. This commenter believes that as a result, there could be a decrease in the number of pharmacies that are able to serve LTC facilities. Commenters also expressed concern that the proposed implementation date of January 1, 2012 might put a strain on the supply of appropriate dispensing equipment. Several commenters stated that failure to delay the implementation date would likely result in rushed transitions to 7-day-or-less dispensing that might jeopardize patient safety (for example, because of inadequate staff training time). Commenters stated that given that the LTC facilities will dictate the uniform dispensing techniques to be used in their facilities, pharmacies may need to work with the facilities one at a time, which will require additional time and resources.

Response: We are persuaded by the comments that a 1-year delay in the implementation of these requirements is appropriate. Therefore, we are revising § 423.154 to specify that it will take effect January 1, 2013.

This delay will give LTC facilities and pharmacies more time to evaluate dispensing methodologies and make decisions regarding the most effective and efficient systems. In particular, we are persuaded by the comments that indicate that more pharmacies will convert to the more efficient dispensing systems if given more time to make arrangements for those systems. We also believe, based on the comments, that if the affected parties have more time to make measured and fully considered decisions about capital investments in dispensing technologies, they will be more likely to immediately extend shorter cycle dispensing to both brand and generic drugs in order to maximize the return upon their investment. We believe that these decisions will increase program savings in the long run and lead to greater savings than if, because of an earlier implementation date, the parties did the minimum necessary and merely made minor adjustments to their current systems to meet the requirements.

We also are persuaded by the comments suggesting that the delay will give Part D sponsors sufficient time to negotiate contractual changes and finalize dispensing fees with LTC pharmacies in advance of the 2013 bid deadline, thereby allowing Part D sponsors to submit accurate bids. We would be concerned that bids that could not accurately account for yet-to-be renegotiated dispensing fees would increase program costs in other ways and could potentially offset savings resulting from implementing the requirement for 2012, potentially defeating the purpose of section 3310 of the ACA.

We further are persuaded that, given that we do not have concrete data about the amount of savings that could be achieved, and consistent with our

incremental approach to the dispensing requirement, a 1-year delay will reduce the burden on Part D plans, pharmacies and LTC facilities by permitting a more orderly transition to the new dispensing requirement. In addition, the delay will more closely align the reporting requirement for unused drugs with the availability of an electronic informational reporting transaction that could be used for this purpose, which we believe will further reduce the burden of data collection on pharmacies and Part D sponsors. Finally, we are persuaded that that a delay will give pharmacies and LTC facilities more time to transition to different workflows, new systems and operational requirements, and conduct appropriate staff training. We believe this will mitigate any potential start up issues, such as medication errors, and thus will increase patient safety.

As a result of comments, in our final rule, we modify § 423.154(a)(1)(i) to dispense solid oral brand name drugs, as defined in § 423.4, to enrollees in LTC facilities in no greater than 14-day increments at a time. We modify § 423.154(a)(2) to collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section and on the quantity of unused brand and generic drugs, as defined in § 423.4. Reporting on unused brand and generic drugs is waived for Part D sponsors' when their pharmacies dispense both brand and generic drugs, as defined in § 423.4, in no greater than 7-day increments. We modify § 423.154(b) to exclude from the requirements under paragraph (a) of this section: (1) Solid oral doses of antibiotics; and (2) solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives). We modify § 423.154(c) to include a waiver for I/T/U pharmacies. We modify § 423.154(d) to change the effective date from January 1, 2012 to January 1, 2013. We modify § 423.154(e) by eliminating the extension for certain pharmacies and adding a requirement that regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply. Finally, we modify § 423.154(f) by eliminating paragraph (f)(1) and combining paragraph (f)(2) with the introductory clause of paragraph (f).

12. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

In our November 2010 proposed rule, we proposed to implement a new requirement under the authority of section 3311 of the ACA to require MA organizations and Part D sponsors to respond to complaints. Specifically, we proposed to require that MA organizations and Part D sponsors use our existing Health Plan Management System (HPMS) Complaints Tracking Module (CTM) to document the closure of complaints and provide a detailed complaint resolution summary when the complaint is resolved. That is, we proposed to require an MA organization or Part D sponsor to provide an explanation of the way in which the complaint was closed, rather than simply providing the words "complaint closed" in the CTM.

In our proposed rule, we proposed applying these requirements to both MA organizations and Part D sponsors ensure beneficiary access to medical services and drugs under the MA and Part D programs. We also indicated that we were considering adding a drop down checklist to CTM for MA organizations, and Part D sponsors to use as the documentation method when closing complaints, as opposed to requiring free text descriptions of complaint closure, and we invited comments on this approach.

As provided under section 3311 of ACA, we developed a model electronic complaint form on the Medicare.gov Internet Web site and on the Internet Web site of the Medicare Beneficiary Ombudsman. We proposed that plans be required to prominently display the CMS-developed complaint form on their Web site and directly link to the CMS Medicare.gov Web site and the Web site of the Medicare Ombudsman. As we explained in the proposed rule, when we completed our development of the model electronic complaint form was made available on the internet Web sites as in December 2010.

In our proposed rule, we stated the new requirement for plans to prominently display the electronic model on their Web sites would be effective January 1, 2012 and indicated that following the issuance of this final rule, we would be developing guidance to instruct MA organizations and Part D sponsors on how to comply with this new requirement.

Comment: We received a significant number of comments regarding our proposed requirement in § 422.405(a)(15)(i) and § 423.405(b)(22)(i) regarding the addition of a drop down checklist in CTM that would provide clear and consistent closure categories. Many commenters supported this proposed new requirement. Two commenters recommended that, in addition to the drop down menu, we include a text box for plans that desired to add comments about the resolution of complaints. These commenters believed that this modification would improve specificity of the responses. A few commenters requested that we define the term complaint in order that a complaint might be clearly distinguished from a grievance or an appeal.

Response: We appreciate the support expressed by the commenters. The purpose of the CTM system is to record and track complaints we receive from beneficiaries, provider, and others regarding Medicare health plans and prescription drug plans. While our current instructions to MA organizations and PDP sponsors indicate that when a complaint is resolved the plan should concisely summarize the complaint closure in CTM, we have found that many sponsors failed to do so. Rather, they have merely entered, "Complaint Closed" without any explanation of the action taken. After reviewing many complaint entries, we also discovered that "complaint closed" has often been used inappropriately. For example, it has been used when the sponsor has been unable to reach the beneficiary by phone, which alone does not constitute a reasonable basis for closing a complaint.

We agree with the commenters that a text box in addition to the drop-down menu in the CTM would be helpful for capturing information on the MA organization's or PDP sponsor's resolution of a complaint. Therefore, we are adding a text box to the complaint form. We will clarify in instructions that CMS and plan users must select at least one item in the drop down box or use the text box in CTM to resolve a complaint. Thus, the system will not permit the complaint to be resolved if at least one of the available options is not selected.

Regarding the commenters' request that we define a complaint, we note that the Frequently Asked Questions section of CTM describes the difference between a complaint and grievance. It states that grievances are received directly by the plan from beneficiaries and that plans are required to report

grievances to CMS per the Part D reporting requirements. CTM complaints, however, are received by CMS (through 1–800–Medicare call centers, phone calls to the CMS regional office, *etc.*) and are entered into CTM for resolution by either the plan or CMS. We require that plans track grievances separately from CTM complaints.

Comment: Many commenters supported our proposed requirements that MA organizations and PDP sponsors address and resolve all complaints in the CMS complaint tracking system and link to the electronic complaint form on the Medicare.gov and Internet Web site of the Medicare Ombudsman from each sponsor's main Web page. However, a few commenters expressed opposition to the requirement to link to the electronic complaint form, stating that a direct link on the plan's Web site could potentially discourage use of other plan resources available for issue resolution and confuse beneficiaries. One commenter suggested that, by imposing this requirement, we would create an additional administrative expense that would add little to enhance either the complaint resolution process or beneficiary satisfaction. Another commenter requested the opportunity to review and comment on the new electronic complaint form prior to its implementation.

Response: We appreciate the support commenters expressed for these requirements. Congress has directed the Secretary to annually report the number and types of complaints reported in CTM, any geographic variations that exist in the complaints, the timeliness of CMS' and the plan's responses, and the resolution of such complaints. Given the importance that Congress has placed on complaints and their resolution, it is important that we have reliable and complete data not only prepare our annual report to Congress, but also to monitor complaint resolution for oversight purposes.

We do not agree with those who claimed that having a direct link on the plan's Web site to the Medicare.gov Web site and the Web site of the Medicare Ombudsman would discourage use of plan resources for resolving issues, confuse beneficiaries or create additional administrative costs. It has been our experience that beneficiaries go directly to their MA organization or PDP sponsor with issues of concern, including complaints, prior to contacting CMS for assistance. We have no cause to believe that requiring sponsors to directly link to the Medicare.gov Web site and the Web site of the Medicare Ombudsman would alter the beneficiaries' practice of seeking to resolve their issues by first contacting their plan. We also do not believe that requiring a link from the sponsor's Web site to the Medicare Web sites will add significant administrative costs. Since the proposed requirement is similar to existing requirements regarding a plan's Web site, we expect that any costs related to this requirement are currently reflected in the organization's bid.

We appreciate the commenter's interest in commenting on the new electronic complaint form prior to its implementation, but as we noted previously, we have already posted the model electronic complaint form which is available at *https://www.medicare.gov/MedicareComplaintForm/home.aspx.*

For the reasons discussed previously, we are finalizing these requirements as proposed with an effective date of January 1, 2012 for the requirement that MA organizations and Part D plans create a link from their main Web page to the CMS-developed electronic complaint form on the *http://www.Medicare.gov* Web site.

13. Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128 and § 423.562)

Section 3312 of the ACA amends section 1860D–4(b)(3) of the Act by adding a new section (H) that requires, effective January 1, 2012, each PDP sponsor to use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and to provide instant access to such processes through a toll-free telephone number and an Internet Web site.

In accordance with the new section 1860D–4(b)(3)(H) of the Act, we proposed in the November 2010 proposed regulation to revise the regulation at § 423.562(a) to require Part D plans to use a single, uniform exceptions and appeals process that includes procedures for accepting oral and written requests for coverage determinations and redeterminations. In addition, we proposed to revise the regulation at § 423.128 paragraphs (b)(7) and (d) to identify specific mechanisms that plan sponsors must have in place in order to meet the uniform appeals requirements of section 1860D–4(b)(3)(H) of the Act. Most notably, at § 423.128(b)(7), we proposed adding paragraph (i) to require that plan sponsors make available a standard form to request a coverage determination and a standard form to request a redetermination, to the extent such standard request forms have been approved for use by CMS. (Note that in the context of appeals, the term "standard form" or "standardized form" is generally used to refer to a form that would be the only permissible vehicle for requesting a coverage determination or redetermination.)

Section 3312 of the ACA also requires plan sponsors to provide instant access to the coverage determination and appeals process through an internet Web site. Consistent with the requirement, we also proposed to add paragraph (ii) to § 423.128(b)(7), which would require sponsors to provide immediate access to the coverage determination and redetermination processes via an Internet Web site. We requested comments and ideas regarding how this should work and any issues that needed to be addressed before operationalizing this requirement. Section 3312 of the ACA also specifies that plan sponsors must establish a toll-free telephone line that provides instant access to the coverage determination and appeals processes. Because plan sponsors are currently required to offer a toll-free customer call center as part of the provision of information requirement at § 423.128(d), we proposed to revise § 423.128(d)(1) to include a requirement that sponsors provide enrollees with access to the coverage determination and redetermination processes through their toll-free customer call center.

To codify the proposals that plans make available standard forms for requesting coverage determinations and redeterminations (to the extent that standard request forms have been approved for use by CMS), and establish a toll-free telephone number and Web site for accepting requests for coverage determinations and redeterminations, we proposed to amend § 423.562 by adding a new paragraph (a)(1)(ii) which cross-references the requirements in § 423.128 paragraphs (b)(7) and (d)(1)(iii), and redesignating paragraphs (a)(1)(ii) and (a)(1)(iii) as paragraphs (a)(1)(iii) and (a)(1)(iv), respectively. Finally, we proposed that Part D sponsors modify their electronic response transactions to pharmacies so that they can transmit codes instructing the pharmacy to provide a standardized point-of-sale (POS) notice to enrollees when a prescription cannot be filled. Specifically, we proposed at § 423.128(b)(7)(iii) to require that Part D sponsors modify their systems so that the plan sponsors are capable of transmitting codes to their in-network

pharmacies and that the pharmacy will be notified to populate or provide a notice that can be printed by the pharmacist at the point of sale. We indicated that we would develop a model notice to ensure that messaging at the pharmacy is consistent with and in accordance with CMS rules. Consistent with this proposal, we also proposed to revise § 423.562(a)(3) by deleting the reference to posting the pharmacy notice and instead requiring the sponsor to arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist. We proposed that the pharmacy notice be provided in writing, consistent with the standards established in § 423.128(b)(7)(iii), and include instructions explaining how enrollees can request a coverage determination by calling their plan sponsor's toll free customer service line or accessing their plan sponsor's Web site.

Comment: We received a large number of comments on the merits of requiring the use of a standard form for requesting Part D exceptions and appeals. Several commenters expressed the belief that standard forms are not feasible, noting that a single form cannot accommodate the wide variations that exist among plan formulary and utilization management requirements, and would therefore hinder access to the exceptions and appeals processes. Some commenters stated that, particularly for biotech or other specialty drugs, drug-specific forms improve access to coverage because they give enrollees and prescribers clearer information on the specific plan requirements for coverage. Other commenters asserted that a single form would simplify the processes for enrollees, prescribers and plans.

Response: We have carefully considered all the comments we received on this issue, both in the context of the overarching statutory requirement that Part D plans use a "single, uniform exceptions and appeals process" as well as keeping in mind the requirements and procedures that are already in place with respect to requests for coverage determinations and appeals. (Note that, as set forth in detail in the existing regulations at § 423.578, the term "exception" refers to certain types of coverage determinations, such as a request for a non-formulary drug, that require an oral or written supporting statement from a prescribing physician or other prescriber.)

Our current regulations permit either written or oral requests for a coverage determination (§ 423.568), with the exception of requests for payment, which must be made in writing unless the sponsor has a voluntary policy of accepting oral payment requests. Standard redetermination requests generally are made in writing, under § 423.582; plans may also accept oral requests for standard redeterminations but are not required to do so. Plans must accept oral requests for expedited redeterminations (§ 423.584). Currently, we have developed model forms for requesting a coverage determination—one for beneficiaries and one for prescribers—but there are no comparable model forms for requesting redeterminations. It is also important to note that our existing subregulatory guidance specifies that *any written request* from an enrollee or prescriber is acceptable, and that plans may not require an enrollee or prescriber to make a written request on a specific form (see Section 40 of Chapter 18 of the Prescription Drug Benefit Manual, Part D Enrollee Grievances, Coverage Determinations and Appeals). We believe that the requirement that plans accept any written request builds significant enrollee protection into the coverage determination and appeals processes, and requiring the use of a "standard" form may inadvertently create barriers for enrollees accessing these processes. Thus, introducing a requirement that a standard form be used could actually conflict with the underlying statutory intent of the new provisions which are meant to enhance enrollee access to the exceptions and appeals processes.

Therefore, we are modifying the proposed regulatory language at § 423.128(b)(7)(i) by replacing the proposed reference to a "standard" form with the statutory language referencing use of a "uniform model form." In support of this requirement, we will work with plans, prescribers, and beneficiary advocates to revise the existing model coverage determination request form, including combining the existing enrollee and prescriber request forms into a single model form. We will also develop a separate model redetermination request form for use by enrollees and their prescribers and representatives. Plans will be required to make these model forms available to their enrollees via their websites, and to include the model redetermination request form with any coverage determination denial notice, consistent with the requirement under § 423.568(g)(4) that denial notices comply with notice requirements established by CMS.

The introduction of uniform model forms is not intended to interfere with the current requirements regarding acceptance of oral or written requests, nor does it preclude plans from developing and making available drug-specific coverage determination request forms to supplement the model forms to the extent such forms can enhance access to the exceptions and appeals process. Given that plan formularies, utilization management tools and step therapy requirements can vary widely, we believe that not allowing plans to continue making drug-specific forms available or precluding enrollees from making coverage determination requests through other written vehicles, may actually delay decision-making and/or result in additional unfavorable decisions based on a lack of adequate documentation. Thus, although we acknowledge that making multiple forms available for use may cause some confusion for enrollees, we believe that continuing to permit such variation is in the best interests of Medicare beneficiaries. Plans must comply with the appropriate marketing procedures for approval of forms, including CMS-approved model forms.

Comment: A few commenters noted that adopting a single form for both coverage determinations and redeterminations could lead to confusion and erroneous or unnecessary submissions from enrollees and prescribers because of the often-different rationales and necessary supporting documentation for these processes. This in turn would increase the burden on both enrollees and prescribers and cause delays in accessing prescription drugs.

Response: We agree with the commenters, and as stated previously, intend to develop separate model forms for coverage determinations and redeterminations.

Comment: We received a number of comments with recommendations that CMS work closely with stakeholders in developing standard forms. Some commenters also supported consumer testing and/or piloting standard forms before full implementation.

Response: We thank the commenters for their suggestions. As noted previously, rather than require a standard form, we intend to revise the existing model coverage determination form and develop a new model redetermination form. Stakeholders will have an opportunity to comment on draft versions of these forms via the same process used to solicit stakeholder input on changes to manual guidance.

Comment: Several commenters urged CMS to require that all plan sponsors make standard forms available in multiple languages and make them widely available in plan materials and on plan Web sites.

Response: The regulations in Subpart V of Part 423, and related subregulatory guidance, establish CMS' marketing rules with respect to translated materials. Model coverage determination and redetermination notices are considered post-enrollment marketing materials, and therefore must be translated in accordance with CMS marketing requirements, consistent with the related discussion above.

Comment: Although several commenters were supportive of the proposal related to providing instant access to the coverage determination and appeals process via an internet Web site, many commenters raised concerns about the administrative and technological burdens and costs associated with the development of a Web-based interface that would allow enrollees to access the coverage determination and appeals processes. Several commenters thought that the benefit to enrollees will be minimal compared with the additional costs and operational complexities. These commenters also claimed that plans will not be able to fully realize potential cost-savings in using such a system if they are also required to maintain processes for accepting requests via telephone and mail. CMS also received comments suggesting a pilot program, greater stakeholder input, delayed implementation, and making acceptance of electronic requests optional.

Almost all commenters, whether they opposed or supported the proposal, raised questions about systems specifications and functionality, including whether plan systems for accepting electronic requests must: (1) Accept electronic attachments such as clinical documentation, prescriber supporting statements, enrollee receipts for out-of-pocket expenses, and Appointment of Representative (AOR) forms or, alternatively, be equipped to generate a bar code or other receipt to allow for the separate submission of supporting documents via fax; (2) generate an auto-reply acknowledging receipt of the request; (3) have a user authentication feature; and (4) include mandatory fields or other specifications (for example, font type/size).

Response: As noted in the proposed rule, section 3312 of the ACA states that Part D plan sponsors shall provide instant access to the coverage determination (including exceptions) and appeals processes through an Internet Web site. In the proposed rule, we solicited comments on the viability of a Web-based electronic interface that would allow an enrollee (or an enrollee's prescriber or representative) to immediately request a coverage determination or redetermination via a plan's secure Web site. Our proposal indicated that the interface would be the "electronic equivalent" of the paper coverage determination and appeals forms proposed at § 423.128(b)(7)(i). The proposed rule described a system that would provide some level of interactive functionality on a plan's Web site, such as the ability to populate and submit an online request form.

However, after reviewing all of the comments on this provision, we agree that requiring plans to develop an interactive Web-based system by the 2012 plan year would impose significant costs and operational difficulties on many Part D plans. Therefore, although we are finalizing the regulatory language as proposed, we are clarifying that "immediate access" to the coverage determination and appeals processes can be satisfied through a variety of means. We strongly encourage plans to establish interactive, web-based systems to meet this requirement. At a minimum, however, plans must have a process for allowing an enrollee to initiate a coverage determination or appeal request by sending a secure e-mail to an e-mail address that is prominently displayed on the plan's Web site. In response to such requests, plans must provide notice of decisions in a timely manner, consistent with all existing requirements in Subpart M of our regulations. We believe that this approach takes into consideration the plans' differing technological capabilities, while implementing the statutory requirement that plans provide access to the coverage determination and appeals processes via plan Web sites. Although plans that have the capability to deploy a more robust and sophisticated Web-based system are encouraged to do so, we do not intend to specify systems functionality for plan Web sites, beyond the requirement that an enrollee (and an enrollee's prescriber or representative) be able to initiate a request by sending a secure e-mail via the plan's Web site.

Finally, we note that enrollees (and their prescribers and representatives) will retain the right to make requests for oral coverage determinations and expedited appeals which serve as another means of obtaining instant access to the coverage determination and appeals processes.

Comment: We received some comments regarding the requirement that plans provide immediate access to the coverage determination and redetermination processes through a toll-free phone number. Commenters opposed to this requirement indicated that maintaining a toll-free line creates an undue burden on plans, provides minimal benefit to enrollees and increases confusion among enrollees. These commenters also requested a delayed implementation date. Commenters who support the proposed requirement requested that CMS require plans to disseminate the toll-free number and related information widely in plan materials, and support stakeholder input in the development of model scripts for customer service representatives (CSRs) who staff these toll-free lines.

Response: The existing regulations at § 423.128(d)(1) already require plan sponsors to maintain a toll-free customer call center, and existing subregulatory marketing guidance clarifies applicable call center coverage requirements for coverage determinations and redeterminations. The proposed change we intend to finalize adds the requirement that plans provide immediate access to the coverage determination and redetermination processes through their toll-free customer call centers. If using an existing toll-free number for receiving and processing oral coverage determination and appeals requests could potentially cause delays and/or missed time frames, plans may establish a dedicated toll-free customer service line for receiving these requests. We note that plans are currently required under § 423.568(a) and § 423.570(b) respectively, to accept oral requests for both standard coverage determinations (excluding reimbursement requests) and expedited coverage determinations, and under § 423.584(b), to accept oral requests for expedited redeterminations. In the proposed rule, we noted that a CSR could potentially access the plan's web-based application for coverage determinations and appeals and enter information supplied by the enrollee via telephone. However, as discussed previously, we are scaling back our expectations with respect to plan capabilities for having an interactive web-based application for coverage determinations and appeals. As such, we expect that plans will continue to utilize existing mechanisms for receiving and processing oral coverage determination and appeal requests, including those received outside normal business hours. Requests made through the toll-free number would still be subject to existing processing guidelines

and timeframes outlined in Subpart M of the regulations.

Comment: Several comments were received regarding the proposed requirement that Part D sponsors revise their payment systems to notify network pharmacies that they need to generate a printed notice containing information for enrollees about how to contact their plan to request a coverage determination, including an exception, when a prescription cannot be filled as written. Commenters indicated that because the POS notice would not provide enrollees with any more information than what is already provided on their member ID cards, it is an undue burden on pharmacies, and is not "green."

Response: We disagree with the commenters' concerns regarding the lack of utility in the distribution of a POS notice. Other commenters have expressed concern that enrollees are not aware of their right to request a coverage determination and that having the notice posted at the pharmacy counter is only useful to the extent the enrollee is directed to it by his/her pharmacist.

We also do not agree that the distribution of the POS notice is an additional burden on pharmacies. It is likely the POS notice will relieve pharmacy staff from being queried by enrollees as to why their prescriptions could not be filled as written, because the notice refers the enrollee directly to their plan to obtain a coverage determination. Furthermore, we believe that eliminating the current option of directing enrollees to a posted notice and requiring that they receive a printed notice strengthens enrollee access to the coverage determination process because the enrollee will leave the pharmacy with printed instructions about contacting the plan to request a coverage determination.

Comment: Several of the comments regarding the proposed requirement to distribute POS notices incorrectly referred to the POS transaction at the pharmacy counter as a denial of prescription drug coverage (an adverse coverage determination).

Response: We reiterate our position in previous rulemaking and existing subregulatory guidance that plan sponsors are not required to treat the presentation of a prescription at the pharmacy counter as a request for coverage determination. Accordingly, the plan sponsor is not required to provide the enrollee with a written denial notice at the pharmacy as a result of the transaction.

Comment: Several commenters supported the requirement that a POS notice be distributed at the pharmacy, but stated that the notice should be tailored to each individual's situation, including a description of why the prescription could not be filled as written.

Response: We agree it would be useful for enrollees to have additional information such as the name of the drug and the specific reason(s) the prescription cannot be filled as written as part of the POS notice. However, such situation-specific messaging cannot be generated at this time. Until we have the opportunity to work with the industry, specifically the National Council of Prescription Drug Programs (NCPDP), to develop and standardize codes that will assist Part D sponsors, processors and pharmacies with generating this kind of information as part of the transaction, we cannot require Part D sponsors or their processors to code their systems to generate such a notice.

We are finalizing the proposed language in § 423.128(b)(7) and § 423.562, with the modifications to § 423.128(b)(7)(i) described previously. Consistent with section 3312 of the ACA, these new requirements will be effective January 1, 2012.

14. Including Costs Incurred by AIDS Drug Assistance Programs (ADAPs) and the Indian Health Service Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

Section 1860D–2(b)(4)(C) of the Act provides protection against high out-of-pocket expenditures for Part D eligible individuals. Under the standard Part D benefit, a beneficiary is entitled to reductions in cost sharing under the catastrophic phase of the benefit once his or her true out-of-pocket (TrOOP) expenditures reach the annual Part D out-of-pocket threshold. Prior to enactment of the ACA, TrOOP expenditures represented costs actually paid by the beneficiary, another person on behalf of the beneficiary, or a qualified State Pharmaceutical Assistance Program (SPAP).

Thus, prior to the passage of the ACA, supplemental drug coverage provided by the Indian Health Service (IHS), Indian tribes and organizations, and urban Indian organization facilities (as defined in section 4 of the Indian Health Care Improvement Act) were not considered to be TrOOP eligible because these entities fell under our definition of "government-funded health program," under § 423.100. Similarly, the Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program-funded AIDS Drug Assistance Programs (ADAPs) cost sharing were not counted toward TrOOP for the purpose of meeting the out-of-pocket threshold at which catastrophic coverage under the Part D benefit begins. As explained in the preamble in the January 2005 final rule (see 70 FR 4240 and 4241) implementing the Part D program, ADAPs were not considered SPAPs because these programs received Federal funding. With the passage of the ACA, CMS regulations, as they relate to IHS/Tribes and ADAPs, have been superseded effective January 1, 2011. Section 3314 of the ACA amends section 1860D–2(b)(4)(C) of the Act to specify that costs borne or paid for by IHS, an Indian tribe or tribal organization, or an urban Indian organization, and costs borne or paid for by an ADAP will be treated as incurred costs for the purpose of meeting the annual out-of-pocket threshold. Based on these amendments, we proposed to revise the definition of incurred cost at § 423.100(2)(ii) to include payments by the IHS (as defined in section 4 of the Indian Health Care Improvement Act), an Indian tribe or tribal organization, or an urban Indian organization (referred to as I/T/U pharmacy in § 423.100) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service). We also proposed to amend § 423.464(f)(2) to specifically exclude expenditures made by IHS, an Indian tribe or tribal organization, or an urban Indian organization (referred to as I/T/U pharmacy in § 423.100) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service) from the requirement to exclude such expenditures for the purpose of determining whether a Part D enrollee has satisfied the out-of-pocket threshold.

Comment: We received a comment requesting that CMS revise regulations at § 423.100 and § 423.464(f)(2) to reference section 4 of the Indian Health Care Improvement Act in the parenthetical following the phrase "urban Indian organization," and replace the term "payments" in § 423.464(f)(2) with the phrase "costs borne or paid by" to more closely track the statutory language provided in 3314 of ACA.

Response: We agree with this comment and revise the regulation text at § 423.100 to reference section 4 of the Indian Health Care Improvement Act. In addition, in response to this comment and to avoid confusion, we are removing the redundant reference to ADAPs and IHS/tribes/tribal organizations in § 423.464(f)(2)(i)(B). Because costs borne or paid by these organizations already are included in the definition of "incurred costs" as

referenced in § 423.464(f)(2)(i)(A), they need not be expressly referenced in § 423.464(f)(2)(i)(B). We also revised § 423.100(2)(ii) to remove the cross reference to § 423.464.

Comment: Another commenter requests that CMS provide a list of ADAP BINs (bank identification numbers)/PCNs (processor control numbers) to ensure proper TrOOP calculation for ADAP members by the Part D sponsor.

Response: Both CMS and the Health Resources and Services Administration (HRSA) have provided training and assistance to ADAP grantees about CMS' coordination of benefits (COB) data exchange process and its relationship to the member's TrOOP calculation. Participation in this process will allow ADAPs to provide the BIN and PCN directly to CMS' COB contractor, who will then identify ADAPs as TrOOP-eligible payers as part of transactions sent from our TrOOP facilitator to Part D sponsors.

Except for the technical amendments to the proposed regulations text noted previously, we are finalizing the regulation as proposed.

15. Cost Sharing for Medicare-Covered Preventive Services (§ 417.454 and § 422.100)

Effective January 1, 2011, sections 4103 and 4104 of the ACA revised sections 1833 and 1861 of the Act to create new coverage of Personalized Prevention Plan Services (PPPS) or "annual wellness visits" and establish a requirement that no cost sharing may be charged to beneficiaries under Original Medicare for the annual wellness visit, the initial preventive physical exam (IPPE) and Medicare-covered preventive services graded as an A or B by the U.S. Preventive Services Task Force (USPSTF).

In light of the new legislative requirements for Original Medicare, and the importance of preventive services in managed and coordinated care, we included information related to coverage and cost sharing for preventive services in guidance issued via the Health Plan Management System (HPMS) on April 16, 2010 ("Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011") and May 20, 2010 ("Supplemental 2011 Benefits Policy and Operations Guidance on Application of the Mandatory Maximum Out-of-Pocket (MOOP) for Dual Eligible SNPs, and Cost Sharing for Preventive Services"). In this guidance, we strongly encouraged MA organizations to provide all in-network Medicare-covered preventive services without cost sharing charges under their MA plans in contract year 2011, indicated our intention to consider rulemaking to require that such preventive services be provided with no cost sharing, and provided instructions on how to reflect the zero cost sharing in their plan benefit package (PBP) submissions for contract year 2011.

As required at section 1852(a)(1)(A) of the Act (except as provided in section 1859(b)(3) of the Act for MSA plans and in section 1852(a)(6) of the Act for MA regional plans), each MA plan must provide to its members all Parts A and B benefits included under the Original Medicare fee-for-service program as defined at section 1852(a)(1)(B) of the Act. We agree that the utilization of preventive services should be encouraged by providing such services without cost sharing. Therefore, we believe it is necessary, and appropriate, to provide this same incentive to all Medicare beneficiaries, whether they receive their benefits through Original Medicare, under an MA plan, or under a section 1876 cost contract.

Therefore, under our authority in section 1856(b)(1) of the Act to establish MA standards by regulation, and our authority in section 1857(e)(1) of the Act to establish requirements we find "necessary and appropriate," we proposed to add a new paragraph (k) to § 422.100, and under our authority in section 1876(i)(3)(D) of the Act to impose "other terms and conditions" deemed "necessary and appropriate," new paragraph (f) to § 417.101, to require MA organizations and section 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing, consistent with the new regulations for Original Medicare-covered preventive benefits.

For specific information about the list of preventive services covered under Original Medicare without cost sharing and information about what is included in the annual wellness visit, we directed plans to go to the following Medicare Web sites: *https://www.cms.HospitalOPPS/* and *http://www.cms.gov/PhysicianFeeSched/*.

Comment: Commenters expressed their support for our proposal to require MA organizations and section 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing, consistent with the new regulations for Original Medicare-covered preventive benefits. Some of those commenters also requested that CMS clarify that only in-network preventive services will be required to have zero cost sharing and that MA plans will be required to cover the same preventive services at zero cost sharing as are provided under Original Medicare without cost sharing.

Response: We thank the commenters for their support. We clarify that the preventive services to be provided by MA plans without cost sharing are those provided in-network and that they are to be the same services that are covered under Original Medicare with zero cost sharing and will take into consideration the commenters' concerns as we move forward with other guidance and educational materials.

Comment: We received one comment requesting that we extend the requirement for preventive services' zero cost sharing to out-of-network settings. The commenter believes that because preventive services are so important for beneficiary health CMS should provide equal access to them no matter where the beneficiary receives them.

Response: Our policy for cost sharing is limited to in-network Medicare parts A and B services and we made no proposal to change that policy. Furthermore, we believe that the nature of the specified preventive services is such that there is not a need for beneficiaries to have the same access to them out-of-network as is provided in-network. We believe that the services are most beneficial to an enrollee when provided in-network because communication among the enrollee's providers is an integral part of a successful prevention plan. By receiving in-network preventive services the enrollee's needs for any follow-on services will be identified and furnished and this is less likely to occur if individual preventive services are received elsewhere.

Comment: We received a comment expressing concern that some of the policies related to implementation of zero cost sharing for Medicare-covered preventive benefits would create beneficiary confusion on specific elements and that such confusion would lead to complaints that could have an impact on plans' quality bonus payments.

Response: We appreciate the commenter's concern and going forward, we will continue to make every effort to educate beneficiaries and providers about the services and situations in which zero cost sharing applies.

Comment: We received a few comments requesting that additional services be included as Medicare-

covered preventive services with zero cost sharing.

Response: We thank the commenters for their suggestions but they are beyond the scope of this proposed rule.

Comment: Two commenters objected to our codification in the proposed rule of our proposal to extend the requirement for plans to charge zero cost sharing for CMS-specified in-network preventive services to section 1876 cost plans by adding new paragraph (f) to § 417.101, which otherwise does not govern cost plans. The commenters suggested that instead we may want to propose to add a new paragraph to § 417.454, Charges to Medicare Enrollees.

Response: We thank the commenters for alerting us to this codification issue. In this final rule, we will not make a change to § 417.101 and will instead add new paragraph (d) to § 417.454 to require that no cost sharing may be charged by section 1876 cost plans for CMS-specified in-network preventive services.

We have considered all of the comments received on this proposal and will finalize our proposed policy to amend § 422.100 by adding new paragraph (k) to require that there be no cost sharing for in-network Medicare-covered preventive services, as specified by CMS annually. In addition, we are adding new paragraph (d) to § 417.454 as previously specified.

16. Elimination of the Stabilization Fund (§ 422.458)

Section 221(c) of the MMA added section 1858 of the Act to establish rules for MA Regional Plans. Section 1858(e) established an MA Regional Plan Stabilization Fund (the Fund) for the purpose of providing financial incentives to MA organizations that offered new MA Regional Plans nationally, or in each MA region without one.

Section 10327(c) of the ACA repealed section 1858(e) of the Act, eliminating the Stabilization Fund. Therefore, we proposed to delete paragraph (f) from § 422.458, since the statutory basis for the Fund no longer exists. We received no comments on this proposal and therefore are finalizing this provision without modification. We are also adopting § 422.258(f) as proposed in this final rule.

17. Improvements to Medication Therapy Management Programs (§ 423.153)

As required by section 1860D–4(c)(1)(C) of the Act, Part D sponsors must establish Medication Therapy Management Programs (MTMPs). Section 1860D–4(c)(2) of the Act requires MTMPs to be designed to ensure that, with respect to targeted beneficiaries described in section 1860D–4(c)(2)(A)(ii) of the Act, covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. As noted in our November 2010 proposed rule, these requirements are codified in § 423.153(d) of the Part D regulations.

Effective January 1, 2013, section 10328 of the ACA amends section 1860D–4(c)(2) of the Act to require prescription drug plan sponsors to perform a quarterly assessment of all "at risk" individuals who are not already enrolled in an MTMP, establish opt-out enrollment for MTM, and offer medication therapy management services to targeted beneficiaries. These MTM services must include, at a minimum, an annual comprehensive medication review (CMR) that may be furnished person-to-person or via telehealth technologies and a review of the individual's medications, which may result in the creation of a recommended medication action plan, with a written or printed summary of the results of the review provided to the targeted individual. The law also requires that the action plan and summary resulting from the CMR be written in a standardized format.

In our November 2010 proposed rule, we noted that prior to the passage of the new legislation, we had already made several improvements to the MTM program. We also indicated that in comparing the requirements in section 10328 of the ACA to those codified in the April 2011 final rule containing policy and technical changes under the Part C and Part D programs (see 75 FR 19772 through 19776 and 19818 and 19819), we found that a number of the provisions are consistent. Specifically, the April 2011 final rule requires the use of an opt-out method of enrollment for targeted beneficiaries, an annual comprehensive medication review (CMR) with a written summary, quarterly targeting of beneficiaries for enrollment into the MTMP, and quarterly targeted medication reviews for individuals enrolled in the MTMP with follow-up interventions when necessary. However, to ensure that our policies are fully consistent with the new requirements added by section 10328 of the ACA, we proposed to amend the current regulations to clarify the Part D MTMP requirements relating to the required use of a standardized format for the written summary and action plan that may result from the CMR. Thus, in our November 2010 proposed rule, we proposed to amend § 423.153(d)(1)(vii) to add the requirement that Part D sponsors use a standardized format for the action plan and summary resulting from a review of the targeted beneficiary's individual medications, and to provide the individual with a written or printed copy of the summary. We also noted our plan to award a contract to an outside entity, pending the availability of funding, to work in consultation with stakeholders in order to develop a standardized format for the action plan and summary which may result from annual or quarterly targeted medication reviews.

In our November 2010 proposed rule, we also proposed to amend the MTMP requirements at § 423.153(d)(1)(vii) to explicitly permit the use of telehealth technologies to conduct the required annual CMR as referenced under the ACA, to allow the sponsors to attempt innovative techniques that provide care at a distance in order to better serve the beneficiary, especially beneficiaries who cannot travel to the provider's location, or who reside in a remote location or in a different time zone. We emphasized as well that when using telehealth technologies, personal health information privacy and security must be ensured. This would involve the establishment of appropriate administrative, technical, and physical safeguards to protect the confidentiality of data and to prevent unauthorized use of, or access to, it. The safeguards must provide a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A–130, Appendix III—Security of Federal Automated Information Systems) as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems"; and Special Publication 800–53 "Recommended Security Controls for Federal Information Systems." The use of unsecured telecommunications, including the Internet, to transmit individually identifiable information would, therefore, be prohibited.

In addition to the proposed regulatory changes required to implement the ACA provisions, in our November 2010 proposed rule, we proposed to amend the MTMP requirements related specifically to MTM services furnished in LTC facilities. As provided under sections 1819(b)(4) and 1919(b)(4) of the Act, LTC facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the

needs of each resident. In our November 2010 proposed rule, we noted this requirement is codified in regulations at § 483.60 which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility, including a drug regimen review at least once a month for each facility resident. We stated further that, although Part D sponsors are required to provide MTM services to all beneficiaries meeting the target criteria, it is not clear that these services are being made available to nursing home residents meeting these criteria. We noted our concern that if MTM is provided, in the absence of coordination, the MTMP and the consultant pharmacist's drug regimen review could result in conflicting recommendations relating to medication management. Therefore, we proposed to amend § 423.153(d)(5) to require Part D sponsors to contract with LTC facilities to provide appropriate MTM services to residents in coordination with the monthly medication reviews and assessments performed by the LTC consultant pharmacist. We expressed our belief that this approach would enable beneficiaries to receive the full benefits of the sponsor's MTMP and would also result in coordinated assessments that would be more likely to discover evidence of adverse side effects and medication overuse, and solicited comments from the public on how such coordination between sponsors and LTC facilities might work best.

Comment: One commenter noted that much evidence has been provided over the years indicating the superior results of face-to-face encounters between patients and health care providers and asked that the regulation specifically identify pharmacists as face-to-face providers.

Response: While we recognize that some MTM providers may prefer face-to-face encounters, section 1860D–4(c)(2)(C) of the Act requires the annual comprehensive medication reviews include either an interactive person-to-person or telehealth consultation. We believe that, given the variability of beneficiary circumstances and needs and the advances in technology such as telehealth, it is important that MTM providers take advantage of this flexibility in the methods of delivery of MTM services in order to maximize beneficiary access to these services. We note further that the proposed regulation at § 423.153(d)(1)(vii)(B) specifies that the annual comprehensive medication reviews must be performed by a pharmacist or other qualified provider. We will retain this requirement in the final rule.

Comment: Several commenters expressed strong support for the use of telehealth technologies in conducting CMRs; one commenter emphasized the importance of face-to-face counseling in the MTM context; and another commenter opposed the use of remote MTM for long term care (LTC) beneficiaries. This latter commenter noted that many LTC residents have cognitive impairments and, thus, will rarely be able to interact with, or respond to, MTM services.

Response: We appreciate the support commenters expressed for the use of telehealth technologies for CMRs, but note that use of these technologies is an option. The ACA amended section 1860D–4(c)(2) of the Act to require an annual CMR "furnished person-to-person *or using telehealth technologies*" (emphasis added). We agree that the use of telehealth technologies for conducting CMRs may not be appropriate for all beneficiaries. We also recognize and agree with the commenter that beneficiaries residing in LTC facilities who have cognitive impairments may be unable to participate in an interactive CMR. The current regulations at § 423.153(d)(1)(vii)(B) reflect this awareness by exempting sponsors from offering interactive CMRs to targeted beneficiaries in LTC settings. The Act, as amended by section 10328 of ACA, does not provide a basis for distinguishing the offering of MTM services based on setting. Since the ACA requirements are not effective until January 2013, we will undertake additional rulemaking to further amend the current regulations at § 423.153(d)(1)(vii)(B) to clarify the requirement for MTM programs to offer CMRs to targeted beneficiaries in LTC settings.

Comment: One commenter recommended that we ensure that when MTM services are provided by individuals who are not pharmacists and who have not received the extensive training in medications that a pharmacist receives, these individuals are qualified to provide MTM consultations.

Response: We are not aware of consensus within the industry regarding the qualifications necessary to provide MTM consultations. As a result, we are not prepared at this time to establish requirements regarding MTM provider qualifications. However, we may perhaps do so in the future and would welcome information to assist us in defining the qualifications.

Comment: Numerous commenters expressed support for a standardized format for the written summary and action plan resulting from an annual comprehensive medication review CMR). One commenter applauded our plan to work with stakeholders to develop the standardized formats. Another commenter asked how the stakeholders who would be included in the development of the standardized formats would be determined. Several more commenters recommended we consider input from all industry stakeholders, including plan sponsors, PBMs, pharmacy organizations, and current MTM providers. Two commenters expressed an interest in working on the development and testing of the formats. Two commenters noted that there may be substantial administrative costs associated with implementing these new standardized documents and recommended that we issue the formats in draft for comment and carefully review the comments received to minimize the implementation costs and burden.

Response: We appreciate the support as well as the interest expressed by commenters in participating in the development process and we agree with the recommendation to provide opportunity for the industry to review and comment on the draft formats. The statute specifies that the standardized formats for the action plan and summary will be developed in consultation with relevant stakeholders. It is our intention to examine existing model summaries and action plans in current use and to create draft formats based on the existing models. We have already begun to solicit copies of the existing models in use today and are in the process of reviewing the documents received in response to our request. Once the draft standardized formats have been developed, we will issue them for industry review and comment. We will consider the input from all stakeholders and revise the draft standardized formats based on the comments received. Additional opportunities for public review and comment will be available as the revised formats undergo the OMB approval process required by the Paperwork Reduction Act (PRA). We believe our plan for developing the standardized formats by offering multiple opportunities for public review and comment will be adequate to permit all relevant stakeholders to provide input. We will carefully consider the comments received at all points in the process to ensure that the standardized

formats do not present an undue implementation burden.

Comment: Several commenters suggested that the standardized formats should be limited and offer adequate flexibility for plan sponsors to tailor the summaries and action plans to meet the needs of beneficiaries, caregivers, and plan sponsors.

Response: As we interpret the statute, Congress asked for standardized formats. Therefore, although the specific content of the summary or action plan will be tailored to the beneficiary, there will not be much variability in the style, organization, and general appearance of these documents.

Comment: Two commenters noted that, with the exception of correcting his or her non-adherence, a beneficiary cannot make medication changes without a prescriber's intervention and, as a result, suggested that a copy of the CMR summary also should be provided to all the beneficiary's prescribers that are known to the plan.

Response: We believe the results of the medication review should be shared with the prescribing physicians as necessary, based on the professional judgment of the reviewer and needs of the beneficiary. In our view, mandating that review summaries are always sent to all prescribers would add unnecessary administrative burden and cost.

Comment: One commenter questioned whether the standardized format would require sponsors to use vendor software. This commenter also asked when the standardized formats would be available and if the formats would be required for the targeted medication reviews (TMRs) or only CMRs.

Response: Use of the standardized summary and action plan formats will not require sponsors to use a specific vendor's software. As noted previously, we expect to create draft formats based on existing models and issue the draft for review and comment. Since we have already begun the process of examining some of the existing models in use today, we hope to have a draft available for review within the next few months. With regard to the required use of the formats, the ACA amended section 1860D–4(c)(2) of the Act to require that a CMR include the provision of a written or printed summary and may also result in the creation of an action plan. The statute expressly required the development of standardized formats for summaries and action plans that are provided as part of the CMR. However, we would encourage plans to use these formats for TMRs as well.

Comment: One commenter requested that we define telehealth.

Response: Section 1860D–4(c)(2) of the Act states that an annual CMR must be "* * * furnished person-to-person or using telehealth technologies (as defined by the Secretary) * * *" The U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) defines telehealth as "the use of telecommunications technologies to deliver health-related services and information that support patient care, administrative activities and health education. The technology is a means to improve access to care, while reducing cost of transportation and increasing convenience to patients care." This definition is available on the ONC Web site at *http://healthit.hhs.gov/portal/server.pt?open=512&objID=1224&parentname=CommunityPage&parentid=27&mode=2&in_hi_userid=11113&cached=true.*

The ONC Web site also includes descriptions of various telehealth applications that may be considered for performing a CMR, including for example—

- Live videoconferencing: Audio and video feeds used to connect two or more geographically dispersed health care facilities to enable patients and physicians to consult in real time; and
- E-visits/e-consults: Evolved from secure email or phone based encounters, e-visits can be offered by health insurers through a secure Web portal.

Whatever telehealth technology is used for the CMR, it must enable the MTM provider to perform an interactive consultation with the targeted beneficiary.

Comment: A few commenters suggested that we monitor the outcomes and methods for conducting CMRs, including tracking the technology used and outcomes for various telehealth technologies.

Response: We agree that it is important to evaluate outcomes and identify best practices in MTM, including possibly the use of telehealth technologies. We will consider such monitoring in the future.

Comment: A few commenters strongly supported our proposed requirement to coordinate MTM with LTC consultant pharmacist evaluation and monitoring. A large number of commenters, however, expressed concerns regarding the proposed requirement for Part D sponsors to contract with all the LTC facilities in which their Part D enrollees reside and many offered alternative contracting arrangements or approaches for ensuring that LTC beneficiaries receive the benefits of the sponsor's MTM program and that evidence of adverse side effects or medication overuse is discovered and addressed. Several commenters suggested we delay implementation and work with industry stakeholders to identify and evaluate alternatives.

Response: We appreciate the support expressed for our proposed requirement, but we also agree that there may be a less burdensome approach for achieving our goal. Therefore, we are not finalizing the proposed requirement in § 423.153(d)(5) and will work with stakeholders to develop an alternate proposal. We thank the many commenters who suggested alternative arrangements and will consider these recommendations as we seek to identify the best approach for coordinating MTM and LTC consultant pharmacist monitoring.

Based on the comments received, we are finalizing this provision with the amendments previously noted. This provision will be effective January 1, 2013.

18. Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

In our November 2010 proposed rule, we noted that paragraphs (b)(3) and (d) of section 1101 of the ACA amended section 1860D–2(b) of the Act by adding provisions that revise the Part D benefit structure to close the gap in coverage that occurs between the initial coverage limit for the year and the out-of-pocket threshold. We noted that the new provisions not only will revise the amount of coinsurance for costs of covered drugs above the initial coverage limit and below the out-of-pocket threshold (that is, within the Part D coverage gap) for applicable beneficiaries, but also will reduce the growth in the annual out-of-pocket threshold from 2014 to 2019.

As stipulated under the new provisions in section 1860D–2(b)(2)(C) and (D) of the Act, effective January 1, 2011, cost sharing in the coverage gap for "applicable beneficiaries" will be determined on the basis of whether the covered Part D drug is considered an "applicable drug" under the Medicare coverage gap discount program as defined at section 1860D–14A(g)(2). Section 1860D–14A(g)(2)(A) defines an applicable drug under the Medicare coverage gap discount program as a covered Part D drug that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (BLA) (other than under section 351(k)). Under standard

prescription drug coverage, coinsurance for applicable beneficiaries in the coverage gap for drugs that are not applicable drugs under the Medicare coverage gap discount program (that is, generic drugs) will be either: (1) Equal to the statutory generic gap coinsurance percentage for the year; or (2) actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program at the statutory generic gap coinsurance percentage for the year, as determined through processes and methods established under section 1860D–11(c) of the Act and implemented at § 423.265(c) and (d) of our regulations. In our November 2010 proposed rule, we explained that for applicable drugs under the Medicare gap coverage discount program, coinsurance in the coverage gap for the actual cost of the drug as defined at § 423.100 minus any applicable dispensing fees will be either: (1) Equal to the difference between the applicable gap percentage for the year and the discount percentage determined under the Medicare coverage gap discount program at section 1860D–14A(4)(A) of the Act; or (2) actuarially equivalent to an average expected payment of the coinsurance for applicable covered Part D drugs at the applicable gap percentage for the year, as determined through processes and methods established under section 1860D–11(c) of the Act and implemented at § 423.265(c) and (d) of our regulations. We stated that, as a result, when the applicable drug is purchased at a network pharmacy, the beneficiary will be fully liable for any dispensing fees, since the statute requires that the coinsurance apply only to the negotiated price of the drug minus dispensing fees.

We proposed to codify these new requirements in § 423.104(d)(4). Additionally, since the terms applicable drug, applicable beneficiary, and coverage gap have not been previously defined in regulation, we proposed new definitions for these terms at § 423.100. Consistent with section 1101 of the ACA, these reductions in cost sharing during the coverage gap will apply only to applicable beneficiaries. In defined standard coverage, cost sharing during the coverage gap will remain unchanged at 100 percent coinsurance for all other Part D beneficiaries (prior to application of any low-income cost sharing subsidy).

As provided under the new provisions in section 1860D–2(b)(4)(B)(i) of the Act, the rate of growth of the annual out-of-pocket threshold will be reduced from 2014 to 2019. In our November 2010 proposed rule, we proposed to amend § 423.104(d)(5)(iii) to state that the annual out-of-pocket threshold for years 2014 and 2015 will be the amount specified for the previous year, increased by the "annual percentage increase" in the average expenditures for Part D drugs per eligible beneficiary currently specified in § 423.104(d)(5)(iv), minus 0.25 percentage point. Further, we proposed to amend § 423.104(d)(5)(iii) and (v) to reflect that for years 2016 through 2019, the annual out-of-pocket threshold will be the amount specified for the previous year, increased by the lesser of: (1) the annual percentage increase in the consumer price index specified in § 423.104(d)(5)(v) for the year involved plus 2 percentage points; or (2) the "annual percentage increase" specified in § 423.104(d)(5)(iv), rounded to the nearest $50. We also noted that the new provisions in section 1860D–2(b)(4)(B)(i) of the Act require us to calculate the annual out-of-pocket threshold for 2020 and later as if no change had been made to the calculation of the out-of-pocket threshold for 2014 through 2019 under the ACA. Thus, we proposed to amend § 423.104(d)(5)(iii) to reflect this requirement.

In our November 2010 proposed rule, we noted the ACA also amended section 1860D–22(a)(2)(A) of the Act by adding a provision with regard to the actuarial equivalence of retiree prescription drug plan coverage to standard coverage. Specifically, the new provision requires that when attesting to the actuarial equivalence of the plan's prescription drug coverage to defined standard coverage, qualified retiree prescription drug plans not take into account the value of any discount or coverage provided during the gap in coverage that occurs between the initial coverage limit during the year and the out-of-pocket threshold for defined standard coverage under Part D. We proposed to codify this new requirement in § 423.884(d).

As indicated in section II.A. of this final rule, the regulations implementing these provisions are effective 60 days after the date of display of the final rule.

Comment: Several commenters expressed support for this provision and the proposed new definitions for "applicable drug," "applicable beneficiary" and "coverage gap." Two commenters urged us to provide stakeholders, including beneficiaries and independent pharmacists, with educational materials regarding program implementation as early as possible.

Response: We appreciate the commenters' support and we agree with those who encouraged us to provide educational materials to inform stakeholders of the changes to close the coverage gap for applicable beneficiaries.

Comment: We received many comments regarding various aspects of the Medicare coverage gap discount program.

Response: Since these comments pertain to the coverage gap discount program as specified in section 1860D–14A of the Act, rather than to the revisions to the Part D benefit structure specified in section 1860D–2(b) of the Act that were the subject of the November 2010 proposed rule, we believe these comments are outside the scope of the proposed rule. However we plan, to address the comments as appropriate in any future rulemaking regarding the coverage gap discount program.

Comment: One commenter requested that the regulatory language define the amount that will be counted toward the beneficiary's true out-of-pocket (TrOOP) cost when the "generic" gap cost-sharing is applied.

Response: We do not believe there is a need to address this issue in regulation. The amount of the applicable beneficiary's TrOOP for generic drugs in the coverage gap will be the coinsurance amount specified in § 423.104(d)(4)(i) and paid by the beneficiary, another individual on the beneficiary's behalf, or by a TrOOP-eligible payer under § 423.100.

Comment: Several commenters recommended revisions to our proposed definition of the term "applicable drugs." Two commenters suggested we exclude all "authorized generics" from the term and one commenter recommended we clarify whether or not the term includes "authorized generics." Another commenter requested we specify that a drug may be an "applicable drug" for a particular applicable beneficiary if the drug is provided through an exception or appeal to that particular applicable beneficiary.

Response: We believe "applicable drug" means all drugs approved under new drug applications (NDAs) and this includes those "authorized generics" licensed by sponsors of NDAs. It is our understanding that while most "authorized generics" are approved under NDAs, others may be approved under abbreviated new drug applications (ANDAs). However, only those "authorized generics" licensed by sponsors of NDAs are applicable drugs. To avoid confusion, we are defining "applicable drug" with respect to an applicable beneficiary as a Part D drug

that is approved under an NDA. We are also removing the superfluous parenthetical phrase that was inadvertently included in the proposed definition.

We agree with the commenter requesting that we specify that drugs provided through an exception or appeal are applicable drugs only for that particular beneficiary. As a result, we are revising the final clause in the definition to state that the drug "is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary."

Comment: One commenter indicated the part of the proposed definition of "applicable beneficiary" that addresses claims that straddle or span the benefit phases is confusing and should be deleted.

Response: We believe it is important to reference straddle claims in the definition of an applicable beneficiary. However, we agree that the punctuation in the proposed definition was incorrect and the source of potential confusion. As a result, we are retaining the clause pertaining to claims that straddle or span the benefit phases and revising the punctuation to clarify that this clause is part of the definition.

Comment: One commenter noted that, in the definition of "coverage gap" we should state that for purposes of applying the initial coverage limit, sponsors must apply their plan specific initial coverage limit under enhanced alternative benefit designs in addition to the basic alternative and actuarially equivalent benefit designs referenced in the proposed definition.

Response: We agree with the commenter and will revise this definition in the final rule to include a reference to enhanced alternative benefit designs.

Comment: One commenter suggested that we clarify that, in addition to dispensing fees, vaccine administration fees are not included in the definition of negotiated price and, therefore, should be excluded from the cost sharing reductions in the coverage gap.

Response: We agree with the commenter. In prior subregulatory guidance, we expressed our belief that vaccine administration fees are analogous to dispensing fees for purposes of the coverage gap discount program and, therefore, must be excluded from the definition of negotiated price for purposes of determining the applicable discount. We noted that unlike sales tax, dispensing fees, and vaccine administration fees pay for services apart from of the applicable drug itself. This is made clear by the fact that a vaccine administration fee may be billed separately from the dispensing of the vaccine. Further, as the commenter points out, the definition of negotiated price would not include a vaccine administration fee billed by someone other than the pharmacy.

Therefore, in finalizing the proposed rule, we will also exclude the vaccine administration fee from the cost sharing reductions and revise the regulatory language in § 423.104(d)(4)(ii) to specify coinsurance in the coverage gap is based on actual cost minus the dispensing fee and any vaccine administration fee.

We also clarify that the reductions to cost sharing in the coverage gap specified in § 423.104(d)(4) apply only to "applicable beneficiaries" by revising the title of this paragraph to "Cost-sharing in the coverage gap for applicable beneficiaries."

Comment: One commenter recommended that when attesting to the actuarial equivalence of a qualified retiree prescription drug plan's coverage to the defined standard coverage, the plan sponsor be permitted to account for the value of drug discounts and/or coverage provided during the coverage gap.

Response: As noted in the preamble to our November 2010 proposed rule, the ACA amended section 1860D–22(a)(2)(A) by adding a new provision requiring that when attesting to the actuarial equivalence of the plan's prescription drug plan coverage to defined standard coverage, qualified retiree prescription drug plans not take into account the value of any discount or coverage provided during the gap in coverage that occurs for defined standard coverage under Part D. Thus, this is a statutory requirement and we cannot accept the commenter's recommendation.

Comment: One commenter recommended that we permit Part D sponsors to use actuarially equivalent copayments as alternatives to the coinsurance amounts for generic drugs in the coverage gap as the enrollee cost-sharing is phased down to 25 percent in 2020.

Response: We agree with the commenter that § 423.104(d)(4)(ii)(B) of this regulation will permit actuarially equivalent cost sharing for generic drugs in the coverage gap. However, we believe that there is a high degree of risk associated with permitting actuarially equivalent copayments for generic drugs in the coverage gap. Due to significant variations in price for generic drugs and the coverage level for these drugs during the first few years of the transition to 25 percent cost sharing, actuarially equivalent co-payments for these drugs will often be higher than the actual cost for commonly used generic drugs. As a result, we are concerned that the majority of beneficiaries will not benefit from the cost sharing reductions in the coverage gap if we permit actuarially equivalent co-payments for these drugs.

We believe that the risk associated with permitting actuarially equivalent co-payments will be mitigated once coverage for generic drugs in the coverage gap reaches a reasonable coverage level for actuarial equivalence. We note that Chapter 4 of the Medicare Managed Care Manual Section 50.1 provides that for an Original Medicare item or service to be considered a reasonable benefit, cost-sharing for that service cannot exceed 50 percent of the plan's financial liability for the benefit. Consistent with this policy, we believe that 50 percent would be a reasonable benefit level at which to permit actuarial equivalence. Therefore, we anticipate permitting actuarially equivalent co-payments in the coverage gap for drugs that are not applicable (that is, generic drugs) starting in 2018 when beneficiary cost sharing for these drugs will be below 50 percent.

For these reasons, we will continue our current policy of not accepting actuarially equivalent co-payments in the coverage gap for drugs that are not applicable (that is, generic drugs) until 2018.

We are finalizing this provision with the amendments previously noted.

19. Payments to Medicare Advantage Organizations (§ 422.308)

In our November 2010 proposed rule, we proposed the revisions to the regulations described below in order to reflect changes in payment rules specified in statute and implemented in the Annual Announcement of MA Capitation Rates and MA and Part D Payment Policies.

a. Authority To Apply Frailty Adjustment Under PACE Payment Rules for Certain Specialized MA Plans for Special Needs Individuals (§ 422.308)

In our November 2010 proposed rule, we noted that section 3205 of the ACA provides the Secretary with the authority to apply a frailty adjustment to payments to certain Special Needs Plans (SNPs) that meet our definition of a fully integrated dual-eligible special needs plan at § 422.2, and have a similar average level of frailty as the PACE program, starting with plan year 2011. The statute permits the Secretary to apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of such section), rather than the

payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

We proposed that payments to Fully Integrated Dual Eligible SNPs that qualify for frailty adjusted payment continue to be calculated using the existing MA payment rules under which all SNPs are paid, with the sole exception of the application of a frailty adjustment. Further, we stated that the new law continued to allow us to use the same methodology to adjust payment to take into account the frailty of SNP enrollees as we use for the PACE program.

As the Secretary determines the adjustment methodology for frailty, which frailty scores will be considered "similar" to PACE program, and how to measure the "average level of frailty of the PACE program," we noted that we will announce any changes to the methodology used to pay for frailty, as well as how we determine PACE program averages, and which SNPs have similar levels of frailty to the PACE program, in the Advance Notice and Rate Announcement for the plan year in question.

In order to have a frailty score that can be compared to the PACE program, we proposed requiring MA organizations sponsoring a dual eligible SNP that meets our definition of a fully integrated dual-eligible SNP to fund any survey used by us to support the calculation of frailty scores. Moreover, we proposed requiring the survey to be fielded such that we can calculate a frailty score at the plan benefit package level for each SNP in question (currently the counts of limitations on activities of daily living (ADLs) used to calculate frailty scores are taken from the HOS or HOS–M), and to adhere to the methodological requirements of any such survey.

Comment: A commenter suggested that CMS should either allow the frailty adjustment to all plans based on a given set of criteria or drop it for all plans. In addition, another commenter suggested that CMS consider applying frailty adjustment on an individual basis instead of at the plan level.

Response: By law, we must use the same payment methodology for all MA plans, except as explicitly provided for in statute. Section 3205 of the ACA changed the law to permit CMS to make frailty-adjusted payments only to certain D–SNPs—those fully integrated dual-eligible special needs plans, as defined in § 422.2., that have similar average levels of frailty as the PACE program. We have considered making frailty payments to all MA plans, but decided that, given the use of the survey-based data collection method, that calculating frailty scores for every PBP across the entire industry was prohibitive. Further, frailty would need to be applied on a budget neutral basis. Given the survey-based methodology used for measuring frailty, a method of reliably calculating individual level frailty scores is not possible. We have explored other methods of measuring frailty, all of which posed substantial challenges to calculating accurate payments.

Comment: Several commenters requested that CMS provide specific and transparent criteria that would be used to determine those plans eligible for frailty in determining similar average frailty levels as PACE, including providing to plans actual frailty scores, the data to be used to calculate the scores and the source of the data, recommended criteria such as using a range of PACE frailty scores, using the same survey methods and data for both populations, and not basing the comparison on an average frailty across all PACE organizations, and requested that CMS provide plans with the eligibility criteria for frailty adjusted payments before plans are required to request participation in PBP level HOS surveys and before they submit their Notices of Intent to offer a Fully Integrated Dual Eligible SNP in the next contract year.

Response: We appreciate these comments and concerns; however, as required by law, CMS provides information on our payment methodology in the Advance Notice and Rate Announcement for the plan year in question.

Comment: A few commenters suggested that the intent of this provision in the ACA was to provide a frailty factor adjustment to all legacy SNPs (that is, the dully integrated plans in Minnesota, Wisconsin and Massachusetts that serve as models for SNP integration).

Response: Section 3205 of the ACA permits CMS to make frailty-adjusted payments to certain D–SNPs—those fully integrated dual-eligible special needs plans, as defined in § 422.2, that enroll beneficiaries with similar average levels of frailty the PACE program, and does not refer to specific plans to which it is to be applied.

Comment: One commenter expressed concerns regarding the requirement to have plans pay for the survey and urges CMS to be flexible in coordinating with and using ADL assessments from the states.

Response: It is a contract requirement that plans are financially responsible for the surveys that support measurement of their performance and quality, including the Consumer Assessment of Health Plan Satisfaction (CAHPS) and Health Effectiveness Data and Information Set (HEDIS), and for reporting payment-related data. The responsibility to finance the HOS is similar. Since SNPs bid and are paid at the Plan Benefit Package (PBP) level, CMS must be able to calculate a frailty score at the PBP level. Further, our frailty payment methodology is based on surveying plan enrollees to determine the plan's average frailty level and the use of assessments conducted by the plans was specifically ruled out in the development of this methodology. Therefore, we must require survey sampling at the PBP level, rather than coordinating with States.

Comment: A few commenters agree with the clarification provided regarding which plans will be eligible for frailty adjusted payments because they meet the definition of "fully integrated dual eligible SNP" as well as the "similar average frailty levels" as PACE plans eligibility criteria.

Response: We appreciate the support expressed for the proposed new provisions.

Comment: Several commenters inquired about the methodology and implementation of the HOS and CHAPS surveys.

Response: We appreciate these commenters' concerns. We will take these comments under advisement in the next survey update.

After considering the comments received, we are adopting § 422.308(a) as proposed into this final rule.

b. Application of Coding Adjustment (§ 422.308)

In our November 2010 proposed rule, we noted that the ACA adds new statutory language clarifying our existing authority to adjust risk scores for coding trends in the FFS sector, under CMS's general authority to conduct risk adjustment in an actuarially equivalent manner under 1853(a)(1)(C)(i) of the Act. Further, this new language extends the mandate that CMS adjust risk scores for differences in coding patterns between MA plans and FFS beyond 2010.

Previously, in accordance with the Deficit Reduction Act of 2005 (DRA), the Secretary was expressly required to conduct an analysis of the differences in FFS and MA coding patterns in order to ensure payment accuracy, and that such analysis was to be completed in time to ensure that the results of such analysis were incorporated into the risk scores

for 2008 through 2010. The ACA made four modifications to this requirement for analysis: (1) The analysis must now be conducted annually; (2) the data used in the analysis is to be updated as appropriate; (3) the results of the analysis are to be incorporated into risk scores on a timely basis; and (4) the application of an adjustment for differences in coding patterns is extended until the Secretary implements risk adjustment using Medicare Advantage diagnostic, cost, and use data.

Moreover, we mentioned that the ACA added two additional requirements to the DRA-mandated requirements. First, the ACA requires that the coding adjustment factor for 2014 be not less than the coding adjustment factor applied for 2010 plus 1.3 percentage points; for each of the years 2015 through 2018, not less than the coding adjustment factor applied for the previous year plus 0.25 percentage points; and for 2019 and each subsequent year not less than 5.7 percent. Second, the ACA requires the Secretary to apply the coding adjustment to risk scores until the implementation of risk adjustment using MA diagnostic, cost, and use data.

Comment: A commenter suggested that the coding intensity adjuster should be modified each year using payment adjustments from the RADV audit process which could be used to determine industry wide averages to estimate industry-wide accuracy. After making this modification, the coding adjuster should then be adjusted downward given that plan payments will be adjusted for inaccuracy through the RADV audits.

Response: As we have noted in previous guidance documents such as the Rate Announcements, the MA coding adjustment factor is not intended to adjust for inaccurate coding in a particular instance, and the specific affects on an individual's risk score, but for the impact on risk scores of coding patterns that differ from FFS coding, the basis of the CMS–HCC model and the Part C normalization factor. RADV audits have the purpose of validating that diagnosis codes submitted for risk adjustment are documented in the medical record and, therefore, are correctly reported for the beneficiary in question.

Comment: One commenter suggested that there should not be a minimum coding adjustment per year and that more detailed information should be released on the coding adjustment calculations for the industry to review.

Response: The minimum adjustment factors are specified in law. For additional information regarding our coding adjustment methodology, please refer to the 2010 Advance Notice and Announcement, published on February 20, 2009 and April 6, 2009, respectively. Any updates to our methodology will be published in the appropriate future Advance Notice.

After considering the comments we received, we are adopting § 422.308 (b) as proposed into this final rule.

c. Improvements to Risk Adjustment for Special Needs Individuals With Chronic Health Conditions (§ 422.308)

In the November 2010 proposed rule, we proposed for 2011 and subsequent years, for purposes of the adjustment under section 1853(a)(1)(C)(i) of the Act, using a risk score for chronic SNP enrollees that reflects the known underlying risk profile and chronic health status of similar individuals, as the Secretary is required to use such risk score instead of using the default risk score that is otherwise used in payment for new enrollees in MA plans.

The risk score developed for this purpose will be used in calculating payments for a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

We proposed for 2011 and periodically thereafter, for the Secretary to evaluate and revise the risk adjustment system under this subparagraph in order, as accurately as possible, to account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions. We also noted that we will publish in the Rate Announcement, as described under section 1853(b) of the Act, a description of any evaluation conducted during the preceding year and any revisions made under such clause as a result of such evaluation.

Comment: Several commenters supported the provisions in the ACA that require the Secretary to evaluate and revise the risk adjustment system in order to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions, as well as to publish as part of an announcement a description of any evaluation conducted during the preceding year and any revisions made as a result of such evaluation. In addition, several commenters pointed out that improving risk adjustment will decrease plan cherry-picking of healthier beneficiaries, improve the plans' incentive to focus on costs, reduce unnecessary costs and stop overpaying for low risk beneficiaries and underpaying for high risk beneficiaries.

Response: We appreciate the support expressed for the provision for an evaluation of the risk adjustment model.

Comment: A few commenters urge CMS to implement some risk adjustment model changes in 2012 and more in 2013 in addition to implementing the methodologies announced in the 2011 Advance Notice.

Response: We continually work to develop improvements to the risk adjustment model. Changes to the model for a particular year are discussed in that year's Advance Notice.

Comment: Several commenters recommended that we consider persistency of multiple comorbid chronic conditions and one suggested CMS use 2 years of data in the model beginning in 2012.

Response: We do not believe that using 2 years of data in the risk adjustment model will improve the risk scores, largely because a model developed using 2 years of diagnostic data would lower the model values for chronic conditions and decrease the predictive power of the model for those with conditions under treatment. While, theoretically, such a model may help plans that do not code well, CMS prefers that plans enrollees are seen by providers and that current diagnoses are documented as part of those visits.

Comment: One commenter recommended that CMS engage in active dialogue with MA organizations to permit CMS to consider MAO experience with these populations.

Response: We appreciate these comments and look forward to working with MAOs on this issue.

Comment: A few commenters expressed that they had no knowledge of any current evaluations performed by CMS evaluating the adequacy of the current risk adjustment methodology or of any CMS research exploring alternative methods of risk adjustment that would include methods such as frailty and disability factors, drug utilization information, or using multiple years of data to calculate risk scores, while a few other commenters expressed that they strongly support the provisions in the ACA, however, note that the proposed rule does not provide

any additional clarity about how CMS intends to implement these policies.

Response: We evaluate the performance of the model regularly. Please refer to the following publications for information on model development and performance: *http://www.cms.gov/HealthCareFinancingReview/Downloads/04summerpg119.pdf*. The ACA specified that the evaluation be published as part of the Announcement. We are planning to publish the evaluation in the 2102 Announcement, published on April 4, 2011.

Comment: One commenter requested that no delays in the evaluation be caused by the collection of encounter data.

Response: We appreciate the commenter's concern. Evaluations of the risk models are ongoing and are not related to the collection of encounter data.

Comment: A few commenters requested that CMS recognize problems in the 10 decile analysis for high risk chronically ill beneficiaries as the model inappropriately treats high spending chronically ill beneficiaries as healthy causing them to be assigned to a lower than "true" risk decile.

Response: We measure model predictive strength by comparing predicted costs to actual costs. We typically group beneficiaries into risk deciles, meaning that we create ten equal-sized groups of beneficiaries, ranging from the group with the highest predicted costs to the group with the lowest predicted costs. For each risk-based group, we then create ratios of predicted costs to actual costs. Using predictive ratios, we find that the CMS–HCC model performs well. Comparing predictive ratios across beneficiaries grouped by actual costs (as the comment implies) is not an actuarially sound way to look at the ability of the model to accurately predict costs. If one looks at the cost data retrospectively (after the fact) the result will always be that high cost beneficiaries are under-predicted as high cost is largely due to random events. Determining whether the costs associated with beneficiaries predicted to be high, medium or low cost is the only actuarially sound way to evaluate the risk adjustment model.

Comment: A commenter inquired as to whether the new C–SNP policy applies only to new Medicare Beneficiaries or to all existing Medicare beneficiaries who are newly enrolling in a C–SNP—and recommended that qualifying for the C–SNP should trigger the assumed payment adjustment.

Response: Current law requires the implementation of the new enrollee model for C–SNPs to apply only to new Medicare beneficiaries.

Comment: One commenter urged flexibility in expanding on the intent of the ACA in the area of risk adjustment for persons with chronic illness, and recommended that the process should apply to all SNPs, noting that persons under age 65 who become eligible for Medicare do so because of a disability and the duals under age 65 are even more likely to have a long history of chronic as well as disabling conditions. They are also more likely to have co-occurring mental health needs and the current risk adjustment system unfairly assumes these "new to Medicare" beneficiaries are healthier than their history shows.

Response: We believe that absent explicit statutory authority we cannot pay Dual or Institutional SNPs differently from regular MA plans. Further, we are not considering applying differential new enrollee risk scores to all SNP enrollees. We believe that for Dual-eligible and Institutional SNPs' our evidence shows that the new enrollee risk scores in the CMS–HCC model are adequate to address the aggregate risk faced by these plans because the current new enrollee risk score model captures the additional costs due to Medicaid and disabled status. In creating the C–SNP new enrollee model, we found that the new enrollee age/sex factors had a similar increment regardless of Medicaid status. This finding indicates that the costs for Medicaid and by age group (including the disabled) are fully accounted for in the current new enrollee model.

Comment: A commenter recommended that prior claims data, currently available through the Medicaid program, be used to set payment upon entry to a SNP.

Response: We disagree with the comment. New enrollee risk scores account for the average risk of the new enrollee population, and already account for additional costs attributable to Medicaid status with an explicit Medicaid status marker. Medicaid status for new enrollees is based on concurrent status in the payment year. This means that a dual Medicare/Medicaid enrollee to an MA plan (SNP or regular MA plan) receives an increment that is adjusted for their age/sex and Medicaid status in the payment year.

After considering the comments we received, we are adopting § 422.308(c) as proposed into this final rule.

20. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate (§ 422.252, § 422.258, and § 422.266)

a. Terminology (§ 422.252)

We proposed revising § 422.252 by adding two new terms and revising one term. We proposed adding the terms "new MA plan" and "low enrollment contract." A new MA plan means, for the purpose of quality ratings under § 422.258(d)(7) (discussed below), with respect to a year, a plan offered by an organization or sponsor that has not had a contract as an MA organization in the preceding 3-year period. A low enrollment contract is a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS®) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

We also proposed revising the definition of Unadjusted MA area-specific non-drug monthly benchmark amount. Effective for 2012, the MA area-specific non-drug monthly benchmark amount is the blended benchmark amount determined according to the rules set forth under § 422.258(d). In addition, this revision clarifies that rate-setting rules for county capitation rates are specific to a time period, as set forth at § 422.258(a). Finally, this revision further clarifies that the term "unadjusted" refers to a standardized amount, reflecting a risk profile based on the national average.

We received no comments on these proposals and therefore are finalizing these provisions without modification. We are also adopting the definitions proposed for "new MA plan" and "low enrollment contract" in § 422.252 in this final rule.

b. Calculation of Benchmarks (§ 422.258)

Section 3201(b) of the ACA establishes a new blended benchmark as the MA county rate, effective 2012, and section 3201(c) of the ACA establishes quality-based increases to the blended benchmark. To implement these rate-setting rules, we proposed to amend § 422.258(a) and § 422.258(c)(3), and add a new paragraph § 422.258(d), which sets forth the provisions for MA blended benchmarks, including increases to the benchmarks for quality bonuses at § 422.258(d)(7).

Section 3201(b)(2) of the ACA introduces section 1853(n) of the Act, which creates a new type of county capitation rate, the "blended benchmark amount" for an area for a year, which also must be—used to determine MA

plans' service area-level benchmarks. Effective 2012 onward, the blended benchmark will be set at some percentage of the county's average FFS expenditure (the FFS rate). There are two components of the blended benchmark: the applicable amount determined under section 1853(k)(1) of the Act and described at § 422.258(d)(1); and the "specified amount" introduced at section 1853(n)(2) of the Act and described at § 422.258(d)(2). The two components must be combined using weights that are specific to the phase-in period assigned each area (county), according to rules set forth at sections 1853(n)(1) and (n)(3) of the Act and implemented at paragraphs (d)(8) and (d)(9) of § 422.258 of the regulations. At the conclusion of an area's phase-in period, the blended benchmark for the area for a year will be the area's specified amount under section 1853(n)(2) of the Act.

Specified Amount. Section 1853(n)(2) of the Act, as implemented by proposed § 422.258(d)(2), (d)(3), and (d)(4), sets forth the formula for the specified amount and the rules for tabulating the components of the formula. Specifically, the specified amount is the product of two quantities: the base payment amount defined at section 1853(n)(2)(E) of the Act (adjusted to carve-out the indirect medical education (IME) amount, as required at section 1853(k)(4)) of the Act and implemented at § 422.306(c); and the applicable percentage defined at section 1853(n)(2)(B) of the Act and implemented at § 422.258(d)(4).

The base payment amount for an area for 2012 is the average FFS expenditure amount determined for 2012, as specified in § 422.306(b)(2). For subsequent years, the base payment amount for an area is the average FFS expenditure amount specified in § 422.306(b)(2), which includes the requirement to rebase (update with more recent data) the FFS rates no less frequently than every 3 years.

The applicable percentage is one of four values assigned to an area (a county) based on our determination of the quartile ranking for the previous year of the area's average FFS expenditure amount (described at § 422.306(b)(2)) relative to this amount for all counties. The FFS rate used for the quartile ranking must be net of the IME amount determined under § 422.306(c) for the year. For the 50 States or the District of Columbia, counties whose FFS rates (net of the IME amount for the year) fall in the highest quartile of all such amounts for the previous year receive an applicable percentage of 95 percent, while counties falling in the second highest quartile receive an applicable percentage of 100 percent, counties falling in the third highest quartile receive an applicable percentage of 107.5 percent, and counties falling in the lowest quartile receive an applicable percentage of 115 percent.

After establishing the basic formula for the specified amount and setting the rules for calculating its components—the base payment amount and the applicable percentage, sections 1853(n) and (o) of the Act provide additional rules for determining the applicable percentage for a county for a year. There are four sets of rules: (1) When to re-rank the county FFS rates to determine whether some counties receive quartile reassignments; (2) how to transition a county from one quartile assignment to another; (3) how to assign a county its transition period of 2, 4, or 6 years, whereby at the conclusion of the transition period, the county's blended benchmark equals 100 percent of the specified amount; and (4) under what conditions the applicable percentage shall be increased to provide quality bonus payments to qualifying plans. The first three types of rules are discussed here, and the fourth rule on quality bonuses is discussed in the next section on paragraph § 422.258(d)(7).

First, section 1853(n)(2)(C) of the Act, implemented at § 422.258(d)(5)(i), provides that the quartile ranking of all county FFS rates (net of the IME carve-out) for a contract year must be re-ranked whenever the FFS rates for the year prior to the contract year are rebased FFS rates, per the rebasing rule set forth at § 422.306(b)(2). Second, section 1853(n)(2)(D) of the Act, implemented at § 422.258(d)(5)(ii), provides that for a year after 2012, if there is a change in a county's quartile ranking for a contract year compared to the county's ranking in the previous year, the applicable percentage for the area for the year shall be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision. Third, sections 1853(n)(2) and (n)(3) of the Act, implemented at § 422.258(d)(8) and (d)(9) respectively, establish the methodology that we must use to assign one of three transition periods to each county—a 2-year, 4-year, or 6-year transition to phase-in the blended benchmark amount to be equal to 100 percent of the specified amount. Assignment of a phase-in period is determined by the size of the difference between the 2010 applicable amount under section 1853(k)(1) of the Act at paragraph (d)(1) and "the projected 2010 benchmark amount" at (d)(8)(i), which is a quantity created at section 1853(n)(3)(C) of the Act solely for the purpose of assigning a transition period to each county. The projected 2010 benchmark amount is equal to one-half of the 2010 applicable amount and one-half of the specified amount; the latter is calculated as if the 2012 effective date for the specified amount were instead 2010. This modified specified amount for 2010 is the product of two quantities: The 2010 base payment amount adjusted as required under § 422.306(c); and the applicable percentage, which is determined under the rules set forth at proposed paragraph (d)(8)(ii)(B). Specifically, all applicable percentages are increased as if all counties were in qualifying plans in 2010 for the purpose of calculating the projected 2010 benchmark amount (thus adding 1.5 percentage points to each county's applicable percentage). Further, we must determine a list of 2010 qualifying counties using the criteria set forth for 2012 onward in proposed paragraph (d)(7)(ii), thus further increasing the applicable percentage of this subset of 2010 counties an additional 1.5 percentage points.

Once the special quantity "projected 2010 benchmark amount" is compared to the 2010 specified amount under section 1853(k)(1) of the Act, the phase-in assignments are made as follows. A county is assigned a 2-year phase-in period if the difference between the applicable amount and the projected 2010 benchmark amount is less than $30, a 4-year phase-in period if the difference is at least $30 but less than $50, and a 6-year phase-in period if the difference is at least $50.

Finally, section 1853(n)(3), implemented at § 422.258(d)(8), sets forth the rules for calculating the blended benchmark depending on the assigned phase-in period. For counties assigned the 2-year phase-in period, the blended benchmark for 2012 is the sum of one-half of the applicable amount at paragraph (1) and one-half of the specified amount at paragraph (2); and or subsequent years, the blended benchmark equals the specified amount. For counties assigned the 4-year phase-in period, the blended benchmark is calculated as follows: For 2012 the blended benchmark is the sum of three-quarters of the applicable amount for the area and year and one-fourth of the specified amount for the area and year; for 2013, it is the sum of one-half of the applicable amount for the area and year and one-half of the specified amount for the area and year; for 2014 it is the sum

of one-fourth of the applicable amount for the area and year and three-fourths of the specified amount for the area and year; and for subsequent years, the blended benchmark equals the specified amount. For counties assigned the 6-year phase-in period, for 2012, the blended benchmark is the sum of five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year; for 2013 it is the sum of two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year; for 2014 it is the sum of one-half of the applicable amount for the area and year and one-half of the specified amount for the area and year; for 2015 it is the sum of one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and year; for 2016 it is the sum of one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and year; and for subsequent years, the blended benchmark equals the specified amount.

Table 4 Blended Benchmark Calculations

	Two Year County Blend		Four Year County Blend		Six Year County Blend	
Year	Pre-ACA	ACA	Pre-ACA	ACA	Pre-ACA	ACA
2012	1/2	1/2	3/4	1/4	5/6	1/6
2013	0	100%	1/2	1/2	2/3	1/3
2014	0	100%	1/4	3/4	1/2	1/2
2015	0	100%	0	100%	1/3	2/3
2016	0	100%	0	100%	1/6	5/6
2017	0	100%	0	100%	0	100%

Comment: One commenter requested that CMS offer plans more information on how payments will be calculated, for example what years will be used for the calculations. *Response:* Detailed payment calculations are available in the Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, published on February 18, 2011 and the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, published on April 4, 2011. These documents are available on the CMS Web site at: *http://www.cms.gov/MedicareAdvtgSpecRateStats/.*

Comment: Several commenters asserted that while counties are distributed evenly across the 4 quadrants, enrollment is skewed heavily toward the top 95 percent quartile. In order to address the inequities inherent in the new benchmark methodology, these commenters recommend that CMS examine alternative benchmark-setting formulas, such as re-stratifying the quartiles based on enrollment numbers, so as to address the disadvantaged plans in the 95 percent quartile that maintain a significant proportion of MA beneficiaries. Additionally, the commenters asserted that the FFS quartile rule causes problems at the cusps of the quartiles, due to the arbitrary drawing of a line between 2 FFS rates that may only be $0.20 different, with the result that gets 107.5 percent of the FFS rate, and the other only 100 percent of the FFS rate. The commenters recommend that CMS study alternative benchmark methodologies to address inequities in the current formula.

Response: The calculation of the blended benchmark and the quartiles are specifically laid out in 1853(n). Any changes to the calculation would require Congressional action.

We are finalizing this provision without modification. We are also adopting § 422.258 as proposed in this final rule.

c. Increases to the Applicable Percentage for Quality (§ 422.258(d))

We proposed regulations reflecting the new statutory requirements that, as of January 1, 2012, provided for increases in MA plan benchmarks based on an MA plan's score under a star quality rating system. For the purposes of this preamble, we refer to these quality-based increases in MA benchmarks as quality bonus payments (QBPs) for MA plans. The 5 star rating system that serves as the basis for making the bonus payment must be based on quality information collected by us under authority of section 1852(e) of the Act.

The blended benchmark for 2012 and future years reflects the level of quality rating at the organization or contract level that will be set forth in a notice to MA organizations for the calendar year in question. As discussed in section II.B.20.b of this final rule, the blended benchmark has two components—the applicable amount and the specified amount. Under the formula set forth in the ACA, a qualifying organization that receives 4 or more stars on a 5 star rating system would receive an increase in the specified amount component of the blended benchmark amount of 1.5 percentage points in 2012, 3.0 percentage points in 2013 and 5.0 percentage points in 2014 and in subsequent years. A qualifying organization in a qualifying county will receive double the applicable percentage increase. A qualifying county is defined as a county that has an MA capitation rate that, in 2004, was based on the amount specified in subsection c1b for a Metropolitan Statistical Area (MSA) with a population of more than 250,000; has at least 25 percent of MA eligible individuals enrolled in MA organizations as of December 2009; and has a per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year. The ACA specified that a new MA contract will receive an increase in the specified amount component of the blended benchmark amount of 1.5 percentage points in 2012; 2.5 percentage points in 2013; and 3.5 percentage points in 2014 and in subsequent years. The ACA provided that MA organizations that fail to report data as required by the Secretary would be counted as having a rating of fewer than 3.5 stars at the organization or contract level.

We proposed that the 5 star ratings system that will be used would be based on the Plan Rating system currently in place for beneficiary information and to identify contract performance issues. Under the Plan Rating system, if an MA–PD organization offers health and drug benefits, both Part C and Part D summary ratings scores are generated. In the Fall of 2010, MA–PDs received a combined Part C and D summary rating to summarize overall contract performance with respect to health and drug issues. This combined rating is used to determine the new QBPs based on quality for MA organizations offering prescription drug coverage. The Part C summary rating is used to determine the QBPs for MA only contracts.

As previously discussed, under § 422.252, we proposed definitions of a low enrollment contract and a new MA plan for the purpose of identifying qualifying organizations eligible to receive a bonus payment. Low enrollment contracts will be qualifying plans for 2012 and in subsequent years. For the purpose of awarding 2012 QBPs, we proposed to define low enrollment contracts as those that could not undertake HEDIS® and HOS data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan. Under the ACA, new MA plans that meet criteria specified by the Secretary are also treated as qualifying organizations for the purposes of QBPs. We proposed to define a new MA plan as an MA contract offered by a parent organization that has not had another MA contract in the previous 3 years; these contracts will qualify for the QBP. Under our proposal, other MA contracts that open in a given year, but have had other contracts offered by the parent organization in the prior 3 years, would be assigned a star rating based on the average enrollment-weighted performance of the other contracts offered by the parent organization to reflect the overall performance of the organization.

In the proposed rule we discussed our plan to transform the rating system in future years in order to advance more ambitious and comprehensive quality improvement objectives. These objectives will include greater emphasis on demonstrable improvements in beneficiary access to care, beneficiary health status and outcomes, beneficiary satisfaction and engagement, prevention and management of chronic conditions as well as coordination across the continuum of care. By designing the MA quality rating system around these types of objectives, we expect to encourage and incentivize MA plans and affiliated providers to transform their delivery systems and processes to provide beneficiaries with high-quality and efficient care. Ultimately, we seek to design the MA quality rating system to ensure that Medicare beneficiaries enrolled in MA organizations receive efficient, high quality care and services every time. Future quality agenda and measurement development will be designed to ensure that MA organizations lead the healthcare industry in providing cutting edge, integrated and coordinated care for our beneficiaries using evidence-based and demonstrable metrics.

We also discussed potential guiding principles for the MA quality agenda. For instance, these principles could be based on aims from the 2001 Institute of Medicine (IOM) Report "Crossing the Quality Chasm: A New Health System for the 21st Century." From this IOM Report, the six aims that have been described are a framework for the MA Quality Strategic Plan. The IOM Report provides the following definitions for the six aims: Safe is defined as avoiding injuries to patients from the care that is intended to help them. Effective refers to providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit. Patient-centered is providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. Timely is defined as reducing waits and sometimes harmful delays for both those who receive and those who give care. Efficient is avoiding waste, including waste of equipment, supplies, ideas, and energy. Equitable is providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status (IOM, 2001).

As a part of developing our long-term quality strategy, we discussed our work to identify measures that can be implemented in the near term to further the MA quality agenda. Looking beyond the 2012 Plan Ratings, we are exploring using measures, such as reportable adverse events and hospital acquired conditions, which are submitted via the Part C reporting requirements, and all-cause readmission rates. We are also examining the use of alternative measurement sets (for example, Assessing Care of Vulnerable Elders (ACOVE)), exploring the use of data collected in other settings (for example, data from the Hospital Inpatient Quality Reporting Program, formerly known as Reporting Hospital Quality Data for the Annual Payment Update (RHQDAPU)), considering incorporating encounter data into quality measures, and are considering development of additional outcome measures designed specifically for MA. The NCQA is also developing measures of ambulatory care sensitive conditions that we will look to implement as they become available.

Further, beyond broadening the goals of the MA quality rating system, for instance by incorporating more outcomes-based measures, we also discussed our desire to continually raise performance targets, so as to incentivize continual quality improvement across established metrics of performance and quality. We invited public comment on appropriate performance and quality benchmarks, and what approach should be used for updating these benchmarks, including frequency of updates. Additionally, we invited public comment on what types of principles or objectives that we should adopt for the MA quality rating system over the longer term. For instance, are there specific frameworks or elements that we should adopt from the National Quality Forum (NQF), National Committee for Quality Assurance (NCQA), the Agency for Healthcare Research and Quality (AHRQ) or other experts in this field? How should these objectives evolve over time so the rating system rewards continual improvement and innovation on the part of MA organizations?

Comment: Several commenters raised concern that the 5 star rating system for Plan Ratings is moving away from clinical measures and more towards regulatory compliance measures. Specifically, it was noted that the star rating system should be an appropriate mix of measures with an emphasis on giving greater weight to clinical or outcome measures that better reflect health outcomes. Another commenter was concerned that Part D measures inordinately weight the Part C and D summary calculations; the commenter suggested that CMS weight Part C and D measures based on the contribution towards health care quality.

One commenter encouraged CMS to consider new and revised metrics that focus more on patient care and experiences and less on administrative segments. Items listed that should receive priority include patient safety and reduction in preventable medical errors, hospital infections and re-admissions, to name a few. This commenter wants CMS to provide opportunities to comment on proposed measures on an annual basis. One commenter suggested that CMS refrain from adding additional measures to the star rating system at this time and recommended that CMS continue to rely

upon the existing indicators to allow plans to focus improvement efforts accordingly. Another commenter stated that many of the evaluation measures in the Staying Healthy domain focus on early detection instead of primary prevention. Also, this commenter suggested that measures should be used that emphasize patient safety and efficiency of care, consistent with the IOM's *Crossing the Quality Chasm* report.

Response: We are committed to continuing to improve the Part C and D quality performance measurement system to increase focus on improving beneficiary outcomes, beneficiary satisfaction, population health, and efficiency of health care delivery. To that end, CMS has been working on developing a more robust system to measure quality and performance of Part C and D contracts. As new measures are developed and adopted, they will be incorporated into the Plan Ratings published each year on the Medicare Plan Finder Web site.

We view the MA quality bonuses also referred to as value-based payments as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations. As we add measures to the Plan Ratings over time, we will consider the following principles:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. We seek to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align its measures with the adoption of meaningful use standards for health information technology, so the collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Our strategy is to continue to adopt measures that are nationally endorsed and are in alignment with the private sector as we do today through the use of measures developed by NCQA and the Pharmacy Quality Alliance (PQA), and the use of measures that are endorsed by NQF.

As we modify the calculation approaches for the Plan Ratings, we are incorporating the following principles:

- Contracts should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

A high priority for the 2012 Plan Ratings is to weight the outcome and clinical measures more than performance measures such as call center measures. This change would limit the impact of performance measures as well as create more incentives for MA plans to improve their outcome measures. Additionally, we are exploring incorporating additional measures focusing on health outcomes in the Plan Ratings. Potential outcome measures currently under consideration for incorporation into the Plan Ratings include: all-cause readmission rates and MA mortality rates. We will provide opportunities for comment on proposed measures annually through the draft Call Letter.

We believe that the current set of quality measures are not driving quality improvement as much as they could be. Many of the existing measures have been collected and reported to CMS for more than 10 years, such as HEDIS®, HOS, and CAHPS, so plans have had ample opportunity to focus on quality improvement. Given the increased focus on the star ratings, we are reevaluating the set of measures included in the star ratings.

In determining whether additional measures will be added to the star rating system, we will consider the value of the proposed measure in improving the star ratings and how it supports the IOM's six aims. These aims state that healthcare delivery should be safe, timely, effective, efficient, equitable and patient-centered. These aims will serve as a framework for selecting additional measures and making methodological enhancements to the Plan Ratings. The comment that new measures should focus on patient safety and efficiency of care is a good point, and one we need to consider in working with NCQA, PQA, and other consensus-building organizations in developing new measures.

The MA quality agenda will also be coordinated with the national priorities for quality that are being set as part of the ACA. As the national priorities for quality are shaped, the MA quality agenda will be aligned with these priorities. We are working on the MA quality agenda and have also established an agency-wide Quality Working Group Advisory Panel. Senior CMS leadership has convened this panel to facilitate the coordination of the CMS quality initiatives in support of the development of the HHS National Strategy for Quality that is required by the ACA. This working group will ensure that the MA quality agenda aligns with other components within CMS and with HHS' national goals. CMS' participation in the HHS-wide Interagency Quality Measures Workgroup will also further ensure that MA quality measures are developed in a coordinated way across the Department.

Accordingly, based on the preceding, we proposed to amend § 422.258 to add a new paragraph (d)(7) to reflect our authority to make bonus payments based on quality. Under § 422.252, we also proposed definitions of "low enrollment contract" and "new MA plan" for the purpose of identifying qualifying organizations eligible to receive a bonus payment.

While the regulations in this section will implement the QBP provisions specified in the ACA on a permanent basis, for CYs 2012 through 2014, MA payment will be determined under the terms of the national QBP demonstration project. Details on the demonstration are provided on CMS' Web site. During the demonstration, the rules for determining QBPs set forth in the ACA and in this final regulation will be waived, and QBPs will instead be determined under the terms of the demonstration.

Comment: We received a number of comments on the QBP Demonstration.

Response: Because this rulemaking establishes permanent regulations implementing the QBP system provided for in the ACA, the proposed regulations did not reflect the terms of the QBP Demonstration. Information on this demonstration project was made available for comment in the Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, which was published on February 18, 2011. We responded to comments in the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, published on April 4, 2011. Both documents are available on the CMS Web site at: *http://www.cms.gov/MedicareAdvtgSpecRateStats/*.

Comment: Numerous commenters supported and encouraged CMS to develop the QBPs, including the current nationwide demonstration program in a fully transparent manner, while emphasizing patient-reported information in the star rating system. The commenters request information regarding the measures used to assess performance, including the method used to weight, score, determine cut points and four-star thresholds, identify benchmarks, and other details be fully disclosed to the public. Further, commenters recommended that CMS continue to include beneficiaries and their representatives in conversations regarding QBPs.

Response: The measures used to assess performance for MA plans are derived from four sources: (1) CMS administrative data; (2) surveys of beneficiaries; (3) plan-reported data; and (4) CMS contractor data. For each contract, and each individual measure, CMS groups the range of actual contract scores for each measure into one of the 5 star groupings and assigns a star-rating score based on a 5 star scale. In establishing individual measure star ratings, we consider whether the measure is intended to achieve a specified regulatory performance standard; if not, we examine the contract's performance on a measure relative to all other contracts' performance on the same measure. The segmentation of scores into groups is based on statistical techniques that minimize the distance between scores within a grouping and maximize the distance between scores in different groupings. Once the star rating of 1 through 5 for each measure is known, a summary score for the contract is computed by calculating a simple average of the individual measure ratings, and adding small consistent bump-up amounts to the average if a contract demonstrates consistency in 3, 4, or 5-star ratings among measures. More details on the methodology to calculate the star ratings are available through the technical notes that are available at *http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp*. The technical notes describe in detail how the star ratings are derived for each of the individual measures, domains, summary ratings, and the overall rating. To ensure contracts are fully aware of future enhancements to the Plan Ratings and have an opportunity to comment on the changes, we will include in the draft and final Call Letter expected changes in the star ratings 1 to 2 years in advance. We will also provide additional information through HPMS memos and presentations to the plans on User calls.

Comment: Some commenters recommended creating a separate star rating system for SNPs with SNP-specific measures that more accurately reflect the quality of care delivered by SNPs. The commenters argued that this will place more focus on the needs of their targeted populations. Some specific suggestions were to create "transitional star ratings" for SNPs until the current star ratings can be modified and to add one-half stars to SNPs that attain thresholds on SNP-specific measures.

Response: We understand that SNPs would like to be rated using SNP-specific measures and would like to be judged using different standards to account for their special populations. We anticipate adding some SNP-specific measures in the 2012 Plan Ratings. As part of the "Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2012 Call Letter," published on February 18, 2011, CMS sought comment on the feasibility of creating a methodology to incorporate SNP-specific measures into Plan Ratings. We are taking into consideration feedback we received as we continue to study SNP-specific measures.

In terms of using different standards for the SNPs, we do not agree and want to ensure performance standards are consistent across all contracts. That said, we typically case-mix adjust measures when the data originate from beneficiary surveys and we will continue to determine the need for case-mix adjustments of any outcome measures added over time. We do not believe a transitional system is needed as we are moving towards adding SNP-specific measures in the coming year.

Comment: Some commenters expressed concerns about the appropriateness and reliability of the HOS data in the star rating system. One commenter urged CMS to work with health plans, providers, and patients to reconsider the best mix of measures for the star rating system.

Response: There has been a published, peer-reviewed independent evaluation of the HOS in 2004 that found that it provides a rich and unique set of reliable data *http://www.hqlo.com/content/2/1/33*. For all measures, we will continue to examine the quality of the data and measure accuracy, validity, and stability. For those measures that are not proven to be reliable and valid, we will determine whether they are appropriate "display measures," which would appear on www.cms.gov but not be used in the plans' star ratings.

Comment: A few commenters recommended that the star ratings be made more equitable by taking geographic and demographic variations into account. One commenter recommended incorporating measures of care coordination, care transitions, readmissions, shared decision-making, health literacy, patient activation, and FFS/MA comparison into the star rating system.

Response: As we pursue more outcome measures, we will ensure that measures are case-mix adjusted. Currently, measures that originate from beneficiary surveys are case-mix adjusted. CMS does not consider geographic differences by themselves as sufficient reasons for adjusting Plan Ratings so every state or region may have a 5 star plan. However, CMS is exploring the feasibility of adjusting for provider shortages, such as Health Professional Shortage Areas (HPSAs).

We are also currently exploring the feasibility of incorporating potential survey measures of care coordination, care transitions and patient activation as well as an all-cause readmissions measure into the star rating system. In terms of the FFS and MA comparisons, we are working internally to identify additional FFS comparison measures.

Comment: Several commenters recommended that CMS periodically evaluate the star rating system and the measures selected for inclusion in the star rating system in order to reflect ongoing evolution of measures and to ensure that the system is more accurate, consistent, and transparent.

Response: We strongly agree with the need to periodically evaluate the star rating system. Given the need for the star ratings to adapt quickly to changes in clinical practices and the state-of-the-art in quality measurement, we plan to each year evaluate the measurement set. We will provide information in the draft and final Call Letters about specific expected changes in the star ratings system.

Comment: One commenter urged CMS not to factor Part D measures into the benchmarks. They argue that since benchmarks are established based on healthcare services provided, adding Part D measures into the benchmarks will not reveal an accurate reflection of the contracts' performance.

Response: Drug services are part of the continuum of care provided by MA organizations so are included in the overall rating.

Comment: A few comments expressed concern about how Medicare Cost contract organizations that convert to MA contracts will be treated for star rating and QBP purposes. It was suggested that instead of treating such converted organizations like other new MA organizations, CMS should recognize the star rating track record the organization earned as a Medicare Cost contractor and use this rating as the basis for the QBP until the converted organization can generate an MA track record.

Response: The contract number of a Medicare Cost contract which converts to an MA organization does not change. Since these cost contracts are required to collect and report the same data as MA contracts, they should have the data needed to continue to receive a star rating. The only difference is that they will be included in the list of contracts that receive a QBP rating because of their new organization type designation.

Comment: One commenter supported the implementation of enhanced, high-quality Medication Therapy Management (MTM) programs as a component of the quality rating system.

Response: For the 2013 Plan Ratings, we are developing MTM-specific measures.

Comment: A commenter asked for an explanation of the rationale for a new and small plan receiving enhanced payments prior to proving that corresponding level of performance.

Response: Under the ACA, the Secretary is required to consider a low enrollment contract that does not have sufficient data to compute a quality rating to be a "qualifying plan" and receive the QBP and that a new MA plan, defined as a plan offered by an organization or sponsor that has not had an MA contract in the prior 3-year period, would qualify for the QBP.

Comment: One commenter expressed concern that HEDIS® specifications for certain measures are inappropriate, irrelevant, potentially harmful and/or not validated by medical literature. For example, self-reported measures when the beneficiary is cognitively impaired or mentally ill were noted.

Response: Each HEDIS® measure does have specific exclusions relevant for that measure that NCQA has determined by the standards of care for that condition and each measure has gone through rigorous clinical review. Additionally, proxy respondents are allowed for the beneficiary surveys. More information about HEDIS® specifications can be found in the HEDIS® 2011 Technical Specifications, Volume 2.

Comment: One commenter questioned whether Plan D sponsors are rated using old data that may not be statistically accurate.

Response: We use the most recent data available in updating each measure. These data represent the best available measures of a plan's performance or quality of care. Some of the data we collect are based on statistical sampling. When samples are used, the sample sizes are chosen to ensure that we produce reliable estimates of true performance.

Comment: A few commenters stated that Part D plans achieve very different star ratings for identical services that are performed by the same Pharmacy Benefits Manager (PBM).

Response: The star ratings assigned to each contract are based on the service or performance in the specific measures, and therefore may differ across contracts associated with the same PBM or other entity. For example, the measures within the Drug Pricing and Patient Safety domain utilize each contract's enrollees' prescription drug event (PDE) data; this is separate and independent of a PBM's function as a Pharmacy & Therapeutics (P&T) committee, claims adjudicator, or exceptions/appeals processor for multiple Part D contracts. Enrollees' utilization patterns differ among contracts, thus the resulting star ratings for contracts will differ.

Comment: One commenter was concerned that the demonstration project would award low performing contract a QBP. The same commenter asked if the weighting can produce anomalous results.

Response: The demonstration project builds on the QBPs authorized in the ACA by providing stronger incentives for contracts to improve their performance thereby accelerating quality improvements during the 3-year period of the demonstration. Since the star ratings we are using for QBPs are the overall rating which combines both Part C and D measures, there are some contracts that have done poorly in Part C or Part D for each of the past 3 years (2.5 stars or below), but their overall rating was a 3. In most cases the Part D measures brought up the overall summary rating to a 3. This is an issue for the demonstration, but not for the ongoing QBP program since contracts after the demonstration will not receive a bonus if they have 3 stars. As changes are made in the weighting of clinical and outcome measures, these anomalies are likely to lessen.

Comment: One commenter suggested that CMS develop outcome measures relevant to Program of All-Inclusive Care for the Elderly (PACE) and institute QBPs for PACE programs.

Response: PACE programs are not MA plans and according to statute do not qualify for QBPs.

After consideration of the public comments we received, we are finalizing § 422.258(d) as proposed.

d. Beneficiary Rebates (§ 422.266)

The final rule for calculation of beneficiary rebates implements section 3202(b)(1) of the ACA, which reduces the amount of beneficiary rebate, and ties the level of rebate to a plan's star rating for quality of performance.

Section 3202(b)(1) of the ACA changes the share of savings that MA plans must provide to enrollees as the beneficiary rebate specified at § 422.266(a). Specifically, this provision mandates that the level of rebate is tied to the level of a plan's star rating for quality of performance. Under the new provisions, the highest possible rebate, for plans with a 4.5 star rating or higher, is set at 70 percent of the average per capita savings. The rebate is reduced further for plans with lower star ratings for a year. These new provisions are phased-in from 2012 through 2014. The demonstration project mentioned in section II.B.20.(c). of this final rule will not affect the rebate percentages associated with a particular star rating, under the terms of the ACA.

We revised § 422.266 by first redesignating paragraph (a) as paragraph (a)(1), and amending it to apply to years 2006 through 2011. We further added paragraph (a)(2), which sets forth the rebate determination rules for 2012 and subsequent years. Section 422.266(a)(2)(ii) states that for 2014 and subsequent years, the final applicable rebate percentage (the percentage applied to the savings amount to determine the rebate amount) is 70

percent in the case of a plan with a quality rating under such system of at least 4.5 stars; 65 percent in the case of a plan with a quality rating of at least 3.5 stars and less than 4.5 stars; and 50 percent in the case of a plan with a quality rating of less than 3.5 stars.

Section 422.266(a)(2)(i) describes the transition period during which the old 75 percent rule at paragraph (a)(1) will be phased-out and the (a)(2)(ii) rules phased in. For 2012, the rebate percentage equals the sum of: two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan or contract under paragraph (ii), based on the plan's star rating for the year. For 2013, the rebate percentage equals the sum of: ⅓ of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan or contract based on the plan's star rating for the year.

Section 422.266(a)(2)(iii) describes the rules for low enrollment contracts. For 2012, the ACA requires that low enrollment contracts shall be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount. Section 422.266(a)(2)(iii) describes the rules for new MA plans. For 2012 or a subsequent years, a new MA plan defined at § 422.252 that meets the criteria specified by us for purposes of § 422.258(d)(7)(v) must be treated as a qualifying plan under paragraph (7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

Comment: One commenter recommended that CMS allow part of the bonus to be reinvested into the carrier's quality program.

Response: The rebate amount must be credited to one of the uses described in section 1854(b)(1)(C) of the Act, as described in the Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter, published on February 18, 2011 and the Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, published on April 4, 2011. These documents are available on the CMS Web site at: *http://www.cms.gov/MedicareAdvtgSpecRateStats/*. Quality improvement program costs are legitimate administrative costs and can be added as such to the plan's bid.

Comment: One commenter urged CMS to analyze the effect of rebate reduction on duals. The commenter believes that since the quality metrics are not scaled in any way by the risk of the population, beneficiaries in plans with high concentrations of complex needs will see a downward trend of available benefits.

Response: We will consider analyzing the effect of rebate reduction on duals. However, as stated previously, the statute at 1854(b)(1)(C) explicitly sets out the savings that MA plans can provide and star rating that the rebate is tied to. Any change to this formulation would require Congressional action.

We are finalizing this provision without modification. We are also adopting § 422.266 as proposed in this final rule.

21. Quality Bonus Payment and Rebate Retention Appeals (§ 422.260)

As noted in the proposed rule, while the ACA provisions establishing the QBP system do not specify a process for requesting an administrative review of the star ratings, historically, we have made an administrative review process available to MA organizations for certain payment determinations. Pursuant to our statutory authority to establish MA program standards under section 1856(b)(1) of the Act, we proposed to implement a process through which MA organizations may request an administrative review of their star rating ("QBP status") for QBP determinations. We proposed that this review process would also apply to the determinations made by us where the organization's Plan Rating sets its QBP status at ineligible for rebate retention.

For calendar years 2012 through 2014, we proposed that QBP payments would be awarded under the terms of a demonstration project; thus, we proposed these regulations would not take effect until after the demonstration project has terminated. We requested comment regarding our proposal to delay the effective date of the appeals process set forth in this final rule until after the end of the demonstration.

We received no comments on this specific proposal; however, based on other comments regarding the appeals process we are aligning the appeals process in the regulation with the administration review process that will be used under the demonstration project.

While we proposed to reserve the right to use the same star rating that applies to the Plan Rating for QBP determinations, we will provide MA organizations notice each year regarding their QBP status. QBP determinations would be considered made, subject to the appeal rights described in this section, when the notice of QBP status is released. We proposed MA organizations would have 5 calendar days from the date of CMS' release of QBP determinations to request from CMS a technical report explaining the development of their QBP status. As stated in the proposed rule, if, after reviewing the technical report, the MA organization believes that we were incorrect in its QBP determination, the MA organization may request an appeal to be conducted by a hearing officer designated by CMS. The organization would be required to make such a request within 7 calendar days of the MA organization's confirmed receipt of the technical report. We proposed the scope of the hearing would be limited to challenges of CMS' application of its QBP determination methodology to the appealing MA organization and, in very limited instances, the accuracy of the data we used to make the QBP determination. As a result, the appeals process would not be used as a means to challenge the validity of the adopted methodology. We also proposed limiting the scope of the hearing officer's consideration to data sets that have not been previously subject to independent validation. We solicited comments on whether this is an appropriate limitation on the scope of a QBP status appeal.

Comment: One commenter would like to be able to appeal audited data.

Response: The auditor and contract work together throughout the entire audit. Any questions about the data or the auditor's assessment of the plan are discussed and documented during the audit, and all resolutions are documented. A contract should raise any concerns with respect to audited data during their audit process. HEDIS® audits, for example, ensure accurate, reliable and publicly reportable data. For this reason, NCQA encourages the organization to collect data simultaneously with the audit. A concurrent audit lets the auditor detect errors in the organization's data collection process while there is time for the organization to correct its methods and minimize the possibility of *Not Reportable* rates.

As provided in the proposed rule, the hearing officer's decision would be final and binding on both the MA organization and CMS. In the event that the hearing officer finds that CMS' QBP determination was incorrect, we would be obligated to recalculate the organization's QBP status based on the hearing officer's findings. We proposed to maintain the right to revise an MA organization's QBP status at any time after the initial release of the QBP determinations through May 15 of each

year. We indicated that we may take this action on the basis of any credible information, including the technical report issued pursuant to the process identified here, which demonstrates that the initial QBP determination was incorrect. We are revising the date that CMS may, on its own initiative, revise an MA organization's QBP status after the initial release of the QBP determinations. While changes may occur after this date based on appeals of QBP status, CMS, on its own initiative, will only have through April 1 of each year to make changes to an MA organization's QBP status. This change will afford MA organizations more time to incorporate their QBP status into their plan bids, due to us by the first Monday in June. Additionally, we did not propose another level of administrative review beyond the hearing officer. We solicited comment on the need for an independent contractor-level review prior to an appeal to be conducted by a hearing officer designated by CMS or an Administrator-level review.

Comment: One commenter recommended that CMS have a three-level appeals process to ensure contracts have a robust mechanism to appeal (such as, Level 1 would be a request for reconsideration, Level 2 would be a request for a hearing, and Level 3 would be a request for CMS Administrator review). Another commenter recommended a second level of appeal for QBP determinations.

Response: Based on these comments, we are strengthening the administrative review process for MA organizations that appeal their star ratings for QBP. We are aligning the process in the regulation with the process used during the demonstration. We will modify § 422.260(d) to create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record. MA organizations will no longer be requesting a technical report from CMS detailing the data and measures used to determine the QBP; however, as part of the reconsideration determination, MA organizations will receive information about how their star rating for the given measure in question was calculated and/or what data was included in the measure. The MA organization may appeal the reconsideration official's decision regarding its QBP status by requesting an informal hearing. The informal hearing will be conducted by a CMS hearing officer on the record.

Comment: A number of commenters requested more than 5 calendar days to submit a request for a technical report and additional days to request the appeal. Some commenters requested extension of the 5 calendar day window to 7 to 15 days, with clarification of calendar or business days.

Response: The timeframes are tight given we want to resolve any issues prior to contracts submitting their bids to CMS. However, in order to be responsive to this concern, we are revising the timeframes. MA organizations will have 10 business days from the time we issue the notice of QBP status to submit a request for reconsideration. MA organizations will have 10 business days after the issuance of the reconsideration determination to request an informal hearing on the record.

Comment: One commenter expressed concern that the appeals process is not fully transparent.

Response: The appeals process is outlined in this regulation. Also, each year MA contracts will receive additional details through HPMS memos about the timing for submitting an appeal.

Comment: A few commenters requested that CMS send technical reports to all contracts, without them having to request one.

Response: The technical notes published at *http://www.cms.gov/PrescriptionDrugCovGenIn/06_PerformanceData.asp* have detailed information about how each of the star ratings is calculated. Also, contracts may request information about how their scores were calculated at any time by e-mailing CMS at *PartCratings@cms.hhs.gov.*

Comment: A commenter requested that Medicare Cost contracts be permitted to submit requests for Technical Reports and have appeal rights.

Response: Medicare Cost contracts may request any additional information during the plan preview for Plan Ratings or at any time by e-mailing CMS at *PartCratings@cms.hhs.gov.* The appeals rights under this regulation are related to using the star ratings for payment for QBPs. Medicare cost contracts are not eligible for QBPs since they are not considered MA contracts.

Based on the comments, we are revising the proposed § 422.260(c) and § 422.260(d) to create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record. We are also extending the timeframes for requests.

C. Clarify Various Program Participation Requirements

The provisions in this section of the final rule clarify existing regulations or implement new requirements consistent with existing policy guidance to assist sponsoring organizations with attaining the goals of the Medicare Advantage and Prescription Drug Benefit programs. These clarifications are detailed in Table 5.

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TABLE 5: Provisions to Clarify Various Sponsor Program Participation Requirements

PROVISION	PART 422		PART 423	
	Subpart	Section	Subpart	Section
Clarify Payment Rules for Non-Contract Providers	Subpart E	§422.214	N/A	N/A
Pharmacist Definition	N/A	N/A	Subpart A	§423.4
Prohibition on Part C and Part D Program Participation by Organizations Whose Owners, Directors, or Management Employees Served in a Similar Capacity with Another 0rganization that Terminated its Medicare Contract within the Previous 2 Years	Subpart K	§422.506 §422.508 §422.512	Subpart K	§423.507 §423.508 §423.510
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	N/A	N/A	Subpart K	§423.509
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	Subpart M	§422.562 §422.566	Subpart M	§423.562 §423.566
Compliance Officer Training	Subpart K	§422.503	Subpart K	§423.504
Removing Quality Improvement Projects and Chronic Care Improvement Programs from CMS Deeming Process	Subpart D	§422.156	N/A	N/A
Definitions of Employment-Based Retiree Health Coverage and Group Health Plan for MA Employer/Union-Only Group Waiver Plans	Subpart C	§422.106	N/A	N/A

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1. Clarify Payment Rules for Non-Contract Providers (§ 422.214)

In our November 2010 proposed rule (75 FR 71223), we proposed adding a new paragraph (c) to § 422.214 to clarify that a request for payment from an MA organization by a non-contracted provider who is paid using a prospective payment system (PPS) methodology under Original Medicare is deemed to be a request to be paid at the Original Medicare payment rate unless the provider has notified the MA organization in writing that it wishes to bill less than the Original Medicare payment amount. We proposed this provision to codify the guidance for plans and out-of-network providers in CMS' Out-of-Network Payment Guide released February 25, 2010. This guidance, which was responsive to questions we had received about this issue, reflects CMS' longstanding policy that if a non-network facility such as a hospital, skilled nursing facility, or home health agency renders services which were not arranged by the plan, a non-private-fee-for-service MA organization may pay the lesser of the Original Medicare amount or a lower billed amount if it is clear that the provider is billing for less than the Original Medicare rate. The guidance also clarified that when a provider of services that is paid under a PPS system under Original Medicare submits the same information to an MA organization that it would submit to Original Medicare for the services in question, this should be considered a bill for the PPS amount (and not the "billed" or "charge" amount from the claim) that Original Medicare would pay in the case of the same submission.

We also proposed adding a new paragraph (d) to § 422.214 to clarify that an MA organization offering a regional PPO MA plan must always pay non-contracted providers at least the Original Medicare payment rate in those

portions of its service area where it is meeting access requirements by non-network means under § 422.111(b)(3)(ii). This is consistent with the Medicare access requirements at section 1852(a)(2)(A) of the Act—which specify that an MA plan may meet access requirements if it pays providers at the Original Medicare payment rate.

After considering the comments received, we are finalizing these provisions as proposed.

Comment: One commenter asked CMS to clarify that our proposed policy that a non-contracted provider's request for payment be deemed to be a request for the Original Medicare payment rate, unless the provider expressly notifies the MA organization in writing that it is billing a lesser amount, does not preclude health plans from negotiating payment terms with contracted providers. Another commenter requested clarification that MA plans can negotiate payment terms with providers for more than Original Medicare rates. Another commenter recommended that our proposed policy be applied in the Medicaid program such that non-contracted provider payments are limited to no more than what the provider would receive under the State's Medicaid fee-for-service program.

Response: Our proposed policy does not preclude MA plans from negotiating payment terms with providers. It implements section 1866(a)(1)(O) of the Act, which applies only where no agreement on payment levels is in place. Extending our proposed policy to the Medicaid program would be beyond the scope of this regulation, which only addressed payments to non-contracted providers for Medicare services provided to MA enrollees.

2. Pharmacist Definition (§ 423.4)

Pursuant to our authority under section 1860D–4(b)(3)(A)(i) and 1860D–4(c)(2)(A)(i) of the Act, we proposed to codify our understanding that, for purposes of the Part D program, a pharmacist is an individual with a current, valid license to practice pharmacy issued by the appropriate regulatory authority of any of the states or territories of the United States or the District of Columbia (DC) (collectively referred to as United States authorities). We proposed adding a definition for the word pharmacist to § 423.4 in Subpart A to reflect this understanding.

The change was prompted by recent Medicare Part D sponsor audit findings in which we found that at least some Part D sponsors were relying on pharmacists not licensed by United States authorities to make clinical judgments associated with the administration of the Part D benefit. As Medicare provides coverage for services throughout the United States, beneficiaries should be able to expect that individuals making clinical decisions related to their access to pharmaceuticals are experts in United States pharmaceutical practice. Requiring pharmacists to be licensed by United States authorities will help guarantee that Part D sponsors meet these expectations.

Comment: CMS received support for codifying this definition from numerous pharmacy associations, industry, and patient/beneficiary advocacy organizations.

Response: We agree with these commenters and appreciate the widespread stakeholder support for this definition. We received only supportive comments for this proposal; therefore, we are finalizing this provision without modification.

3. Prohibition on Part C and Part D Program Participation by Organizations Whose Owners, Directors, or Management Employees Served in a Similar Capacity With Another Organization That Terminated Its Medicare Contract Within the Previous 2 Years (§ 422.506, § 422.508, § 422.512, § 423.507, § 423.508, and § 423.510)

In the April 2010 final rule (75 FR 19678), we modified § 423.508 by adding two paragraphs stating that: (1) As a condition precedent to CMS' consent to a mutual termination, CMS requires language in the termination agreement prohibiting the sponsor from applying for new contracts or service area expansions for a period of up to 2 years absent special circumstances warranting special consideration; and (2) that as a necessary condition to contract as a Part D sponsor, an organization must not have terminated a contract by mutual consent within the 2 years preceding the application. Similar modifications were made for the MA regulations at § 422.508. These changes ensured consistency across all situations in which a sponsor elects— through non-renewal, termination, or mutual termination— to discontinue its participation in the Part C or Part D programs.

In the proposed rule, we proposed to amend the 2-year new contract prohibition in both § 422.508 and § 423.508 by adding a new paragraph entitled "Prohibition against Part C [and Part D] program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that terminated its Medicare contract within the previous 2 years." We also proposed similar clarifying language to the existing language at § 422.506, § 422.512, 423.508, and § 423.510. We stated our belief that to carry out the intentions of the 2-year exclusion we would need to ensure that new contracting organizations are not actually repackaged versions of the same organizations that elected to discontinue their participation in the Part C and Part D programs. Therefore, we proposed to implement a requirement which would allow us to determine whether the primary players in the organization submitting the new application are the same as those in an organization that has recently non-renewed, terminated, or mutually terminated a Medicare contract.

We noted that the proposed requirement would assist CMS in prohibiting and preventing such organizations from gaming the Medicare program by reapplying for a contract as a new organization during the 2-year ban, when the applying organization has common ownership and management control. This proposed requirement would help to ensure that the provisions of the 2-year application prohibition are given full effect.

Therefore, we proposed that the 2-year ban on new Part C or Part D sponsor contracts to which non-renewing, terminating, or mutually terminating organizations are currently subject under the regulation be expanded to include organizations owned or managed by an individual (referred to as a covered person) who served in a similar capacity for a previously terminated or non-renewed Part C or Part D organization. To implement this provision, we proposed to require as part of the contract application process, that applicants supply CMS with full and complete information as to the identity of each covered person associated with the organization. In the proposed rule we defined covered persons to include—

- All owners of applicant organizations who are natural persons (other than shareholders who: (1) Have an ownership interest of less than 5 percent; and (2) acquired the ownership interest through public trading). In addition, is a natural person who is an owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the entity; or

• An officer or member of the board of directors or board of trustees of the entity, if the entity is organized as a corporation.

We solicited comments on whether plan sponsors, or other stakeholders consider the definition of 5 percent or more as truly representing current market conditions. We requested comment on this section because we do not want to arbitrarily decide on the percentage of interest the previously mentioned persons could have in an organization, especially if this percentage does not reflect standard business practices.

We proposed to amend § 422.508 and § 423.507 to make the 2-year exclusion applicable to organizations for which any covered persons were also covered persons for the excluded organization. We also proposed to make similar amendments to § 422.506, § 422.512, § 423.508, and § 423.510.

Comment: Several commenters stated that the definition of covered persons was too broad, and that it should not encompass senior executives of the excluded organization. They noted that in many instances, these executives were not responsible for the organization's decision to terminate or non-renew a Medicare contract, but were simply honoring their fiduciary duty to carry out the instructions of the sponsor's ownership. The regulation as proposed would unfairly limit the opportunities for these senior executives to obtain employment with other Medicare Advantage organizations or PDP sponsors as those employers may not want limit their ability to apply for new Medicare business by hiring such individuals. Also, the proposed language may also prompt senior executives to seek other employment when Medicare contract termination or non-renewal is even discussed within their organization to ensure that they preserve their eligibility for employment with the broadest possible range of other Medicare Advantage organizations or PDP sponsors.

Response: We agree that the definition of covered person, as proposed, is too broad. CMS' intention in drafting the provision was to make certain that organizations subject to the two-year application prohibition did not evade the restriction by simply forming a new corporation. Based on these comments, we have further clarified our thinking to conclude that the focus of the restriction should be on those individuals with absolute responsibility for control of and an ownership stake in the business decisions of the terminating and non-renewing sponsors—the owners of more than 5 percent of the shares of the sponsor and the members of the board of directors. Therefore, we have decided to modify the definition of covered person to delete the term "officer * * * of the entity" in the final rule.

Comment: One organization commented that the inclusion of individuals who own less than 5 percent of the total number of shares of a sponsor's stock acquired other than through public trading in the definition of covered person was unnecessarily broad and would unfairly include individuals who receive shares through an organization's employee stock ownership program.

Response: This comment is based in part on a typographical error in the proposed rule as published at § 422.506(a)(5)(i)(A), § 422.508(d)(1)(i), and § 422.512(e)(2)(i)(A). We intended for the prohibition to apply to individuals who own *more than* 5 percent of the shares of the sponsoring organization. However, in some parts of the proposed rule, the standard was mistakenly stated as *less than* 5 percent. In the final rule, we have corrected the error to make more than 5 percent the standard for stock ownership. Also, we acknowledge that making a distinction between stock shares obtained through public trading and shares obtained through all other means, as we proposed, would create an irrelevant and confusing distinction. This proposed provision was intended to restrict the ability to resume participation in the Medicare Advantage and Part D programs of individuals who could exercise control over a terminating or non-renewing organization through their ownership of a significant portion of the organization. We believe the level of an individual's control is established by the percentage of shares owned, not by the source of those shares. Therefore, we are also modifying the proposed rule to delete the language excluding shareholders who acquired their stock through public trading from classification as covered persons.

Comment: One organization expressed its concern that the inclusion of members of a terminating or non-renewing sponsor's board of directors in the definition of covered person would unfairly restrict organizations with overlapping board membership from eligibility to submit applications. The commenter noted that this could be a problem especially for subsidiaries of the same parent organization where this kind of arrangement is common.

Response: We believe that the arrangement the commenter described represents one of the situations we intended to address through this regulatory change. In drafting this provision, we are trying to make certain that the parties that were responsible for a decision to terminate or non-renew a Part C or D sponsor contract do not subvert the 2-year application prohibition by submitting a new application through the use of a different legal entity over which they similarly exert control. As the commenter has not presented a justification as to why an organization controlled by many or all of the same individuals who controlled a terminating or non-renewing organization should not be subject to the two-year application ban, we are making no change in the final rule to reflect this comment.

Comment: Two commenters asked that we clarify whether the new provision concerning covered individuals will apply to terminations only at the plan benefit package (PBP) level.

Response: The regulation change we make here is intended simply to define which individuals related to an organization already determined to be subject to the 2-year application restriction may cause a second organization to be similarly restricted when it has the same relationship with those individuals. The methodology CMS uses to determine whether organizations are subject to the two-year application restriction is outside the scope of the proposed regulatory change.

In summary, we received several comments on this proposal. In response to the comments opposing the inclusion of a contracting organization's senior management in the definition of a covered person, we have deleted the reference to officer from § 422.506(a)(5)(iii), § 422.508(d)(3), § 422.512(e)(2)(iii), § 423.507(a)(4)(iii), § 423.508(f)(3), and § 423.510(e)(2)(iii). Also, in response to the comments opposing the inclusion in the definition of covered person owners of small amounts of stock acquired other than through public trading, we deleted the phrase "acquired the ownership through public trading" from the proposed § 422.506(a)(5)(i)(B), § 422.508(d)(1)(ii), § 422.512(e)(2)(i)(B), § 423.507(a)(4)(i)(B), § 423.508(f)(1)(ii), and § 423.510(e)(2)(i)(B). We also corrected our typographical errors by replacing the statement "more than 5 percent with less than 5 percent" at the proposed § 422.506(a)(5)(i)(A), § 422.508(d)(1)(i), and § 422.512(e)(2)(i)(A), as we intended only to exclude from the definition of covered persons individuals whose ownership stake is less than 5 percent.

We received no responses to our request for comments concerning whether the use of the 5 percent ownership threshold for covered persons reflected current marketing conditions or standard business practices and have therefore otherwise made final this provision of the proposed rule.

4. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

Federal regulations at § 423.509(a) (1) through (a) (12) clearly define the circumstances under which we have the authority to terminate a Part D sponsor's contract. When we terminate a contract, we must have assurances that the terminated Part D sponsor will maintain sufficient staff and operations to make a smooth transition of the sponsor's enrollees to new Part D coverage in a fashion that facilitates continuity of care and fiscal responsibility. These responsibilities include providing timely documentation requested by CMS, retaining all documents for the periods specified in the Federal laws and CMS regulations (see § 423.505(d) and (e)) and otherwise providing the resources necessary for an orderly transition of Medicare beneficiaries to their newly assigned or selected plan.

In order for a timely and orderly transition to occur, the terminated Part D sponsor must provide us with certain critical Medicare beneficiary data including information to identify each affected beneficiary, pharmacy claims files, true out-of-pocket (TrOOP) cost balances, and information concerning pending grievances and appeals. Data such as TrOOP balances are necessary to place the beneficiary in the correct drug benefit phase and provide the catastrophic level of coverage at the appropriate time.

The requirement to provide such data and files is already clearly articulated for voluntarily non-renewing Part D plan sponsors (§ 423.507(a) (4)); for contracts terminated by mutual consent (§ 423.508(d)); and for contracts terminated by the plan sponsor for cause (§ 423.510(f)). However, the regulation is currently silent regarding contracts terminated by CMS. Therefore, in order to protect both Medicare beneficiaries and CMS and to ensure that the requirement to provide such data and files is clear for all types of contract non-renewals and terminations, we proposed to add a new section (e) Timely transfer of data and files to § 423.509 (Termination of Contract by CMS) to state that should the Part D plan sponsor's contract be terminated by CMS, the Part D sponsor must ensure the timely transfer of any data or files. This language would inform Part D sponsors being terminated by CMS that they are required by Federal regulation to timely transfer all requested data and files to CMS or its designee for the required time as specified under § 423.505(d) and (e). Because the failure to provide this information directly harms beneficiaries, plans that fail to comply with this requirement may be subject to a Civil Monetary Penalty as defined in § 422.752(c) and § 423.753(c).

Comment: Several commenters expressed their support for this provision. One commenter recommended that we go even further by specifying through regulations the time period which terminated Part D sponsors have to transfer data and files.

Response: We appreciate the commenters' support of our proposal. Further specifying the time period for transfer of data in regulation is not possible because circumstances vary from one CMS-initiated termination to the next. We will provide timeframes in guidance to the affected sponsor upon termination.

Comment: One commenter wanted CMS to specify through regulations a plan for the smooth transfer of beneficiaries to a new Part D plan to ensure that patients retain access to needed medications, and that pharmacies and other downstream entities receive the reimbursement for which they are entitled once a Part D plan sponsor is terminated.

Response: As explained in the proposed rule this provision merely adds § 423.509(e) to the existing regulations conforming the rules regarding the timely transfer of critical beneficiary data for Part D sponsors being terminated under any circumstance, and does not address the transfer of beneficiaries nor reimbursement. While these are important concerns, they are outside the scope of these proposed revisions. We do, in fact, have protocols in place to ensure the smooth transfer of beneficiaries to other Part D coverage with minimal interruption in access to medications. With regard to reimbursement of pharmacies, the statute and regulations governing Part D provide for CMS to contract with entities that apply to be Part D sponsors and are determined qualified as provided in § 423.503. Once we evaluate and determine an applicant is qualified to be a Part D sponsor, that sponsor retains the ultimate legal responsibility for adhering to and otherwise fully complying with all terms and conditions of its contracts with downstream providers, such as pharmacies. Nevertheless, we have recently strengthened its ability to ensure that sponsors promptly pay pharmacies by codifying at § 423.520 a requirement that the contract between CMS and all Part D sponsors contain provisions obligating the sponsor to promptly pay claims. As a result, Part D sponsors that do not meet the prompt payment requirements of § 423.520 may be subject to contract compliance actions by CMS.

Having received only support for this proposal, we are therefore finalizing this provision without modification.

5. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

Based on sections 1852(g) and 1860D–4(g) of the Act, we have established procedures for making organization determinations and reconsiderations regarding health services under Part C, and for making coverage determinations and redeterminations regarding covered drug benefits under Part D. These requirements are codified in our regulations at part 422 subpart M and part 423 subpart M, respectively. In the proposed rule, we noted that although the Part C and Part D regulations require physician review of appeals of adverse organization determinations or coverage determinations, respectively, that involve medical necessity, the regulations do not specify who must conduct the initial determinations involving medical necessity. We proposed to modify our requirements in § 422.566 by adding a new paragraph (d) which would require organization determinations that involve medical necessity to be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of the Medicare program. We also proposed to require the physician or other health care professional to have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

As noted in the proposed rule, section 1860D–4(g) of the Act requires Part D plan sponsors to meet the requirements for processing requests for coverage determinations and redeterminations in the same manner as such requirements apply to Part C organizations with respect to organization determinations and reconsiderations. Consistent with the proposed changes to the Part C organization determination process, we

proposed similar changes to the Part D coverage determination process in new § 423.566(d).

Comment: Many commenters expressed strong support for this proposal as it relates to the Part C and Part D programs, but several of those commenters conditioned their support for the proposal on its applicability to only those cases where the plan's initial review (for example, by a non-clinician claims specialist) will result in an unfavorable decision. In other words, the commenters argued that if the initial review of the request will result in a favorable coverage decision for the enrollee, there is no need to involve a physician or other health care professional in reviewing the case. These commenters believe that the additional safeguards of this provision are only necessary if, based on the initial review of the request, the plan expects to issue an unfavorable decision.

Response: We acknowledge that it is common practice for an MA organization or Part D plan sponsor to use a claims specialist (who may not be a clinician) to conduct initial reviews of requests for organization and coverage determinations. We agree that if the initial review of an organization or coverage determination request will result in a fully favorable decision for the enrollee, the request does not require review by a physician or other appropriate health care professional. However, if the initial review of the request will result in the plan issuing a partially or fully unfavorable decision based on medical necessity, a physician or other appropriate health care professional must be involved in reviewing the request prior to the plan issuing a final decision. We believe this approach strikes an appropriate balance between ensuring that organization and coverage determination requests involving medical necessity decisions are subject to review by appropriate health care professionals and allowing MA organizations and Part D plan sponsors to appropriately and efficiently utilize health care professional staff resources. We revised proposed § 422.566 and § 423.566 to reflect this change.

Comment: Some commenters requested that CMS clarify that the statement appropriate health care professional includes a pharmacist for purposes of reviewing Part D coverage determinations involving medical necessity. A few commenters suggested that pharmacists be explicitly listed as health care professionals capable of reviewing medical necessity determinations.

Response: We do not believe it is necessary or advisable to explicitly list specific health care professionals who may appropriately review organization or coverage determinations involving medical necessity. The type of health care professional who may be appropriate to review a particular request will depend on the type of services being requested, related medical necessity issues, and whether the review is consistent with the health care professional's scope of practice under State law.

Comment: Some commenters asked that CMS clarify that the proposed change does not impose a requirement on plans to employ a particular number of physicians or other health care professionals for purposes of reviewing organization or coverage determinations. One commenter noted that the new requirement will result in undue increased cost to plans.

Response: We are not specifying the number or mix of physicians and other health care professionals MA organizations or Part D plan sponsors must employ or otherwise engage to review initial coverage decisions involving medical necessity. Plans are responsible for ensuring adequate staffing levels based on caseload mix and volume and other business factors. We believe that this flexibility, coupled with our clarification in the final rule that a physician or other appropriate health care professional must be involved in a medical necessity review only if the plan expects to issue an unfavorable decision significantly reduces or eliminates any potential burden to plan sponsors. We do not believe it is unreasonable or excessively burdensome for an MA organization or Part D plan to utilize the services of physicians and other health care professionals for medical review activities.

Comment: One commenter noted that, instead of requiring knowledge of the Medicare program as stated in the proposed rule, reviewers need only have knowledge of Medicare coverage requirements.

Response: We agree with the commenter that requiring knowledge of the Medicare program is unnecessarily broad, and that our primary expectation is based on reviewers having knowledge of Medicare coverage requirements. We are revising the proposed language accordingly. However, reviewers are expected to follow all applicable Medicare requirements, such as adjudication timeframes, in the performance of their duties. Plan sponsors are responsible for having adequate internal controls in place to ensure that their reviewers follow all of these requirements. Thus, this change does not in any way negate a plan sponsor's responsibility for ensuring compliance with Medicare's program requirements.

Based on our review and consideration of the comments received on this proposal, we are finalizing both § 422.566 and § 423.566 by revising them to include a new paragraph (d). Under new § 422.566(d) and § 423.566(d), if a plan expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request before the plan issues its decision. We also require the physician or other health care professional to have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

In a related proposal to enhance the plans' clinical decision making process, we also proposed to revise § 422.562(a) by adding paragraph (4) and to revise § 423.562(a) by adding paragraph (5) to require MA organizations and Part D plan sponsors, respectively, to employ a medical director who is responsible for ensuring the clinical accuracy of all decisions involving medical necessity. We also proposed that the medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. As noted in the proposed rule, we believe the requirement to employ a medical director will enhance the coordination and accountability of plan operations and strengthen quality assurance activities within these organizations. We received many comments on these proposed revisions.

Comment: One commenter sought clarification on whether the medical director must review all medical necessity determinations and appeals or whether plans will be required to establish a process for elevating reviews to the medical director. Other commenters sought clarification that the medical director would only review adverse organization determinations and would not review favorable organization determinations.

Response: Under our proposal, the medical director would have overall responsibility for the clinical accuracy of plan decisions. In this oversight role,

we expect there to be a process for elevating issues of concern to the medical director, but we do not expect that a plan's medical director will review each and every decision involving medical necessity. The medical director should collaborate with appropriate staff with respect to all plan operations that involve medical and utilization review, benefits and claims management, and quality assurance activities.

Comment: Some commenters argued that the proposed regulatory language should be revised to permit MA organizations and Part D plans sponsors to retain a medical director who is not directly employed by the MA organization or Part D plan sponsor, but rather performs this function under a contractual arrangement. A few commenters stated that plans may prefer to utilize physicians through a physician organization, or physicians who spend part of their time in clinical practice. One commenter strongly supported direct employment of a medical director, but sought clarification on whether a plan can fulfill this requirement by retaining multiple medical directors (such as, one for Part C and one for Part D).

Response: We acknowledge that plans utilize a variety of subcontracting arrangements to perform some or most of their functions, including subcontracting with physician groups to perform medical review activities. Proper claims adjudication and accurate clinical decision-making in organization and coverage determinations, reconsiderations, and redeterminations are integral to the successful performance of a plan's contract. Those decisions all involve items, services, or medications ordered or performed by a physician or other health care professional. In that vein, it is not unreasonable to expect a plan to employ a medical director to ensure that the decision-making process is clinically accurate, appropriate, and comports with Medicare coverage guidelines. We have already clarified that we do not expect that a medical director would review all decisions issued by the plan, but instead would have the primary responsibility of providing oversight for plan operations that involve medical and utilization review, benefit, formulary and claims management, and quality assurance activities.

It should be noted that all other entities that adjudicate Medicare cases are already required to employ a medical director, including the Medicare Part C and Part D Independent Review Entities (IREs). All Medicare Administrative Contractors (MACs) in the Original Medicare Program are required to employ a Medical Director, as are all of the IREs, known as Qualified Independent Contractors (QICs) in the Original Medicare program. The intent of imposing such a requirement on MA organizations and Part D plan sponsors is the same as it is for those entities—that is, to ensure that such decisions are clinically accurate, appropriate, and comport with Medicare coverage guidelines.

We note that plans are ultimately responsible for the clinical accuracy and appropriateness of their processes and decisions, which includes oversight of their first tier, downstream and related entities. Without a medical director employed by the plan to review decision making processes of contracted entities (such as IPAs or PBMs), the plan would be unable to ensure the decisions were clinically accurate or appropriate. A medical director employed by a contracted entity is ultimately responsible to that entity and is in no position to inform the plan if they believe their employer's procedures or decisions are inappropriate. MA organizations and Part D plan sponsors must evaluate CMS' requirements and make staffing arrangements that will ensure compliance with our requirements. Therefore, we will move forward with implementing the requirement that MA organizations and Part D plan sponsors employ a medical director. We will not, however, specify the staffing level needed for this position. Instead, we will allow plans the discretion to retain a medical director that works less than full time or multiple medical directors as they deem appropriate to comply with our requirements.

Comment: One commenter noted that CMS' rationale in support of the requirement that plans employ a medical director does not support the accompanying requirement that the medical director be a physician.

Response: We disagree with the commenter. In the proposed rule, we noted that MA organizations and Part D plan sponsors will be required to employ a medical director who would be responsible for ensuring the clinical accuracy of all decisions involving medical necessity. This physician oversight requirement is consistent with the existing statutory and regulatory requirements at 1852(g)(2)(B) of the Act and § 422.590(g)(2) and § 423.590(f)(2) that all medical necessity redeterminations and reconsiderations be reviewed by a physician with expertise in the field of medicine that is appropriate for the services at issue. We also noted that, with respect to the Part D program, the proposal to require the employment of a medical director who is a physician would enhance the performance of other critical plan functions such as formulary administration and application of plan coverage rules, and assist in the early identification and correction of potential quality concerns. Given this, we continue to believe that the role of a medical director requires the expertise of a physician, and are retaining the associated requirement.

After consideration of the comments on this proposal, and for the reasons noted previously, we are finalizing the proposal to require MA organizations and Part D plan sponsors to employ a medical director by adding paragraph (4) to § 422.562(a) and by adding paragraph (5) to § 423.562(a).

6. Compliance Officer Training (§ 422.503 and § 423.504)

Pursuant to our authority under section 1857(d) of the Act for Part C, and sections 1860D–4(c)(1)(D) and 1860D–12(b)(3)(C) of the Act (the latter of which incorporates section 1857(d) by reference), we proposed that MA organization and Part D sponsor compliance officers be required to complete annual MA and/or Part D compliance training starting in 2013. Organizations applying for the 2013 contract year that are new to the MA or Part D programs would have been required under this proposal to have their compliance officers obtain training in 2012 to prepare for the upcoming contract year. We proposed to add § 422.503(b)(4)(vi)(B)(1)(i) and (ii) to subpart K of Part 422 and § 423.504(b)(4)(vi)(B)(1)(i) and (ii) to subpart K of Part 423 to reflect this change. We proposed these training clarifications because our reviews have found that many MA and Part D compliance officers lack basic knowledge about the requirements of the MA and Part D programs. Our reviews have also found that many compliance officers do not seem to understand that we expect sponsors to actively ensure compliance with Medicare program requirements; that those requirements are distinct from any commercial health or drug plan benefits they may administer; and that they should not solely rely on subcontractors or CMS to identify and resolve Part C and Part D contract compliance matters for them. We stated our belief that requiring annual training for compliance officers would help to address the knowledge gap by emphasizing the necessity of compliance officer training and the compliance officer's critical role in

maintaining and ensuring program compliance. However, based upon the comments received, CMS will not be codifying these provisions at this time.

Comment: Most commenters supported CMS' proposal to require compliance officer training.

Response: We agree with these commenters that compliance officer training would address our aforementioned concerns about the level of knowledge compliance officers have about the Medicare Part C and D programs, but for reasons discussed below, we are not finalizing our proposals at this time.

Comment: The vast majority of comments regarding compliance officer training were requests for clarification from industry regarding who should take the training and the content, forum, format, and duration of the training. Specifically, commenters were unsure if CMS intended for the organization's corporate compliance officer or for its Medicare compliance officer to attend training. Other commenters suggested that only plan sponsors with poor audit results or significant compliance problems should be required to take training. Nearly all commenters wanted more details about the content or curriculum for the training. Some thought that training should be designed to allow the compliance officer to focus on areas or issues that presented the most risk to their organization. Other commenters wanted to know if the content would focus on compliance programs and plans or if it would focus on Medicare Part C and D programs and compliance with those requirements. With respect to the format of the training, some plan sponsors wanted only CMS to provide the training either in-person or via the Internet, while other plan sponsors wanted compliance courses and conferences offered by non-CMS entities to be counted towards the annual training requirement. Lastly, one commenter suggested that the training should not exceed 12 hours per year.

Response: We agree that more clarification is warranted regarding the audience, content, forum, format, and duration of proposed compliance officer training. Therefore we will not be codifying the proposed rule regarding compliance officer training at this time. We will carefully consider whether to propose a similar rule in the future that will address the clarifications suggested by industry.

Accordingly, we have not included Paperwork Reduction Act (PRA) paperwork burden or regulatory impact analysis estimate for this provision.

7. Removing Quality Improvement Projects and Chronic Care Improvement Programs From CMS Deeming Process (§ 422.156)

Under section 1852(e) of the Act, we have delegated our authority to evaluate whether an MA organization is in compliance with certain Medicare requirements to three private accrediting organizations. Currently, MA organizations may be deemed to meet requirements in a number of areas, including quality improvement (QI), as specified in § 422.156(b).

We currently require all MA organizations to submit their quality improvement projects (QIPs) and chronic care improvement programs (CCIPs) on an annual basis. In our November 2010 proposed rule (75 FR 71227), we proposed to amend § 422.156(b) to specify that, while QI would still be a component of the deeming process, QIPs and CCIPs would be excluded from the deeming process for QI. We also clarified that the QIPs and CCIPs would instead be reviewed and evaluated by CMS or an appropriate CMS contractor. After considering comments we received on this proposal, we are finalizing this provision without modification.

Comment: One commenter supported the removal of QIPs and CCIPs from the deeming process, to the extent that CMS intends to collect QIPs and CCIPs for review on an annual basis. This commenter recommended that, in order to avoid redundancy and unnecessary burden for plans, deeming authorities should not be allowed to request the submission of QIPs and CCIPs as part of the deeming process.

Two commenters stated that removing the QIPs and CCIPs from the deeming process would negatively impact staffing resources for health plan medical management, since both are reviewed by NCQA during site visits. These commenters believed that maintaining two unique reporting formats for the same quality programs would be duplicative.

Response: We appreciate commenters' concerns about duplication of efforts. In our proposed rule, we proposed to exclude the QIPs and CCIPs as components of the deeming process for QI precisely because we were aware of the duplication of effort associated with submission of this information to both CMS and NCQA, as well as auditing efforts by both entities. As we stated in our proposed rule, removing the QIPs and CCIPs from the deeming process for QI will avoid redundancy and reduce burden for MA organizations. We believe removal of QIPs and CCIPs from the deeming process for QI is essential to improving consistency in the evaluation and assessment of the QIPs and CCIPs, especially given that some elements therein may be incorporated into future plan ratings. Therefore, we are finalizing our proposal without modification.

Comment: One commenter advised that removing two important elements of the overall QI program would make it almost impossible for NCQA to provide a balanced and comprehensive assessment of the overall QI program and recommends that CMS reconsider this proposal.

Response: We disagree with the commenter's assertion that removal of QIPs and CCIPs will result in NCQA's inability to assess the QI program plans of its deemed entities. There are a number of quality performance measures that an accreditation organization may use to measure QI for purposes of deeming. Therefore, we are finalizing our proposal without modification.

Comment: Several commenters recommended that CMS consider allowing MA plans the flexibility to focus on QIPs and CCIPs that meet the unique needs of their target populations.

Response: Irrespective of whether or not CMS identifies a list of specific clinical and/or non-clinical topics for QIPs and CCIPs, MA plans will retain the flexibility to develop their own special projects. Furthermore, plans' QIPs and CCIPs must always address the target population for a specific plan in order to demonstrate QI under their plans. Identification of the appropriate target population is a key component for ensuring QI and is the first element CMS assesses when reviewing the QIPs and CCIPs.

Comment: One commenter recommended that CMS release standards that will be used in determining if QIP and CCIP program standards are met.

Response: We appreciate the commenter's interest in this issue. The submission of QIPs and CCIPs will be an ongoing annual QI assessment activity for all MA organizations and SNPs. In an effort to improve consistency, we are reviewing the current QIP and CCIP program standards in an effort to determine where improvement is necessary. Guidance regarding changes to the QIP and CCIP program standards will be provided in separate guidance such as an HPMS memoranda and annual call letters.

Comment: Several commenters recommended that CMS continue to permit MA organizations that currently use the deeming process to continue to

do so, and apply our proposed requirement only to MA organizations that avail themselves of the deeming process in the future.

Response: We disagree that our proposed requirement should apply only to MA organizations not currently using the deeming process. While MA organizations may continue to utilize the deeming process for areas specified in § 422.156, including QI, we are finalizing our proposal without modification and clarify that it will apply to all MA organizations including SNPs.

Comment: One commenter recommended that CMS should consider allowing plans with a high star rating on quality measures the option to use the deeming process.

Response: We clarify that the goal of our proposal in our November 2010 proposed rule was not to eliminate deeming, or even deeming for QI requirements but, rather, to exclude QIPs and CCIPs as deemable QI elements.

8. Definitions of Employment-Based Retiree Health Coverage and Group Health Plan for MA Employer/Union-Only Group Waiver Plans (§ 422.106)

In our November 2010 proposed rule (75 FR 71227), we stated our concern that, since enactment of the MMA, MA organizations have been contracting with entities that cannot properly be characterized as employment-based group health plan coverage (for example, professional or group associations) to provide coverage to MA beneficiaries via employer group waiver plans (EGWPs) or individual MA plans. Specifically, some MA organizations have characterized contracts with professional or group associations as employment/union coverage. We stated we believed that this was inconsistent with the requirement in section 1857(i) that such waivers facilitate a contract between an MA organization and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or a combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, as this language is interpreted in guidance in Chapter 9 of the Medicare Managed Care Manual (*http://www.cms.gov/manuals/downloads/mc86c09.pdf*), entitled "Employer/Union Sponsored Group Health Plans. This guidance clearly restricts employer/union group health plan enrollment in EGWPs and individual MA plans to beneficiaries who are Medicare eligibles of an employer/union sponsored group health plan. Such a plan is one that is employment-based health coverage through an employer/union group health plan that has entered into a contractual arrangement with an MA organization to provide coverage or that has contracted directly with CMS to provide coverage for its Medicare eligibles. To clarify our requirements for offering employment-based retiree coverage via an MA plan, we proposed to codify definitions of the terms employer-sponsored group MA plan, employment-based retiree health coverage, and group health plan at § 422.106(d)(4) through (6). We also proposed to change the reference to an MA plan at § 422.106(d) to a reference to an employer-sponsored group MA plan. In proposing these definitions, we noted that they were consistent with those provided for Part D sponsors at § 423.454 and § 423.882. We solicited comment on our proposals to revise these definitions.

After considering comments received on these proposed changes, we are finalizing these provisions without modification.

Comment: One commenter agreed with CMS that membership in an association would by itself not have a sufficient employment nexus to qualify as employment-based coverage and also noted that our proposed definitions of the terms employer-sponsored group MA plan, employment-based retiree health coverage, and group health plan are consistent with the comparable definitions for Part D sponsors at § 423.454 and § 423.882.

Two commenters believed that our proposed definitions of the terms employer-sponsored group MA plan, employment-based retiree health coverage, and group health plan would unintentionally exclude coverage by associations that is truly tied to employment in such associations, and that a wholesale exclusion of associations and similar entities from the definition of employment-based retiree coverage would be overly broad and inconsistent with coverage in the commercial market. One of these commenters explained that there are a variety of types of associations, including (but not limited to) an association of farm bureaus, for which eligibility for health coverage is tied to membership in the association or bureau.

Response: We do not believe that Congress envisioned granting access to EGWP waivers based on membership in an association or any entity that did not meet the definition of a group health plan, as defined under the Employee Retirement Income Security Act (ERISA). Our intent in defining an employer-sponsored group MA plan, employment-based retiree health coverage, and a group health plan was not to preclude all associations from enrolling Medicare beneficiaries in EGWPs and individual MA plans, but, rather, to ensure that a beneficiary's enrollment in one of these MA plans is based on his/her receipt of employment-based health coverage from and employer/union group health plan sponsor. To the extent that membership in an association is based on employment, that association could meet the definition employment-based retiree coverage. For example, an association may elect to provide coverage via an EGWP or individual MA plan to retirees who were formerly employed by the association. We also clarify that we believe that employers such as school districts could form an association for the purpose of purchasing employer coverage on behalf of retirees from the school districts and that this would be acceptable because, independently, each school district would be eligible to enroll its retirees in an EGWP or individual MA plan. Therefore, two or more school districts could combine to form an association for the purpose of purchasing retirement coverage for their retired employees. However, an association of farm bureaus would not meet this test if membership in a farm bureau were not exclusively based on former employment by these farm bureaus.

Comment: Two commenters expressed concern that our proposed definitions of employment-based retiree coverage and a group health plan at § 422.106(d)(5) and § 422.106(d)(6), respectively, would preclude employers that do not contribute financially to retirees' health care costs—including cases where an employer plan is provided at no cost to the employer or the employer furnishes a pension in lieu of payment for health care coverage for its retirees—from enrolling retirees in an employer-sponsored group MA plan. This commenter recommended that CMS revise its proposed regulatory language to ensure that the definition of employment-based coverage is not tied to a financial contribution from the employer.

Another commenter stated that employers that are not contributing financially to retirees' health care costs, which is an increasing trend in the marketplace, can still meaningfully contribute to their retirees' health care coverage by bargaining with an MA organization on behalf of its retirees for

the best possible deal on premium and benefit design. This commenter also noted that employers may choose to assist their retirees by administering the MA plan premium payment process.

Response: Our proposed definitions would require that employment-based retiree coverage include coverage of health care costs in accordance with the ERISA definition of a group health plan. While there is not a minimum amount an employer must contribute toward such employment-based retiree coverage, we believe it is important that an employer make both a financial contribution toward coverage and negotiate on behalf of its retirees for a benefit package and cost sharing levels which are as favorable as possible for them. We are therefore finalizing our proposed revisions to § 422.106(d) without modification.

Comment: One commenter requested that CMS ensure that coverage offered by a union or trust is considered employment-based as recognized by the section 1857(i) of the Act.

Response: We agree that members or former employees of unions and trusts, as recognized under section 1857(i) of the Act, generally meet the definition of employment-based retiree coverage and could offer MA coverage to retirees who are Medicare eligible individuals through an EGWP or individual MA plan.

D. Strengthening Beneficiary Protections

This section includes proposed provisions aimed at strengthening beneficiary protections under Parts C and D. Some of the provisions affecting both Parts C and D include proposed regulations codifying the requirement that MA organizations and Part D sponsors provide interpreters for non-English speaking and limited English proficient callers, and periodically disclose to each beneficiary specific data for enrollees to use to compare utilization and out-of-pocket costs in the current plan year to the following plan year. Changes affecting only Part C include an extension of the mandatory maximum out-of-pocket (MOOP) amount requirements to regional PPOs, and under Part D, we address the delivery of adverse coverage determinations.

In the area of Parts C and D marketing, proposed provisions include a proposal requiring MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program and a proposal to extend annual training and testing requirements to all agents and brokers marketing and selling Medicare products.

This information is detailed in Table 6.

TABLE 6: Provisions to Strengthen Beneficiary Protections

PROVISION	PART 422		PART 423	
	Subpart	Section	Subpart	Section
Agent and Broker Training Requirements	Subpart V	§422.2274	Subpart V	§423.2274
Call Center and Internet Website Requirements	Subpart C	§422.111	Subpart C	§423.128
Require Plan Sponsors to Contact Beneficiaries to Explain Enrollment by an Unqualified Agent/Broker	Subpart V	§422.2272	Subpart V	§423.2272
Customized Enrollee Data	Subpart C	§422.111	Subpart C	§423.128
Extending the Mandatory Maximum Out-of-pocket (MOOP) Amount Requirements to Regional PPOs	Subpart C	§422.100 §422.101	N/A	N/A
Prohibition on Use of Tiered Cost Sharing by MA Organizations	N/A	N/A	N/A	N/A
Delivery of Adverse Coverage Determinations	N/A	N/A	Subpart M	§423.568
Extension of Grace Period for Good Cause and Reinstatement	Subpart B	§422.74	Subpart B	§423.44
Translated Marketing Materials	Subpart V	§422.2264	Subpart V	§423.2264

1. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

a. CMS Approved or Endorsed Agent and Broker Training and Testing (§ 422.2274 and § 423.2274)

In the November 2010 proposed rule, in implementing sections 1851(h)(2), 1860D–1(b)(1)(B)(vi), 1851(j)(2)(E), and section 1860D–4 (l)(2) of the Act, we proposed revising § 422.2274(b) and (c) and § 423.2274(b) and (c) to require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS-endorsed or approved training program. We proposed this revision to move toward greater standardization of agent broker training and testing and ensure that agents and brokers selling Medicare products have a comprehensive and consistent base of understanding of Medicare rules.

In addition, we proposed that following the implementation of the final rule, we would review and endorse or approve one or more entities to provide annual testing and training to Medicare agents and brokers. We specifically requested comments and suggestions on alternatives to using a competitive request for proposals (RFP) process under the Federal Acquisition Rules to effectuate this effort.

We further proposed that these new requirements also be applicable to section 1876 cost contract plans, since in our April 2010 final rule (75 FR 19784 through 19785), we extended the MA marketing provisions in part 422 to section 1876 cost contract plans.

Comment: Many of the comments received supported the proposal and responded to our request for suggestions. The suggestions offered in conjunction with the approval were (1) provide a low-cost option to the public or non-profit sector; (2) provide uniform training and testing materials that can be graded by an outside independent entity; (3) create a separate test for the general Special Needs Plan (SNP); and (4) include information regarding SPAPs, COB rules and eligibility in the training.

Response: The purpose of standardizing the training and testing is to ensure continuity, accuracy and quality of training and testing vehicles. We will evaluate and approve vendor products by developing specific criteria against which training and testing programs will be assessed. We will take into consideration and evaluate the options for lower cost offerings to the public and non-profit sector and will also consider the suggestions for developing training and testing modules.

Comment: One commenter requested clarification of our use of the terms CMS "endorsed" training program and CMS "approved" program.

Response: Although the intent of the language was to use the two terms interchangeably, we note that the final selections of the developed vendor products will first be approved by our agency and subsequently certified or endorsed.

Comment: One commenter recommended that CMS apply the same bid process as we apply to the plans using the training portal. They expressed full support for having a certified company provide the training and a certification that they can accept without having to provide that training themselves.

Response: We believe this commenter was referring to our pilot agent/broker training and testing module in 2009. We do not believe the development approach taken for that module is appropriate for the current effort, given that we developed the training under that approach and solicited volunteer plan sponsors to train and test their agents via the pilot training and testing module. We will consider all access and value options prior to and throughout the solicitation of training and testing information and technical proposals.

Comment: One commenter supported CMS's proposal to require specific training for agents and brokers and also recommended that CMS training be specific to the plan the agent/broker is actually selling. Other commenters requested that plan sponsors be allowed the option of continuing to develop and administer training and testing that complies with CMS specified criteria. Specifically, the commenter stated that plans should continue to be responsible and held accountable for adequate training regimens, and requested that CMS continue to impose training obligations on plans rather than contracting with third-party entities to provide such training to plan employees and contractors.

Response: We do not have the resources at this time to initiate development by vendors of training and testing vehicles that would contain plan-specific details for each plan type for which organizations contract with CMS. Plan sponsors will continue to be responsible for administering plan specific training and testing to brokers and agents. Our development of an "approved or endorsed" training and testing program will ensure consistency and accuracy across plan sponsors.

Comment: One commenter proposed that we allow plans to review training and testing products before they are finalized and to make further recommendations regarding the specific companies and organizations that would develop the specific products. The commenter urged that CMS provide a transparent process and agreed with using the RFP process to develop an "approved or endorsed" training and testing curriculum. The commenter stated that the curriculum and its development should not be considered proprietary, even if it is developed by a private contractor.

Response: We will not consider a plan preview of products prior to finalizing our decisions. We will develop specific requirements and implement a process for reviewing proposals to ensure participants meet the requirements and develop a training and testing program as specified in future guidance. Furthermore, we believe that allowing plans to review the training and testing proposals and recommend approval of specific organizations might interfere with our ability to ensure a level playing field.

Comment: One commenter noted that it is not a practice of PACE programs to utilize agents and brokers in their efforts to inform the public about their program. The commenter requested the CMS clarify that the training and testing requirements to not supersede or modify the requirements currently applicable to PACE programs.

Response: PACE plans are governed by separate requirements which are not included in these provisions. These requirements do not supersede or modify the current requirements applicable to PACE programs.

b. Extending Annual Training Requirements to All Agents and Brokers (§ 422.2274 and § 423.2274)

In the November 2010 proposed rule, we proposed a change in the regulations text that would correct an omission in our current regulations at § 422.2274(b) and (c) and § 423.2264(b) and (c). These regulations currently require MA organizations and Part D sponsors to ensure that independent agents selling Medicare products are trained and tested annually on Medicare rules and regulations specific to the plan products they intend to sell. Consistent with our statutory authority at sections 1851(j)(2)(E) and 1860D–4(l)(2) of the Act, we proposed to revise § 422.2274 and § 423.2274 to correctly apply these requirements to all agents and brokers marketing and selling Medicare products, whether independent agents or employees.

In addition, we also noted that these new requirements would be applicable to section 1876 cost contract plans, since in our April 2010 final rule (75 FR 19784 through 19785), we extended the MA marketing provisions in Part 422 requirements to section 1876 cost contract plans.

After considering the comments we received, we are finalizing our proposal without further modification.

Comment: One commenter expressed support for correcting the error in § 422.2274(b) and (c) and § 423.2264(b) and (c) that applied training requirements only to independent agents and brokers.

Response: We agree that all agents and brokers, including those employed by MA and Part D plans, should be subject to the same training and testing requirements. Therefore, we are adopting as final our proposed correction to § 422.2274(b) and (c) and § 423.2264(b) and (c).

2. Call Center and Internet Web site Requirements (§ 422.111 and § 423.128)

a. Extension of Customer Call Center and Internet Web site Requirements to MA Organizations (§ 422.111)

Under the authority of section 1852(c) of the Act, which requires MA organizations to disclose MA plan information upon request, as well as the authority of section 1857(e) of the Act

to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed to extend call center and Internet Web site requirements to MA organizations to parallel to those applicable to Part D sponsors. We proposed to amend § 422.111 by adding a new paragraph (g) to expressly require MA organizations to operate a toll-free customer call center that is open during usual business hours and provides customer telephone service in accordance with standard business practices, as well as to provide current and prospective enrollees with information via an Internet Web site and in writing (upon request). We proposed this amendment to ensure that current and prospective enrollees of MA plans have the same access to customer service call centers and information via an Internet Web site as current and prospective enrollees of a Part D plan in order to obtain more information about plan coverage and benefits. We also noted that although similar call center and Internet Web site requirements were never codified for MA plans, we have required through subregulatory guidance (the Medicare Marketing Guidelines at *http://www.cms.gov/ManagedCareMarketing/Downloads/R91MCM.pdf*) that MA organizations comply with the same requirements regarding customer service call centers as Part D sponsors, and, for those offering Part D benefits through MA–PD plans, all Part D sponsor Internet Web site requirements.

As part of the proposed rule, we also proposed removing paragraph § 422.111(f)(12), which requires that certain information—including the evidence of coverage, summary of benefits and information about network providers—be posted to an Internet Web site in the event that an MA organization has a Web site or provides MA plan information through the Internet, and moving these requirements to § 422.111(g)(2)(i).

After considering comments on our proposal, we are adopting these provisions as final with one modification, proposed paragraph (g) is redesignated as paragraph (h).

Comment: Several commenters expressed their support of our extending the call center and Web site requirements to MA plans. One commenter that supported our proposal believed that these requirements will serve to ensure beneficiaries receive the information needed to make informed decisions on their healthcare options.

Response: We thank the commenters for their response. We believe this change will allow MA enrollees the same access to customer service call centers services as a current or prospective members of a Part D plan. Therefore, we are finalizing our proposal without modification.

Comment: One commenter noted that regulations governing the PACE program provide for a waiver of the requirement to maintain customer call centers as well as the requirement to provide information via an Internet Web site.

Response: PACE plans are governed by separate requirements that are not included in these provisions. These requirements do not supersede or modify the current requirements applicable to PACE programs.

Comment: One commenter recommended that since the open enrollment period that existed for the first 3 months of the year has been replaced with a period during which an MA enrollee may disenroll from an MA plan, CMS should allow extended call center hours to coincide with the new 45-day annual period. Additionally, the commenter indicated that there is no need for continued weekend call center coverage by live agents after the 45-day period ends.

Response: We have taken these comments into consideration and will be proposing revisions to our Medicare Marketing Guidelines for contract year 2012 that would require all plan sponsors to have extended call center hours during the 45-day annual disenrollment period (January 1 to February 14 of each contract year).

b. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

Pursuant to our authority under sections 1857(e)(1) and 1860D–4(a)(3)(A) of the Act to specify additional contractual terms and conditions the Secretary may find necessary and appropriate, we proposed to codify Medicare Part C and D requirements regarding current and prospective enrollee toll-free customer call centers. Specifically, we clarified that MA organizations and Part D sponsors must provide interpreters for all non-English speaking and limited English proficient (LEP) callers. We proposed to add new paragraphs § 422.111(g)(1)(iii) (redesignated as paragraph (h)) and § 423.128(d)(1)(iii), respectively, to reflect this clarification.

This clarification is a result of findings from our call center monitoring, which revealed that a significant percentage of MA organizations and Part D sponsors were not providing foreign language interpreters for non-English speaking callers. This clarification addressed the problem by explicitly codifying the requirement to provide interpreters for LEP callers in regulations.

Comment: Several commenters from advocacy groups and industry supported codification of CMS' requirement that MA organizations and Part D sponsors must provide interpreters for non-English speaking and LEP individuals.

Response: We agree with these commenters because requiring interpreters ensures LEP beneficiaries have access to Medicare Part C and D benefit information.

Comment: A few commenters asked for clarification regarding the requirement that interpretation services should be available for "all" languages. Commenters offered alternatives such as providing interpreters for languages that meet a 10 percent threshold or require plan sponsors to provide interpreters for all languages spoken by more than 10 percent of the plan's membership.

Response: We agree with commenters who noted that "all" may be too inclusive, as there are more than 6,000 languages spoken world-wide. As such, we are striking the word "all" from the proposed language. Based on data collected during the 2000 U.S. Census, more than 300 languages are spoken in the United States. We revised the regulatory language to read as follows, "Provides interpreters for non-English speaking and limited English proficient (LEP) individuals." Our expectation is that MA organizations and Part D sponsors' call centers will provide interpretation services for all languages that are served in common by the largest commercial interpretation service providers in the U.S., as these organizations are experts in assessing the languages for which interpretation services are needed. Currently these large organizations provide interpretation services for approximately 150 to 180 languages, which accommodates the vast majority of interpretation needs. Our Medicare Marketing Guidelines have long established the expectation that MA organizations and Part D sponsors provide interpretation services to any LEP caller. Our monitoring of this area has demonstrated that MA organizations and Part D sponsors' call centers are capable of providing interpreters to meet the needs of LEP callers when they use commercial interpretation service providers.

We do not accept the suggested alternatives, that is, to require that plan sponsors only provide an interpreter for languages that meet a 10 percent threshold or require plan sponsors to provide interpreters for all languages spoken by more than 10 percent of the

plan's membership. Because beneficiaries are not required to indicate their primary or preferred language when they enroll in a plan, it would be impossible for a plan sponsor to know all the languages they would need to interpret. Moreover, the availability of commercial interpretation service providers for these 150–180 languages is a cornerstone of CMS' effort to establish the widest practical safety net for providing access to those individuals who are outside of the translation threshold requirement for translating marketing materials found in § 422.2264 and § 423.2264.

Comment: One commenter asked CMS to clarify whether MA organizations and Part D sponsors are required to have interpreters on-site.

Response: We clarify that MA organizations and Part D sponsors may use on-site interpreters, contract with a commercial interpretation service provider, or employ some combination of both approaches. For instance, many MA organizations and Part D sponsors provide Spanish language interpretation on-site while using one of the numerous and readily available commercial interpreter services to providers for other languages.

Comment: One commenter requested clarification as to whether the Program of All-inclusive Care for the Elderly (PACE) program is subject to the requirement that plan sponsors maintain toll-free customer call centers.

Response: Although this comment is not within the scope of the proposed rule, we clarify that PACE programs are not subject to this requirement.

Comment: One commenter suggested that CMS provide best practices for plan sponsors regarding interpretation services. The commenter also asked CMS to discuss methods for preventing long wait times for non-English speaking callers.

Response: We agree with this comment, and we have made a concerted effort to disseminate best practices on this topic. In a Health Plan Management System (HPMS) memo published to all plan sponsors on January 2, 2008 entitled "Best Practices for Addressing the Needs of Non-English Speaking and Limited English Proficient (LEP) Beneficiaries," We provided guidance to plans, which addressed, among other topics, call center phone systems and customer service representative staffing, training, and oversight. Additionally, when we issue informational memos or compliance letters to plan sponsors regarding our call center monitoring results, we include a special section that lists tips for how an organization can improve its service to LEP beneficiaries.

With regard to concern about long wait times for LEP callers, data collected during our call center monitoring study indicated that the average hold time for an interpreter was one minute and sixteen seconds. This hold time is below our existing 2 minute hold time standard in the Medicare Marketing Guidelines.

In summary, we are finalizing this provision, and the only change from the proposed version is to strike the word "all."

3. Require Plan Sponsors To Contact Beneficiaries To Explain Enrollment by an Unqualified Agent/Broker (§ 422.2272 and § 423.2272)

Current regulations (§ 422.2272 and § 423.2272) require plan sponsors that use independent agents and brokers for their sales and marketing to only use State licensed and appointed agents or brokers. Under these provisions, plan sponsors must also report the termination of agents or brokers to the State. Based on information uncovered during program audits, we proposed revisions to § 422.2272(c) and § 423.2272(c) to require MA organizations and Part D sponsors to terminate unlicensed agents upon discovery and notify any beneficiaries who were enrolled in their plans by unqualified agents. Since beneficiaries rely heavily on information they receive from agents regarding plan benefits and costs, we believe they should have the opportunity to ask additional questions or reconsider their enrollment when they have been enrolled in a plan by an unqualified agent.

In addition, we noted that these requirements would be applicable to section 1876 cost contract plans, since in our April 2010 final rule (75 FR 19784 and 19785), we extended the MA marketing provisions in part 422 to section 1876 cost contract plans.

After considering the comments we received, we are modifying the proposal as described below.

Comment: Several commenters were concerned that the requirement to notify beneficiaries when they have been enrolled by an unqualified agent is duplicative of the outbound enrollment verification call requirement and is unnecessary.

Response: The intent of this provision is not to duplicate the outbound enrollment verification process. Rather, it is to ensure that beneficiaries are fully informed of the circumstances of their enrollment and to allow them the opportunity to reconsider their options given the new information about the agent. While we do not anticipate that many beneficiaries will want to make plan changes based on notification that the agent is unqualified, especially considering that the plan sponsor likely would have already conducted the required outbound verification call, we believe that it is important that beneficiaries are fully informed of the details of their enrollment in the event the agent misrepresented the package of benefits in any way. Additionally, to ensure that we do not confuse beneficiaries with duplicative information, we have modified our original proposal at § 422.2272(c) and § 423.2272(c) to indicate that plan sponsors are required to provide affected enrollees with information about their options to confirm enrollment or make a plan change (including a special election period) at the beneficiary's request.

Comment: A few commenters requested clarification of our proposal, since plan sponsors are not allowed to use unlicensed agents.

Response: In the proposed rule, we used the term "unlicensed" and "unqualified" interchangeably. However, there is an important difference between the two terms. Being unlicensed is just one criterion for determining whether an agent or broker is qualified to sell Medicare plans. In addition to having a license (in States that require one), agents and brokers must also be trained annually, pass a Medicare test annually (with a score of 85 percent or better), and be appointed in States with appointment laws.

The final provisions would require plan sponsors to terminate unlicensed agents and report them to the State upon discovery. However, we have modified our original proposal at § 422.2272(c) and § 423.2272(c) to replace the term "unlicensed" with "unqualified" with respect to the beneficiary notification requirement. We did not propose terminating all unqualified agents or brokers because there may be circumstances in which an unqualified licensed agent should not be terminated—for example, an agent who takes an automated test, but a software bug notifies the agent that he has passed the entire test when he only passed the first component of the test. In this case, the plan sponsor would not be required to terminate the agent or report him/her to the State upon discovery; however, the plan sponsor would be required to notify individuals enrolled by that agent of his/her unqualified status.

Comment: One commenter suggested that CMS sanction plans that have repeated instances of unlicensed agents selling for them, and that agents be

required to include their national producer number (NPN) on the application.

Response: Due to the fact that some States do not participate with the National Insurance Producer Registry (NIPR), we are not considering requiring the agent NPN on the enrollment application. However, we will continue to evaluate ways to better monitor agent behavior, as part of our current surveillance, compliance, and enforcement processes. We will also monitor plan compliance with this new requirement.

Comment: A couple of commenters stressed the importance that beneficiaries not be pressured to enroll in another plan offered by the plan sponsor during the notification call.

Response: The purpose of the call is to notify beneficiaries that an unqualified agent was involved in their enrollment, not to persuade them to join other plans. We anticipate that most beneficiaries will appreciate the notice and may have some questions, but we do not anticipate that the majority of them will want to make a plan change. Plan sponsors will be expected to take the lead from the beneficiary, rather than initiate conversation about plan changes. We will provide more specific instructions for plans in subregulatory guidance.

Comment: One commenter asked whether a special election period (SEP) would apply when a beneficiary is enrolled by an unqualified agent, if the requirement would apply only during the AEP or throughout the year and what should a plan sponsor do if it is unable to reach the beneficiary.

Response: There will be no SEP specifically tied to enrollment by an unqualified agent; however, these circumstances will be treated just like any other complaint regarding marketing misrepresentation by an agent. The requirement will apply throughout the plan year because beneficiaries eligible for an SEP (for example, dual eligibles and those who move outside their plan's service area) can enroll in a new plan at other times during the year, and plans can market to these individuals. The contact requirements will be similar to the contact requirements for outbound enrollment verification calls. We will provide more direction through subregulatory guidance.

Comment: One commenter asked whether this requirement applied to family, friends, or others presenting themselves as agents.

Response: This requirement does not apply to situations in which family members or friends (who are not agents) give advice or recommendations to beneficiaries. However, plan sponsors should report individuals impersonating agents to the State Department of Insurance as unlicensed agents.

4. Customized Enrollee Data (§ 422.111 and § 423.128)

In our November 2010 proposed rule (75 FR 71230), we discussed our concern that information that MA organizations and Part D provide their enrollees annually in the annual notice of change/evidence of coverage (ANOC/EOC) document may not be enough to prompt enrollees to actively evaluate their plans annually with respect to plan costs, benefits, and overall value. Therefore, we proposed to require MA organizations and Part D sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. We proposed to add new paragraphs (12) and (11) to § 422.111(b) and § 423.128(b), respectively, to specify this requirement. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the ANOC/EOC.

We discussed several options for implementing this data disclosure requirement (75 FR 71230 through 71233), and we noted that the proposed rule only specified our authority to require such a disclosure. We sought suggestions and comments from MA organizations, Part D sponsors, the beneficiary community, and other external stakeholders related to the design, content, and the cost calculations to assist us in implementing these provisions. In addition, we noted that we were considering implementing a pilot program for CY 2012 with a few MA organizations and Part D sponsors to test approaches to conveying customized beneficiary data, based on the comments and suggestions that we received.

We also solicited comments on the possibility of exempting dual eligible special needs plans (D–SNPs) from the requirement to provide such customized enrollee data through a customized out-of-pocket cost statement or an explanation of benefits (EOB), since enrollees in these plans generally do not incur out-of-pocket costs. We sought comment on exempting D–SNPs from this requirement.

After considering the comments we received, we are modifying our original proposal, as described below.

Comment: Many commenters expressed appreciation for our effort to identify the best ways to provide useful information to beneficiaries. However, while a few commenters supported requiring a customized statement that would provide an estimate of future costs, most commenters opposed this model, citing the administrative and financial burden on plans.

Many commenters stated that a customized estimate of future costs would create more significant administrative, financial and IT resource burdens on MA plans and Part D sponsors than CMS anticipated in its proposal. These commenters stated that the expense and operational burden of the proposal could not be justified relative to its value to beneficiaries, considering the potential for beneficiary confusion and dissatisfaction that may result from any projection of future costs. Other commenters stated that such a requirement would likely result in the need for additional funding of audits as well as rigorous quality assurance programs consistent with HIPAA requirements related to the dissemination of this type of document with the ANOC/EOC. Several commenters expressed concerns that such a requirement would result in a need to significantly increase call center or 1–800–Medicare staffing to handle the questions resulting from the documents; or that it would also result in more complaints to monitor in the Complaints Tracking Module. One commenter suggested that the significant costs of producing and distributing a custom statement would increase administrative costs that, in turn, might increase plan bids and result in a negative impact on benefits and or premiums.

Several commenters suggested that providing these reports for Part D benefits would be very burdensome, even assuming that drug prices will not change in the following year. They stated that it would be difficult to estimate future expenses related to the initial coverage limit and coverage gap. Several commenters also stated that since enrollees already receive Part D EOBs, a customized out-of-pocket cost statement would be redundant and confusing for beneficiaries. Another commenter asked how plans would be expected to coordinate between the medical and prescription drug portions of their benefit to the extent that we required a customized out-of-pocket cost statement to include information about Parts C and D costs.

Many stated that requiring a customized out-of-pocket cost statement to be "bundled with" the ANOC and EOC presents an insurmountable timing problem due to the change in the annual

enrollment period (AEP). They expressed concern that, due to the timing of bid approvals, usually in August, that the remaining four-to-six week period would be much too short to prepare these data and mail a customized statement to each beneficiary with his/her ANOC/EOC. Several commenters stated that it is an expensive and time consuming process to place an extra customized document into an envelope package with a standard ANOC/EOC. However, one commenter recommended that any customized enrollee data be based on current year utilization only and that data should be included in the ANOC instead of a separate document to save on costs associated with development, printing, and fulfillment of an incremental document while creating just one document for beneficiaries to read.

One commenter stated that a standard, CMS-designed report would eliminate the existing flexibility that plans have to tailor enrollee communications to their particular needs.

A few commenters expressed concerns related to the ability of network providers receiving capitated payments for medical services to calculate out-of-pocket costs. Several commenters noted that some plans have established limited mechanisms to calculate the MOOP, but that these systems may not incorporate necessary utilization data such as the specific service the enrollee received and that this information would have to be extracted from multiple sources.

Response: We appreciate the many thoughtful and detailed responses submitted by commenters. As we noted in our proposed rule (75 FR 71230), we have been concerned that the ANOC/EOC information alone may not be enough to prompt enrollees to actively evaluate their plans annually with respect to plan costs, benefits, and overall value. We also acknowledged receiving requests from the beneficiary advocacy community to require that MA organizations and Part D sponsors provide enrollees with a personalized dollar estimate of their out-of-pocket costs in the coming contract year based on their use of services in the current contract year. We noted in the proposal that we are aware of the inherent difficulties in accurately estimating future year plan costs, especially the unknown variable of specific service utilization, and presenting that information to beneficiaries in a clear, concise, and useful way. We also recognized the impact of an earlier annual election period (AEP) beginning in CY 2011, as well as plans' ability to gather a sufficient amount of utilization data to make useful and accurate projections of costs for the following contract year.

Based on the comments we have received, we are modifying our original proposal and finalizing § 422.111(b)(12) to state that CMS may require an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422. We do not plan to test a customized out-of-pocket cost statement that estimates future costs in CY 2012. Rather, we intend to work with MA organizations, Part D sponsors and beneficiary advocates to develop an EOB for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e), and we will test that model through a small pilot program with volunteer organizations in CY 2012. We will consider integration of Part C and Part D EOBs, level of detail, and frequency of EOB dissemination as part of the pilot program. Our goal is to finalize a model EOB document in the future based on the pilot program and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits. In addition, since an EOB requirement already exists for Part D enrollees, we will not finalize the language proposed for § 423.128(b)(11). We believe that delaying full implementation of this requirement will provide MA organizations with sufficient time to prepare for periodic dissemination of a Part C EOB.

Comment: Many commenters expressed concerns that a customized statement, especially with future projections, would not be meaningful or useful for beneficiaries. Some stated that it would create significant confusion in relation to Part C costs and Part D costs as medical and medication requirements change over time or their Low Income Subsidy (LIS) status changes. One commenting organization stated that it has encountered problems with beneficiary understanding of the maximum out-of-pocket (MOOP) limit, believing that it is a financial obligation on the beneficiary. This commenter was concerned that a similar misunderstanding would accompany a customized EOB or statement with estimated future costs. Other commenters believed that it would create a false assurance of future costs as well as an expectation of what their costs will be in the following year, and significant dissatisfaction if their actual costs are higher than projected. They stated that if the beneficiary's costs are materially higher, beneficiaries are likely to be alarmed, dissatisfied or confused. Some commenters also expressed concern about beneficiaries' expectations of plan liability if their costs are higher than the estimate. Another commenter was concerned about perceived credibility of the plans to their enrollees if inadequate or confusing information was to prompt beneficiaries to move to a plan that turns out to be of lesser value.

Some commenters also stated that any information projecting future costs only for an enrollee's current plan would be of limited use to beneficiaries because it would provide no similar data for any alternative plan. They expressed concern that such a statement using partial year data would not provide information that is comparable to the annual cost estimates available through the Medicare Plan Finder (MPF) tool. These commenters disagreed that CMS would improved an enrollee's ability to compare plans to make better enrollment choices from year to year with a customized statement including estimated future costs.

In addition, many commenters raised concerns that fluctuations in utilization of services per year and past utilization of "one-time" services would mislead a beneficiary with respect to his/her decision. Some stated that beneficiaries would not consider what would happen if their health needs change. Another commenter stated that enrollee-specific information based on past utilization has the potential to de-emphasize the value of considering future needs. Another commenter suggested that any comparison of expenses should include a comparison to Medicare FFS and Medicare FFS with the most popular Medigap plan (Plan F) as benchmarks in order to give the data context and to facilitate informed choice.

Response: We agree with commenters' concerns that the information presented to beneficiaries must be clear, concise and useful, without creating a false expectation of costs. We had similar concerns and therefore requested comments about the types of information as well as the format plans could use to provide customized utilization data. We also agree that the data that is presented to beneficiaries should be of a type that it would lend itself to comparisons with Medicare FFS, as well as other plans' information, and could be understandable to beneficiaries with a range of levels of health literacy. As previously discussed, we intend to consider these issues in our CY 2012 pilot program.

Comment: Several commenters provided comments on the example tables we included in our proposed rule. A few commenters stated that Table 7 (75 FR 71232), which breaks out Medicare Part C services by inpatient care, outpatient care and supplemental services, would provide the most useful information to beneficiaries with respect to services. Several commenters suggested that this table should present premium data for the entire year instead of six months. Several other commenters recommended that Table 6 in our proposed rule (75 FR 71232), presenting an average monthly cost and combining all Medicare Part A and B services, but excluding supplemental services, would be the best choice.

Several commenters contended that data for a 6-month period does not generally accurately reflect the enrollee's year-long utilization or out-of-pocket cost-sharing. One of these commenters recommended that CMS use at least nine months of data and allow the out-of-pocket cost information to be sent after the ANOC/EOC to give beneficiaries a more complete picture and to reduce burden on MA organizations during the ANOC timeframes. Many commenters were also concerned about errors in estimating future costs and the limited value of these estimates due to future changes in beneficiary health status or one-time high expenditure items (such as a power wheelchair).

One commenter suggested that CMS study the feasibility of requiring plans to use a minimum of 12 months of data over 2 or more contract years and whether this would provide more reliable data. This commenter also suggested that CMS incorporate more information from the ANOC into the estimate, such as page references for more information about cost sharing for specific services.

Another commenter suggested that CMS implement procedures to ensure that the systems and calculations developed by plan sponsors are uniform, especially in regard to estimating future costs to minimize the potential for fraudulent and misleading practices by plans in order to retain members.

Response: We appreciate the detailed responses provided by commenters concerning the type and amount of data, the presentation of the data, and procedures to ensure uniform calculations and data population. As previously discussed, we believe that requiring an EOB that summarizes incurred costs but does not project future costs will address a number of these concerns. We will continue to take data calculation and presentation issues into consideration as we develop a model EOB.

Comment: Many commenters supported the use of an EOB to give enrollees ongoing information throughout the year about their Part C utilization and their cost-sharing and to help them in decision making during the AEP. One commenter recommended that a Part C EOB should clearly distinguish between in- and out-of-network costs and supplemental benefits, as well provider and date of service. Others commenters opposed an EOB and considered it too costly and burdensome to plans without clear value to beneficiaries in comparing utilization or costs from year to year. Commenters supporting an EOB model supported different frequencies of distribution, including monthly, quarterly, bi-annually and annually.

One commenter recommended requiring an annual EOB that contains utilization data for the months of January through September, to be received at the start of the annual election period, so that it would provide important information at the most appropriate time for the beneficiary. This commenter also stated that requiring a monthly EOB would not provide any additional benefit to beneficiaries beyond that of an annual EOB, but it would add significantly to plans' administrative expenses through printing, postage and increased volume of customer service calls.

One commenter recommended that instead of enrollee out-of-pocket expenses, CMS develop a list of common services for which plan sponsors would calculate out-of-pocket costs under the current plan year and the upcoming plan year. The commenter believed that this would create a comparable format, consistent across all plans, that would be a more economically viable option and could be produced in the limited time frame of the new AEP dates.

Another commenter asked that CMS consider allowing MA organizations to provide enrollees with comparison information upon request only. This commenter suggested that plans could advise members via their websites or in a notice with premium bills of the opportunity to receive this comparison.

Response: We agree with commenters that a Part C EOB without future projections would be a useful tool for beneficiaries, allowing them to keep track of costs throughout the plan year. While it would not achieve the goal of specifically linking utilization to projected costs, we do believe that it would be a valuable tool in annual plan choice decisions. We will also continue to consider commenters' suggestions for the development of a list of common services tied to utilization and the option of plans providing comparison information to beneficiaries upon request.

Comment: Several organizations supported the use of a pilot to test approaches to conveying custom beneficiary data, but requested that CMS delay finalizing the requirement in regulation until a pilot program can be conducted and evaluated. Another commenter requested that the pilot aim to identify other potential alternatives for providing this information, such as ways to enhance the MPF tool. Several commenters suggested that CMS conduct consumer focus groups to ascertain the type and extent of information consumers/beneficiaries would find useful. A commenter suggested that we include beneficiaries with a range of health literacy and decision making skills to determine which models are the most beneficiary-friendly and effective. Others recommended that CMS convene a CMS-industry-advocacy working group to examine the value in this proposed requirement and determine what design, content and timing might enhance that value.

Several commenters recommended that CMS instead put its resources into enhancing the MPF tool, since many beneficiaries already rely on and are familiar with this tool. They stated that these enhancements would permit enrollees to input their utilization data and receive direct comparisons of plans based on specific data. Another commenter stated that their plan already uses an online portal where members can view all claims made, pending, and paid. This commenter stated their belief that this "real time" data is more useful to beneficiaries to estimate their costs than 6 months of data the plans would use to estimate costs.

Other commenters requested that we put more resources instead into government agencies, community organizations and other groups that provide one-to-one counseling to beneficiaries to help them choose the best plans for them. One commenter requested that we retain existing market basket estimates instead of individual estimates, because they provide useful comparative information and accomplish some goals of this provision. Another commenter suggested that we require plans to make MOOP information more prominent in member materials instead of providing more information that would be marginally helpful.

Response: We appreciate the commenters' suggestions. We do not believe that it is necessary to delay finalizing the statement of authority in regulation, but we note that our final regulation text for § 422.111(b)(12), will allow us to move forward with a pilot program while allowing sufficient room to modify our initial requirements based the results of the pilot, to continue to modify requirements over time, or to extend the pilot program if necessary before full-scale implementation. We agree with commenters that enhancing the MPF tools to be able to input utilization data and generate enrollee specific information on plan choices would be an ideal option. However, we do not foresee this as an option that could be accomplished in a relatively short timeframe of a year or two. While the suggestion that CMS invest more resources into organizations that provide one-on-one counseling to beneficiaries is a valuable one, it is outside the scope of this regulation. Also, only MA organizations have the individual utilization data that would be needed to enhance the MPF tools and improve one-on-one counseling for beneficiaries. Therefore, both improving the MPF tool and improving one-to-one counseling would require plans to track and disclose individual Part C utilization data.

Comment: A few commenters recommended that EGWPs be exempt from the requirement to distribute customized beneficiary data. Commenters noted the limited range of choices available to beneficiaries who receive coverage through these plans; MA organizations' lack of knowledge regarding the contribution EGWP retirees make toward the cost of the premium for their plan; and changes made by the employers to their EGWP MA plans that are not known to the MA organization at the time these summaries are to be provided to enrollees. Another commenter stated that any summary sent to enrollees who have employer group commercial group coverage primary and Medicare as secondary payer, and who enroll in their employer's EGWP MA plan to obtain this Medicare secondary coverage, will not be accurate because it would be based on MA plan out-of-pocket cost-sharing but would not account for the commercial group coverage cost-sharing that these enrollees actually pay. This commenter also stated that some enrollees will not have had the "minimum enrollment period" of 6 months, so the plan would have to exclude them from receiving the summary.

Response: We disagree with these commenters and do not intend to exempt EGWPs from the requirement § 422.111(b)(12). Given that we are modifying our original proposal to provide CMS with authority, under to require an MA organization to furnish directly to enrollees, a Part C EOB, we do not believe that many of these comments are relevant. We also note that EGWPs currently must comply with all MA marketing requirements under § 422.111, although they have flexibility through previously granted waivers with respect to submission, CMS review, and timing requirements. Since a Part C EOB would be part of MA disclosure requirements under § 422.111, we expect EGWPs would be afforded these same times of flexibility but would still be required to comply with the requirement.

Comment: Several commenters responded to our request for comments related to exempting dual eligible special needs plans (D–SNPs) from the requirements. Several commenters recommended that D–SNPs and/or chronic and institutional care SNPs should be exempt from the requirement to furnish customized enrollee data on out-of-pocket costs. Another commenter recommended that CMS exempt any dual eligible beneficiary that enrolls in an MA plan that is not a D–SNP. These commenters believe that since the States' Medicaid plans generally pay enrollees' out-of-pocket costs, providing customized enrollee data through a customized out-of-pocket cost statement or an EOB would be unnecessary and confusing for enrollees.

Response: We appreciate the responses from commenters, but given the modification of our original proposal, we believe that an EOB allowing beneficiaries to track utilization of services as well as any out-of-pocket costs would be a useful tool for dual eligible MA enrollees. While we are not exempting any MA plan type from the requirements at § 422.111(b)(12) at this time, we intend to study the issue of applicability to dual eligible MA enrollees—regardless of whether they are enrolled in D–SNPs—further under our pilot program.

Comment: A few commenters requested confirmation that cost plans will be exempt from furnishing customized enrollee data, since we did not specifically include cost plans in the proposal. One commenter stated that cost plans should not have to provide an EOB due to the difficulty of gathering the information and the significant cost and time required. One commenter also stated that because out-of-network services are paid directly by Medicare Administrative Contractors (MACs), cost plans do not know a member's full out-of-pocket costs. This commenter also stated that for most cost plans, the MACs process claims before sending them to the cost plan; thus there could be a delay in receiving the information, resulting in an inability to produce customized enrollee documents in time to be distributed with the ANOC/EOC.

Response: We did not propose to include cost plans in the proposal for customized enrollee data and, therefore, will not include them in this final policy. However, we will continue to study whether to apply the EOB requirement to cost plans in the future.

5. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

In our April 2010 final rule (75 FR 19709 through 19711), we established a mandatory maximum out-of-pocket (MOOP) requirement for local MA plans effective contract year 2011. As provided at § 422.100(f)(4), all local MA plans, including HMOs, HMOPOS, local PPO (LPPO) plans and PFFS plans, must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which will be set annually by CMS. As provided at § 422.100(f)(5), LPPO plans are required to have a catastrophic limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the dollar amount of which also will be set annually by CMS. Since a statutory MOOP requirement was already in effect with respect to RPPO plans, we had proposed to apply the new mandatory MOOP requirement only to local MA plans, and thus in our April 2010 final rule (75 FR 19711) subjected only local MA plans to the requirement that they meet the MOOP dollar amount specified. We encouraged RPPOs to adopt either the mandatory or voluntary MOOPs established in CMS guidance, stating that, to the extent an RPPO sets its MOOP and catastrophic limits above the mandatory amounts set by CMS for other plan types, it may be subject to additional CMS review of its Parts A and B services cost sharing amounts. We also expressed our intent to address this discrepancy in future notice-and-comment rulemaking.

In our November 2010 proposed rule (75 FR 71233 and71234), we proposed to extend these mandatory MOOP and catastrophic limit amount requirements to RPPO plans beginning in contact year 2012, in order to make it easier for beneficiaries to understand and compare MA plans. Each RPPO plan would establish an annual MOOP limit

on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which would be set annually by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services would be included in RPPO plans' MOOPs. We proposed to codify this requirement by revising § 422.100(f) to include regional MA plans. In addition, we proposed revisions to paragraphs (d)(2) and (d)(3) of § 422.101(d) to specify that the catastrophic limits set by RPPOs may not be greater than the annual limit set by CMS.

After considering the comments received, we are finalizing these proposed provisions without further modification.

Comment: We received several comments on this proposal, most of which expressed support for our proposal to extend the mandatory MOOP and catastrophic limits to RPPOs and agreement that doing so would make it easier for beneficiaries to understand and compare plans.

However, a commenter argued that since CMS is paying MA plans based on projected costs of providing Parts A and B benefits under the fee-for-service program, we should not require MA plans to provide richer benefits than Parts A and B required benefits without being compensated for the additional cost.

Response: We agree with commenters that extending the MOOP and catastrophic limit requirements applicable to RPPOs will make plan-to-plan comparisons easier and will level the playing field for RPPOs relative to LPPOs.

We disagree with the commenter that recommended that MA plans be compensated for the additional cost of including MOOP and catastrophic limits in their benefit packages. As discussed previously in our April 2010 final rule (75 FR 19710), we believe that requiring the inclusion of a MOOP limit is an important step to ensure that individuals who utilize higher than average levels of health care services are not discouraged from enrolling in MA plans that do not have such a limit in place. Given that RPPO plans are required by statute to have such a liability limit in place, we were concerned that enrollees with high out-of-pocket costs would be discouraged from enrolling in RPPOs if similar protection from high out-of-pocket costs is not offered under those plans. We continue to believe that requiring a mandatory MOOP and catastrophic limits set by CMS does not unduly disadvantage MA plans relative to original Medicare.

We are therefore finalizing our proposal to extend the mandatory MOOP and catastrophic limit requirements to RPPO plans at § 422.100(f) and § 422.101(d). Effective contract year 2012, each RPPO plan must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which would be set annually by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services will be included in RPPO plans' MOOPs and catastrophic limits.

Comment: Several commenters recommended that we eliminate the MOOP requirement for dual eligible SNPs (D–SNPs) because members are not responsible for out-of-pocket costs.

Response: We disagree with these commenters. As we explained previously in our April 2010 final rule (75 FR 19711), dual-eligible individuals entitled to have their cost sharing paid by the State and enrolled in a SNP may experience mid-year changes in their Medicaid eligibility. In those cases, these individuals may be required to directly pay the plan cost sharing that otherwise would be the obligation of the State. Accordingly, we will not exempt D–SNPs from the requirement that they implement MOOP and catastrophic limits as established annually by CMS. Like all MA plans, D–SNPs must establish a MOOP limit to provide this enrollee protection, even though the State Medicaid program is usually paying those costs on the enrollee's behalf. For purposes of tracking out-of-pocket spending relative to its MOOP limit, a D–SNP must count only the enrollee's actual out-of-pocket spending. Thus, for any D–SNP enrollee, MA plans must count only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost sharing toward the MOOP limit rather than the cost-sharing amounts for services the plan has established in its plan benefit package.

6. Prohibition on Use of Tiered Cost Sharing by MA Organizations (§ 422.262)

As provided in section 1854(c) of the Act and implemented at § 422.100(d)(2), an MA organization offering an MA plan must offer the plan to all Medicare beneficiaries residing in the service area of the MA plan at a uniform premium, with uniform benefits and levels of cost sharing throughout the plan's service area, or segment of the service area, as provided at § 422.262(c)(2). In spite of this regulatory guidance, we have become aware that an increasing number of plans are charging beneficiaries different amounts of cost sharing for services depending on, for example, which provider group the beneficiary selects, the plan's network of hospitals, or how frequently the beneficiary uses selected services.

In an effort to ensure that MA organizations establish cost sharing that is fully consistent with the intent of the uniformity requirement in section 1854(c) of the Act, we proposed to revise § 422.262 to stipulate that MA organizations cannot vary the level of cost sharing for basic or supplemental benefits for any reason, including based on provider groups, hospital network, or the beneficiary's utilization of services.

Comment: We received many comments that opposed our proposal to prohibit "tiered" cost sharing on the basis of provider group or hospital network. Comments stated that prohibiting tiering would create an overly restrictive environment and would prevent plans from developing benefit designs that encourage enrollees to compare providers on the basis of price. For example, plans would be prevented from implementing various value-based insurance designs. Others asserted tiering allows plans to develop benefit designs that encourage enrollees to compare providers on the basis of price and is valuable component of the MA program. Further, some stated that tiered cost sharing is an integral component of HMO point-of-service and PPO plans' benefit structures and is generally an acceptable practice in health insurance. One comment stated that CMS should not restrict a plan's ability to create innovative benefit package designs that would encourage member participation in programs that support increased access to quality care and allow members to seek services from lower cost providers.

In addition, commenters expressed their concern that the CMS proposal failed to recognize the value of using cost sharing incentives to encourage enrolled beneficiaries to choose high quality, efficient providers. They stated the belief that tiered networks that group providers into tiers based on quality and efficiency may be used to promote quality, and that lower cost sharing could be used to encourage enrollees to receive care from high-value providers rather than low quality or inefficient providers. Other commenters mentioned that plans may use tiering to encourage enrollees to join patient-centered "medical homes" that improve quality while reducing hospitalizations, ER visits, and per capita cost.

Several commenters stated that rather than prohibiting tiered cost sharing for

medical services CMS should use revised summary of benefit (SB) sentences and plan benefit package (PBP) software revisions to make transparent plans' tiered cost sharing.

Response: Our proposal to prohibit tiering of medical benefits would not restrict the benefit design of PPO or HMO–POS plans, as beneficiaries are able to clearly distinguish cost sharing differences on the basis of in-network and out-of-network providers. Our proposal addressed designs that would create sub-networks with varying levels of cost sharing for in-network services that may not be clearly distinguishable and/or accessible by beneficiaries.

We do not disagree with commenters that believe it is important for plans to be able to design benefit packages that allow enrollees to choose providers based on both quality and cost. Our concerns about tiered cost sharing for medical services are focused on the potential barriers to access that may be created if plans implement differential cost sharing by provider network (or on any basis) and the lack of transparency to beneficiaries as they compare plans, and to providers and enrolled beneficiaries that are participants of any such benefit design. We require that all enrollees in a plan's service area must have adequate access to plan providers and that permitting different levels of cost sharing for provider networks or provider groups may create inconsistent access to providers at each cost sharing tier. We believe some enrollees in a service area could have access only to the highest cost providers or that implementation of tiered cost sharing could disrupt an established relationship with a provider that becomes one of those grouped into a higher cost sharing level or that the enrollee would begin paying the higher cost sharing, not realizing that lower cost providers are available.

We also are committed to ensuring that beneficiaries are able to understand their choices of plan offerings and there is currently no system to facilitate the disclosure of tiered cost sharing to beneficiaries as they compare plans or to beneficiaries that are enrolled in the plan. Further, tiered cost sharing based on provider group or network complicates referrals within the plan network as the providers themselves must be informed about the enrollee costs to see other plan providers to effectively manage enrollees' health care needs.

Finally, we are committed to ensuring that enrolled beneficiaries have access to high quality, efficient providers and to supporting MA plans that create innovative benefit packages that would provide enrollees with low cost, high quality services. We greatly appreciate the comments that expressed plans' same goal of providing enrollees with affordable, high quality care and their belief that enrollees appreciate having choices about providers and the amount they are spending for care.

To date, we are aware of only a few instances of tiered cost sharing for medical services but, in those cases, we believe the differential cost sharing was not based on quality of care or value but rather, on a plan's ability to negotiate favorable rates with providers. That is not to say that we are not persuaded that it may be possible to allow plans more flexibility to design benefit packages that include some differential cost sharing in order to encourage enrollees to seek care from the most efficient providers. In fact, we have decided that we will not finalize at this time our proposal to prohibit tiered cost sharing. After carefully considering all of the comments, we have determined that it would be appropriate for us to consider this policy more broadly. We will provide future guidance and investigate a number of aspects for possible future policymaking related to tiered cost sharing, including, but not limited to: possible revisions to the PBP and SB sentences that would enable transparency; methods for verifying that any tiered cost sharing for medical benefits does not impede access to care for a plan's enrollees; identifying methods for evaluating quality of care furnished by providers or provider networks; processes by which plans could submit for review proposed tiered benefit structures.

Further, we note that although we are not finalizing our proposal, based on our authority at section 1852(b)(1) of the Act and as codified at § 422.100(f)(2), we prohibit tiered cost sharing based on utilization as a type of cost sharing that discriminates against beneficiaries, promotes discrimination, discourages enrollment or encourages disenrollment, steers subsets of Medicare beneficiaries to particular plans or inhibits access to services. Thus, although we included tiered cost sharing based on utilization in our proposal to prohibit all tiered cost sharing, it is also prohibited because it is discriminatory against beneficiaries.

Comment: There were many comments that supported our proposal to prohibit tiered cost sharing on any basis.

Response: We thank the commenters for their support of the proposal but, as explained previous comment, we are not finalizing our proposal at this time.

Comment: There were two commenters that specifically supported the prohibition of tiering based on utilization and several others that stated tiering based on utilization could result in most plan members having lower cost sharing obligations because the first few provider services would have low cost sharing and only the minority of plan enrollees that over-utilize services would have to pay the higher cost sharing amounts charged for more frequent use of services.

Response: We believe that increasing enrollees' cost sharing to charge more to enrollees as they use more services is an example of discriminatory cost sharing which we prohibit under our authority as codified at § 422(f)(2). While the commenters believe that some enrollees are over-utilizing services, we must consider that the enrollees who use the most services may be the sickest enrolled beneficiaries who need more services than do most enrollees. We expect plans to manage enrollees' care and believe there are tools available that enable plans to do so without implementing policies that inappropriately create barriers to access to care. Our policies (for example, cost sharing standards, benefit package review) are designed to prevent discriminatory cost sharing and are in place to protect sicker enrollees from plan designs that charge higher costs for more frequent or more costly utilization in order to discourage use of needed services.

Comment: There were several commenters that requested general clarification of the proposal. There were other comments that stated the proposal was inconsistent with the objectives of the ACA. One plan's comment also requested clarification of what the proposal does to prohibit plans from varying cost sharing by place of service in order to manage cost. For example, lowering cost sharing for physical therapy delivered in the PCP's office compared to the hospital outpatient setting, since such variation is instrumental in plans' efforts to encourage enrollees to utilize the most effective setting for care and to manage cost. Another commenter explained tiering allows health plans to experiment with alternative cost sharing structures that promote better access to care for sicker beneficiaries and better compliance with treatment regimens. For example, by waiving co-payments for certain services provided to diabetics. The commenter also suggested that tiering can be found throughout the Medicare FFS and MA programs since plans are allowed to

charge different cost sharing for out-of-network services and providers.

Response: We believe these disagreements with our proposal are based on a misunderstanding of what we mean by tiered cost sharing, specifically the examples regarding the prohibition of higher cost sharing for out-of-network services and the special cost sharing arrangements for diabetic services/supplies. These examples cited by the commenters are not what we define as tiering of medical services. Therefore, we would like to clarify that even under our proposal, higher cost sharing would have been permitted for out-of-network services (for example, PPOs) and incentivizing enrollees through cost sharing to use more cost-effective settings to receive the same service (for example, charging lower cost sharing for the same service in a PCP's office than in the hospital outpatient department, or for services in a freestanding imaging facility than in the outpatient department of a hospital).

Comment: One commenter questioned CMS's elimination of tiered cost sharing, especially as the industry moves towards patient centered medical homes and accountable care organizations to ensure quality care and tiered cost sharing could be one way to encourage these types of organizations.

Response: We recognize that there is an evolving market for new models for care such as medical home and accountable care organizations. We do not believe that MA cost sharing standards create barriers to plans providing access to those high quality care delivery organizations. CMS will take these comments into consideration in future rulemaking.

Comment: One commenter wanted to clarify whether this prohibition of tiered cost sharing would be at the Plan Benefit Package (PBP) level.

Response: The tiered cost sharing we have observed has been at the PBP level and our proposal would have prohibited tiering at the PBP level.

Comment: One commenter sought clarification on whether or not the proposal applies to the drug portion of Part C plans and encouraged CMS to apply the proposed change to the drug portion of Part C plans. Another commenter proposed that CMS allow differential cost sharing based on provider group or hospital, or modify the meaningful differences test to allow for evaluation of differences in network or referral requirements between plans.

Response: Our proposal targeted tiering of all medical benefits, including Part B drugs under Part C. We thank the commenters and will include the suggestion that allowing differential cost sharing and including the resulting differentiation in provider networks to be considered in our evaluation of meaningful differences during bid review, in our future policy discussions and rulemaking.

Comment: One commenter stated that tiering is the core of modern drug therapy management.

Response: We would like to clarify that our proposal would have no effect on the drug tiering under the Medicare Part D drug benefit.

Comment: One commenter suggested expanding the proposed prohibition to the Part D Program.

Response: We thank the commenter for their suggestions but tiering within Part D is beyond the scope of this proposed rule.

Comment: One commenter requested that CMS establish an employer group waiver excepting MA plans offered through employer/union group health plans from the tiered cost sharing.

Response: We thank the commenter for the suggestion, but we believe that employer group plans must be subject to the same cost sharing as other MA plans in order to provide the beneficiaries enrolled in those plans the same protections as beneficiaries enrolled in other MA and cost plans.

Based on the comments received on this proposal, we will not finalize the proposal to amend § 422.262 by revising paragraph (c)(1). We will consider further rulemaking related to this practice in the future.

7. Delivery of Adverse Coverage Determinations (§ 423.568)

Section 1860D–4(g) of the Act requires Part D plan sponsors to establish procedures for processing requests for coverage determinations and redeterminations. Those procedures must apply to Part D plan sponsors in the same manner as they apply to MA organizations with respect to organization determinations and reconsiderations under Part C. Under § 422.568(d), an MA organization must provide written notice when it makes an unfavorable standard organization determination.

In accordance with section 1860D–4(g) of the Act, we created a parallel notice provision in § 423.568(f) for unfavorable Part D standard coverage determinations. We proposed to revise § 423.568(f) by allowing a Part D plan sponsor to first provide oral notice of an adverse standard coverage determination decision, so long as it also provides a written follow-up notice of the decision within 3 calendar days of the oral notification.

As noted in the proposed rule, we believe this change is necessary because of the short decision-making timeframes under Part D. As we also noted in the proposed rule, this change is consistent with § 422.572(c) whereby an MA organization may choose to meet the 72-hour notification timeframe for adverse expedited organization determinations by first providing oral notice of its decision within 72 hours, so long as it also sends a written follow-up notice within 3 calendar days after providing oral notice.

After considering the comments received in response to this proposal, we are adopting this provision without modification. Thus, we have revised § 423.568(f) to allow a Part D plan sponsor to provide initial notice of an adverse standard coverage determination decision orally, so long as it also provides a written follow-up notice within 3 calendar days of the oral notice.

Comment: Several commenters supported this policy. Some of the comments in support of the proposal also requested that CMS clarify that plan sponsors have 3 business days from the date of the oral notice to send written notice. Other commenters requested that plans have the option of mailing the notice within 3 days of receipt of the request if oral notice is not provided, citing the difficulty in providing oral notice in cases where the plan does not have a telephone number for the enrollee or the enrollee is difficult to reach by telephone.

Response: The regulations in Subpart M of Part 423 related to providing notice to enrollees refer to calendar days, not business days. We do not believe there is a good reason to deviate from that approach for purposes of § 423.568(f). Accordingly, if a plan chooses to provide the initial notice orally, the written follow-up notice must be mailed to the enrollee within 3 calendar days of the oral notice. We appreciate commenters' concerns about those instances where the enrollee cannot be reached by telephone. However, providing oral notice is optional. If the plan does not provide oral notice of a standard coverage determination to deny a drug benefit, the plan sponsor must notify the enrollee of its determination in writing as expeditiously as possible, but no later than 72 hours after receipt of either the request or, for an exceptions request, the physician or other prescriber's supporting statement.

Comment: One commenter expressed concern that the intent of the provision to provide enrollees with information quickly will be diminished if

beneficiaries have to wait to receive the written notice to learn the reason for the denial and appeal rights. The commenter requested that the regulation require the oral notice to include the reason for the denial and information about requesting a redetermination. The commenter also requested that CMS issue guidance to plans and develop model scripts.

Response: We believe that the written notice plans must send the enrollee following the oral notice is the most effective means of providing detailed information on the coverage decision and an explanation of appeal rights. However, we agree there is value in providing guidance to plans on the information that should be conveyed to enrollees when providing an oral decision. Therefore, we will provide guidance in relevant manual provisions regarding the content of oral notification provided by plans.

8. Extension of Grace Period for Good Cause and Reinstatement (§ 422.74 and § 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D–1(b)(1)(B) of the Act generally directs us to use disenrollment rules for Part D sponsors that are similar to those established for MA plans under section 1851 of the Act. Consistent with these sections of the Act, the Part C and D regulations set forth our requirements with respect to involuntary disenrollment procedures under § 422.74 and § 423.44, respectively.

Currently, § 422.74(d)(1)(i)(B) specifies that an MA organization must provide, at minimum, a 2-month grace period before disenrolling individuals for failure to pay the premium. Similarly, under current regulations at § 423.44(d)(1)(ii), Part D sponsors must also provide a 2-month minimum grace period before disenrolling individuals for failure to pay the premium. For both Part C and Part D, involuntary disenrollments are not mandatory and, thus, organizations may choose to implement longer grace periods or forgo involuntary disenrollments entirely as long as they apply their policy consistently. MA and Part D plans that choose to disenroll beneficiaries for failure to pay premiums must notify the beneficiary of the delinquency and provide the beneficiary at least 2 months to resolve the delinquency. The plan must also be able to demonstrate to CMS that it has made reasonable efforts to collect the unpaid premium amounts.

Since beneficiaries who are disenrolled from an MA or Part D plan for failure to pay premiums generally are not eligible for a special enrollment period, the next opportunity to enroll in another plan is during the annual election period in the fall. As a result, these beneficiaries may lose their prescription drug coverage for the remainder of the year, and may incur a late enrollment penalty if they subsequently choose to re-enroll in Part D. For these reasons, and to be consistent with the provision for delinquent premium payments for Supplementary Medical Insurance (Part B of Medicare), we proposed to permit reinstatement of enrollment in an MA or Part D plan for instances in which the individual was involuntarily disenrolled for failure to pay plan premiums, but subsequently demonstrated good cause for failing to submit the premium payment timely. We proposed that good cause would be established only when an individual was prevented from submitting timely payment due to unusual and unavoidable circumstances beyond his or her control.

Specifically, we proposed amending § 422.74(d)(1) and § 423.44(d)(1) regarding disenrollment for non-payment of premiums to allow for the reinstatement of enrollment for good cause subsequent to an involuntary disenrollment associated with the failure to pay premiums within the grace period. A reinstatement of enrollment would remove the involuntary disenrollment from the enrollment record, resulting in continuous coverage as if the disenrollment never occurred. Further, before such reinstatement could occur, we proposed to require that the individual pay in full all premium arrearages on which the disenrollment was based, as well as all other premiums that would have been due since the disenrollment. Consistent with the provision for delinquent premium payments for Supplementary Medical Insurance (Part B of Medicare), we proposed that the disenrolled individual would have a maximum of 3 months from the disenrollment date in which to request the good cause reinstatement and resolve all premium delinquencies.

Comment: The overwhelming majority of commenters expressed support for the proposed regulatory revision. Several commenters further requested that CMS provide additional guidance to plans regarding the circumstances that would constitute "good cause" and would allow for reinstatement of enrollment following an involuntary disenrollment for failure to pay premiums. It was also suggested that CMS require plans to include in their information to beneficiaries an explanation of a grace period, including the eligibility criteria.

Response: We appreciate the support for this proposal and are adopting it as proposed. We will provide additional guidance regarding implementation of these new provisions in manual guidance (Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual).

Comment: A commenter favored an extension of the minimum required grace period for nonpayment of premium from 2 months to 3 months and supports the development of provisions for payment plans for circumstances in which the beneficiary owes more than 1 month's premium. Another commenter asked that CMS consider a waiver of the grace period requirements for employer group waiver plans (EGWPs), stating that some employers pay a portion of the beneficiary's premium and may not be financially able to incur the cost of members not paying their portion of the premium during a 2 month grace period.

Response: Issues involving the length and applicability of the minimum grace period have been the subject of recent rulemaking (see our April 2010 final rule (75 FR 19678)), and we do not believe it would be appropriate or warranted to revisit these issues in this final rule, given that they were not raised in the proposed rule. With respect to the request that we require plans to establish payment plans for premium arrearages, plans are by no means precluded from establishing such arrangements with beneficiaries, but we do not believe such arrangements should be mandatory.

Comment: Several commenters who supported our proposal expressed concern about the examples in the proposed rule preamble of circumstances that likely would not constitute good cause. They suggested certain scenarios they believed would warrant a good cause determination. For example, some commenters opposed the statement in the preamble indicating that we would not expect to find good cause in instances where an individual's legal guardian or authorized representative was responsible for making premium payments but failed to do so in a timely manner. The commenters indicated that beneficiaries may be penalized for errors made by their appointed representatives in situations when the beneficiary is unable to manage his or her affairs and may be unaware of the delinquency or

pending disenrollment. It was requested that CMS direct plans to find good cause in situations where a caregiver, authorized representative or legal guardian is responsible for making payment, but failed to do so timely. In addition, commenters suggested allowing for reinstatement of enrollment if the request is supported by a physician who states that any lapse in coverage could seriously jeopardize the beneficiary's health due to the potential for a disruption in care or if a member of a State Pharmaceutical Assistance Program (SPAP) is disenrolled because the SPAP failed to provide appropriate premium payments.

Response: The examples provided in the proposed rule were intended to be illustrative, and we do not intend to codify those principles in regulation. Accordingly, we will take these comments into consideration as we develop additional "good cause" guidance to plans in the Medicare Managed Care and Medicare Prescription Drug Benefit Manuals. However, we note that the fundamental basis of a good cause determination rests on the circumstances that prevented timely payment of the premium. Thus, a physician's statement about the health consequences of a coverage lapse would not appear to be germane to whether a good cause determination was warranted.

Comment: Two commenters requested clarification as to whether our proposal applied to cost plans.

Response: Cost plans were not a part of our proposal and we did not set forth any proposed changes to 42 CFR part 417. We may consider expanding this policy to cost plans in future rulemaking.

9. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Pursuant to our authority under sections 1851(d)(2)(C), 1860D–1(c), and 1860D–4(a) of the Act, we proposed to codify existing MA and Part D guidance for marketing materials in markets with a significant non-English speaking population or large percentage of limited English proficient (LEP) individuals. We proposed to include a requirement in the regulations that plan sponsors must provide translated marketing materials in any language that is spoken by more than 10 percent of the general population in a plan benefit package (PBP) service area. We proposed revisions to § 422.2264(e) of Subpart V and § 423.2264(e) of Subpart V to reflect this clarification.

The proposed clarification would codify existing guidance regarding translated marketing materials. We proposed taking this step as a result of frequent complaints to CMS from beneficiaries and advocacy organizations that revealed plan sponsors were not providing translated marketing materials upon request in languages spoken by more than 10 percent of the general population of a particular PBP service area. The August 15, 2005 version of the Medicare Marketing Guidelines and every version thereafter, included language stating, "Organizations/plan sponsors should make marketing materials available in any language that is the primary language of more than 10 percent of a plan's geographic service area." Nevertheless, plan sponsors have indicated they were uncertain whether translated marketing materials were required. For example, plan sponsors we talked to were confused about whether the 10 percent threshold applied to a specific age group (for example, only those 65 and older, which does not take into account younger beneficiaries who are Medicare-eligible based on disability). Other plan sponsors assumed they did not have to conduct a language analysis for their plan because they were not aware of any LEP enrollees in their plans. By explicitly codifying the requirement to translate marketing materials for LEP individuals, we are addressing the problem of plan sponsor confusion by removing any ambiguity concerning the translation requirement that may have been created by differences between the language of § 422.2264 and § 423.2264 and the Medicare Marketing Guidelines. Additionally, Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin by recipients of Federal financial assistance. Recipients must take reasonable steps to provide persons with limited English proficiency meaningful access to their programs and activities. This may require the translation or interpretation of certain information into languages other than English. Under an Executive Order 13166, issued in 2000 and reaffirmed in February 2011 by the Attorney General, each Federal agency must also implement a system by which LEP persons can meaningfully access the agency's programs. This codification is consistent with that obligation.

Comment: We received more than 100 comments regarding the proposal to codify the 10 percent threshold standard. The majority of commenters proposed new, more rigorous threshold standards. The most commonly suggested threshold standard was 5 percent of the population or 500 people in a service area, whichever is lower. A small number of commenters suggested a 1 percent threshold. None of these commenters quantified the improvement in access that these standards, particularly the 500 person minimum or 1 percent options, would bring. Some of the commenters recommending this translation standard were unaware that this regulation would only pertain to the Medicare population enrolled in Part C or D plans or that the proposed rule was only requiring translation of marketing materials and not lab test results or patient instructions. Additionally, some commenters supporting the 5 percent or 500 people threshold indicated that many of the LEP individuals they serve are illiterate in any language.

A variety of industry representatives indicated that they supported CMS' rule. Some of these commenters further recommended, however, that CMS base the standard on an individual's primary language in order to focus on individuals that were proficient in only a non-English language rather than those who were bi-lingual. One commenter from industry suggested the standard should be based on the Medicare population; another suggested the standard should be based on the PBP's membership; and another suggested we should look at only individuals age 65 and older. Industry commenters justified their suggestions for modifying CMS' current standard based on their experience that they only receive a few requests for hard copies of the materials each year. The industry commenters also expressed concern about the cost of developing and printing translated materials when they anticipate a low demand.

Response: In response to both industry and advocacy stakeholders that commented on the proposed rule, we will move the standard population-based translation threshold from 10 percent to 5 percent. Further, we will revise our methodology for calculating these thresholds by focusing on individuals who primarily speak a non-English language and who have a limited ability to read, write, speak, or understand English, as opposed to also including individuals who are at least bilingual. Specifically, we will require plan sponsors to translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals who reside in a PBP's service area.

At this time, we will continue to use the U.S. Census Bureau's American Community Survey (ACS) data to determine the languages spoken in each sponsor's PBP's service area. However,

we recognize that the ACS data may be superseded by more accurate or timely data in the future; therefore, we will continue to monitor and review data sources that are available to all plan sponsors. In particular, we will continue to evaluate forthcoming data sources that most accurately identify individuals who are unable to read English-language materials, but are literate in non-English languages. We prefer to use data sources that are publicly available in order to reduce the burden on plan sponsors. We will, as we have done since 2009, continue to calculate, on behalf of all plan sponsors, the specific languages that meet the threshold for each PBP service area.

From a public policy perspective, moving to a 5 percent threshold and focusing on individuals' primary language produces the best outcome because it will focus sponsor resources on individuals with the most need for translated materials. We conducted an impact analysis of how this standard and revised methodology would change current translated materials offerings. The results of our analysis indicated moving to 5 percent and focusing on primary language will slightly reduce the burden on plan sponsors because a small number of them will no longer be required to translate materials at all. (There was a slight net reduction, which may vary from year to year. Under the new standard, some PBPs that did not require translation in the past will now be required to translate.) Additionally, focusing on the primary language spoken by individuals more closely aligns with the HHS definition of a LEP individual. The HHS Guidance to Federal Financial Assistance Recipients Regarding the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (HHS LEP Guidance) defines LEP individuals as those "who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English." Focusing on individuals' primary language is more consistent with the definition than our current practice of looking at any languages spoken by the general population.

We disagree with the other suggested translation threshold approaches from the commenters for several reasons. First, the suggested standard threshold of 5 percent or 500 people, whichever is less, would result in all PDPs and nearly all MAOs providing translated materials in all languages captured in the ACS data because 500 is such a small number of speakers. This would be a significant increase in the number of plan sponsors required to translate and the number of languages required for translation, and absent definitive evidence to support the sharp increase, this would result in insupportable costs and burden. The same argument holds true for the suggestion of a 1 percent standard. Second, the suggested standard of 10 percent of a plan's membership (as opposed to population data) would be impossible for plan sponsors or CMS to calculate because beneficiary language preference is an optional field for beneficiaries to complete on a plan enrollment form. There is no guarantee that all LEP beneficiaries would be counted by the sponsor. Also, because we do not collect the enrollment form language preference data from sponsors, we would need to establish a reporting requirement and then wholly rely upon sponsor-generated data when monitoring for compliance. With regard to the suggestion to only look at language data for those age 65 and older, we cannot lose sight of the fact that some individuals that qualify for Medicare (and for participation in the Part C and D programs) are younger than 65. However, we will conduct additional sensitivity analyses in the future to assess if applying a weighted-average to account for the age distribution of the Medicare population would affect translation requirements. Should we ever change our data source or methodology for calculating translation requirements, we will publish that information in subregulatory guidance.

Comment: One industry organization suggested that plan sponsors should not have to translate any documents, and beneficiaries should rely on oral interpretation services available through their call centers.

Response: We do not agree with this comment. In order to ensure that LEP beneficiaries have access to vital information needed to make appropriate decisions about their health care, our goal is to make marketing materials available to beneficiaries, wherever it is reasonable to do so. Because of the particular effort required to make these translations available, we must balance those resource costs with the likelihood of the documents being requested and used. As such, we apply a threshold, and thus our rules do not require translation of marketing materials into all languages. However, call center interpreters, must be made available in virtually all languages spoken in the U.S. Fulfillment of this requirement provides a safety net in geographic areas where only a few beneficiaries speak a particular non-English language. We reached our decision after conducting the four factor analysis in the aforementioned HHS LAP Guidance, and, based on this analysis, a mix of language services (that is, both oral interpretation services and written translated materials when a standard translation threshold has been met), is the most appropriate solution for the population served by the Medicare Parts C and D programs.

Comment: Several comments were outside of the scope of this proposed rule. The comments were technical and operations oriented, and are more appropriate as comments on the Medicare Marketing Guidelines. Industry requested that plans should not have to have pre-printed copies of translated materials on hand; rather, they preferred to meet the requirement through a print-on-demand capability and provide the translated material within a reasonable timeframe to the beneficiary. Another comment suggested CMS require plans to provide enrollment materials in any language that the plan was advertised in via any media (for example, print, radio, Internet, *etc.*). Lastly, a commenter requested clarification regarding which marketing materials required translation.

Response: We agree that these comments raise valid points that merit clarification, and we will consider them in the context of future revisions of the Medicare Marketing Guidelines. However, we remind MA organizations and Part D plan sponsors that, pursuant to the current Medicare Marketing Guidelines, all Medicare marketing materials that are required to be translated and available in print upon request are also required to be posted on the plan's Web site. The specific marketing materials required for translation are contained within the Medicare Marketing Guidelines.

Comment: One industry commenter suggested that CMS provide translations of the model evidence of coverage (EOC) in the top five languages other than English most commonly spoken by Medicare beneficiaries nationally.

Response: We are aware of the cost burden on plan sponsors to produce translated marketing materials, and CMS and beneficiary advocates have concerns about the quality and accuracy of translated materials provided to beneficiaries. In response, for the 2012 contract year, CMS anticipates providing a few translated versions of certain model marketing materials. Our aim is to reduce the burden on plan sponsors and increase the quality, consistency, and accuracy of these marketing materials for beneficiaries. By providing translations of some or all model materials in all languages in

which translation is required for at least one plan benefit package, plan sponsors would merely need to translate their own plan-specific inserts or modifications, in addition to required materials for which there is no model or translation available. In future years we would prefer to translate all required model marketing materials and will actively pursue this goal, but we are uncertain about viability of this practice because we cannot guarantee that we would be able to fund this initiative annually. Additionally, we are exploring creating a 1-page model document that would inform beneficiaries, in multiple languages, that free interpreter services are available when beneficiaries call the plan's customer service call center.

Comment: One commenter requested clarification as to whether the Program of All-inclusive Care for the Elderly (PACE) program is subject to the requirement that plan sponsors provide translated marketing materials.

Response: We clarify that PACE programs are not subject to this requirement.

In summary, we received numerous comments on this proposed rule. In response to commenters, we are finalizing the proposed rule, with modification. We factored in advocacy organizations' comments to reduce the percentage threshold and addressed industry's concerns by refining our methodology, which will slightly reduce sponsors' administrative burden. Further, the revised analysis methodology is more consistent with the HHS definition of an LEP individual than our current practice. Our final rule will require plan sponsors to translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a PBP's service area. This new translation standard will go into effect for contract year 2012; therefore, 2012 enrollment materials must be produced with this new translation standard in mind, in keeping with all relevant deadlines that occur in 2011 in preparation for the 2012 marketing season. As in the past, we will continue monitoring sponsors' compliance with translated materials requirements.

E. Strengthening Our Ability To Distinguish for Approval Stronger Applicants for Part C and Part D Program Participation and To Remove Consistently Poor Performers

This section addresses a number of provisions designed to strengthen our ability to approve strong applicants and remove poor performers in the Part C and D programs. Since the implementation of revisions to the MA program and initial implementation of the prescription drug program in January 2006 as a result of the MMA, we have steadily enhanced our ability to measure MA organization and PDP sponsor performance through efforts such as the analysis of data provided routinely by sponsors and by our contractors, regular review of beneficiary complaints, marketing surveillance activities, and routine audits. This information, combined with feedback we have received from beneficiary satisfaction surveys, HEDIS data, and information from MA organizations and PDP sponsors themselves, has enabled us to develop a clearer sense of what constitutes a successful Medicare organization capable of providing quality Part C and D services to beneficiaries. This information has also allowed us to identify and take appropriate action against organizations that are not meeting program requirements and not meeting the needs of beneficiaries.

As our understanding of Part C and D program operations has deepened since implementation of the MMA, our use of our authority to determine which organizations are qualified to offer MA and PDP sponsor contracts, evaluate their compliance with Part C and D requirements, and make determinations concerning intermediate sanctions, contract non-renewals and contract terminations has evolved as well. The changes identified in this rule will further allow us to make these determinations more effectively. These provisions are described in detail in Table 7.

TABLE 7: Provisions to Strengthen Our Ability to Distinguish for Approval Stronger Applicants for Part C and Part D Program Participation and to Remove Consistently Poor Performers

PROVISION	PART 422		PART 423	
	Subpart	Section	Subpart	Section
Expand Network Adequacy Requirements to All MA Plan Types	Subpart C	§422.112	N/A	N/A
Maintaining a fiscally sound operation	Subpart A Subpart K	§422.2 §422.504	Subpart A Subpart K	§423.4 §423.505
Release of Part C and Part D Payment Data	Subpart K	§422.504	Subpart K Subpart R	§423.505 §423.884
Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds	N/A	N/A	Subpart C	§423.120
Denial of Applications Submitted by Part C and D sponsors with Less than 14 months Experience Operating their Medicare Contracts	Subpart K	§422.502	Subpart K	§423.503

1. Expand Network Adequacy Requirements to All MA Plan Types (§ 422.112)

In our November 2010 proposed rule (75 FR 71236), we proposed applying the network adequacy standards at § 422.112(a)(10) to all MA plans that meet Medicare access and availability requirements by directly contracting with network providers, including MSA plans that choose to use a contracted networks of providers. This proposed change would bring MSA network adequacy requirements in line with those applicable to MA coordinated care (CCP) plans and network private-fee-for-service (PFFS) plans, per a provision finalized in our April 2010 final rule (75 FR 19691 through 19693). This rule established criteria that MA CCP and PFFS plans must meet so that we can ensure that the network availability and accessibility requirements specified in section 1852(d)(1) of the Act are satisfied. We are finalizing this provision without modification.

Comment: One commenter recommended that CMS require all MA plans, including non-network PFFS and MSA plans, to meet the network adequacy requirements at § 422.112(a)(10).

Response: We do not have the statutory authority to require that the network adequacy standards at § 422.112(a)(10) be applied to MSA plans that do not use a network of providers or to PFFS plans that are not required to have a network that meets network adequacy requirements. MSA plans are not required under section 1859 of the Act to establish networks of providers, and section 1852(d)(5) of the Act permits PFFS plans to operate without networks when fewer than two network-based plans are operating in an area.

2. Maintaining a Fiscally Sound Operation (§ 422.2, § 422.504, § 423.4, and § 423.505)

Under the authority of sections 1857(d)(4)(A)(i) and 1860D–12(b)(3)(C) of the Act, which establish requirements for MA organizations and PDP sponsors to report financial information demonstrating that the organization has a fiscally sound operation, we proposed in § 422.2 and § 423.4 to define a fiscally sound operation as one which, at the very least, maintains a positive net worth (total assets exceed total liabilities). We noted that the States' oversight and enforcement of financial solvency of MA organizations and PDP sponsors provides an important protection for Medicare beneficiaries enrolled in MA and Part D plans. However, we also noted that the requirement for plans to report financial information demonstrating that the organization has a fiscally sound operation and our authority to audit and inspect any books and records, is an indication that we have an interest in the organization maintaining a fiscally sound operation and that this interest is separate and apart from the State licensure and financial solvency requirements for an organization. Additionally, under the authority of sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act which afford the Secretary the authority to include terms and conditions in the contracts with MA organizations and PDP sponsors that are necessary and appropriate, we proposed the addition of a contract provision at § 422.504(a) and § 423.505(b)(23), under which the MA organization or Part D sponsor agrees to maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

Comment: One commenter suggested that the standard that "total assets exceed total liabilities" was insufficient and that CMS should set a higher threshold.

Response: We believe that the role of the state insurance departments in providing oversight and enforcement of licensure and financial solvency is the primary tool for financial oversight of organizations and therefore it is unnecessary for CMS to modify this standard.

Comment: One commenter asked if the fiscally sound operation requirement applied only to the Medicare lines of business or to all lines of business.

Response: We have not imposed any new reporting requirement and will rely on the financial reports that are submitted for the organization as a whole.

Comment: One commenter suggested that CMS should publish clear guidelines for when a plan's finances will be declared "unsound."

Response: We have specified in the definitions that a "fiscally sound operation" is one with a positive net worth. We already require that organizations submit the same information that is submitted to their state insurance departments under that state's requirements and guidelines. Therefore it is not necessary for us to set specific guidelines for calculating positive net worth.

Comment: One commenter suggested that CMS should publish its criteria for selecting alternative plans for receiving transitioned beneficiaries.

Response: When appropriate, we would follow all policies and procedures specified in the current guidance in Chapter 2 of the Medicare Managed Care Manual *http://www.cms.gov/MedicareMangCareEligEnrol/Downloads/FINALMAEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf,* entitled "Passive Enrollment by CMS which are used for the smooth transition of beneficiaries to other plans when there are terminations for reasons other than failure to maintain a fiscally sound operation. For prescription drug plans, we would follow all policies and procedures specified in the current guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual, *http://www.cms.gov/MedicarePresDrugEligEnrol/Downloads/FINALPDPEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf,* which contains the Part D guidance on passive enrollment.

Comment: One commenter agreed with the definition for "fiscally sound operation" with the understanding that "total assets" and "total liabilities" were to be as defined by the state insurance departments.

Response: We appreciate the commenter's support for the proposal and confirm that we have not changed our financial reporting requirements and that we continue to use the information that is submitted to the state based on the State's financial reporting requirements and guidelines.

Comment: One commenter suggested that CMS should take into consideration arrangements providing for the financial solvency of an MAO by the parent organization consistent with the treatment of those arrangements by the relevant State insurance department.

Response: We continue to consult regularly with state insurance regulators to ensure that sponsoring organizations are meeting State reserve requirements and solvency standards required for State licensure and their input is included in any action related to fiscal soundness.

Comment: One commenter requested that CMS clarify how the Part D fiscally sound requirement will apply to Medicare cost organizations that also offer Part D services.

Response: As mentioned previously, we will rely on the financial reports that are submitted for the organization as a whole. Therefore, the cost organization, including the Part D benefit, will be held to the fiscally sound operation requirement.

Comment: One commenter was concerned that the fiscally sound

requirement adds new reporting requirements.

Response: As noted in the preamble to the November 2010 proposed rule, a determination of whether there is a positive net worth will be made from the financial reports submitted under the currently approved financial reporting requirements. No additional filings will be required.

Comment: One commenter requested that CMS explain how traditional state regulation has not provided adequate consumer protection such that additional Federal oversight is required and suggested that the proposal be withdrawn to allow the states to maintain primary supervision of plans for fiscal soundness.

Response: As noted in the preamble to the November 2010 proposed rule, licensure does not deem an organization to meet other requirements imposed under Part C or Part D. The requirement for an organization to be licensed under State law and the requirement that an organization must report financial information demonstrating that the organization has a fiscally sound operation are separate requirements in the Act. The authority to license an MA organization or PDP sponsor and set solvency standards rests with the state licensing authority and therefore the primary supervision of plans for fiscal soundness continues to rest with the states. The proposed rule clarifies what we expect from a fiscally sound operation. Further, as stated previously, we consult regularly with state insurance regulators and their input is included in any action related to fiscal soundness.

Comment: One commenter asked how the requirement to maintain a fiscally sound operation will protect beneficiaries if the plan sponsor has already encountered the financial difficulties.

Response: We have historically been limited in our ability to take compliance and enforcement action against an organization solely on the basis of financial problems if the organization is still licensed by the state and is not otherwise out of compliance with CMS requirements. In some cases, we have been made aware by state insurance departments that an organization would inevitably lose its state licensure because of its poor financial condition, but we were unable to take action to terminate the organization's contract and ensure that beneficiaries were smoothly transitioned to a new organization or sponsor, until the full termination process was completed by the state. The proposed rule will allow us to work with the state insurance department and if appropriate, take timely contract action in order to avoid any additional potential risk to enrollees.

After consideration of the comments received in response to the proposed rule, in this final rule, we are adopting the provisions as proposed.

3. Release of Part C and Part D Payment Data (§ 422.504, § 423.505, and § 423.884)

This final rule provides for the Secretary to release Part C and D summary payment data. The Secretary believes these data should be made available because other publicly available data are not, in and of themselves, sufficient for the public (including policy analysts and researchers) either to understand expenditures for the MA and Part D programs, or to inform the public on how their tax dollars are spent.

In the proposed rule, we stated that in keeping with the President's January 21, 2009, Memorandum on Transparency and Open Government (74 FR 26277), we were proposing to routinely release summary Part C and Part D payment data. We stated that additional purposes underlying release of these data included allowing public evaluation of the MA, prescription drug benefit, and RDS programs, including their effectiveness, and reporting to the public regarding expenditures and other statistics involving these programs.

In the proposed rule, we stated our belief that the availability of the payment data would permit potential plan sponsors to better evaluate their participation in the Part C and D programs, as well as facilitate the entry into new markets by existing plan sponsors. As a result, the availability of plan payment data would enhance the competitive nature of the programs. We stated that in knowing the per member per month payment amounts and other components of plan payment (plan rebates and risk scores), new business partners might emerge, and better business decisions might be made by existing partners. Thus, we believed that including a provision in our contracts with plan sponsors regarding the release of summary payment data was both necessary and appropriate for the effective operation of those programs.

We proposed that these data would be routinely released on an annual basis in the year after the year for which payments were made. The data release would occur only after the final risk adjustment reconciliation has been completed for the payment year in question and, for Part D, after final payment reconciliation of the various subsidies. Thus, we would release data for payment year 2010 in the Fall of 2011.

We stated this proposed timeframe would not apply to the release of RDS payment data, since we do not reconcile RDS payment amounts until 15 months following the end of the plan year. The majority of our sponsors provide retiree drug coverage on a calendar year basis. Thus, if an applicable RDS plan year ended December 31, 2010, the payment reconciliation would not be due until March 31, 2012, which would be after the Fall 2011 target for release of other Part C and D payment data. Therefore, we proposed that we would release the most current RDS payment data available at the time the Part C and D payment reconciliation has been completed and at the same time those other Part C and D payment data are compiled and released.

Specifically, as we indicated in the November 2010 proposed rule, beginning in the Fall of 2011 we would release reconciled payment data as follows:

- Part C

++ Reconciled payment data summarized at the plan benefit package level including average per member per month (PMPM) payment for A/B (Medicare covered) benefits standardized to the 1.0 (average risk score) beneficiary and average PMPM rebate amounts.

++ The average Part C risk score for each plan benefit package.

++ Reconciled aggregated Part C payment data by county including the average PMPM payment amounts for A/B benefits standardized to the 1.0 (average risk score) beneficiary and average rebates amounts at the plan type (including HMO, PPO, RPPO, and PFFS) for each county in which such plan types are represented.

- Part D

++ Reconciled payment data summarized at the plan benefit package level including average PMPM payment for the direct subsidy standardized to the 1.0 (average risk score) beneficiary, the average low-income cost sharing subsidy, and the average Federal reinsurance subsidy.

++ The average Part D risk score for each plan benefit package.

++ Final payment reconciliation data arrayed by parent organization, number of plan benefit packages, the gross reconciliation amount broken out by risk sharing reconciliation amount, reinsurance reconciliation amount, and low income cost sharing reconciliation amount.

++ Retiree drug subsidy (RDS) data including the gross aggregate reconciled

subsidy amount paid to each eligible sponsor of qualified retiree prescription drug coverage and the total number of unduplicated Medicare eligible retirees for each sponsor.

We noted that because the proposed provisions would apply to all Part C and Part D sponsors, it would apply to any entity offering either Part C or Part D plans, including MA organizations offering and not offering prescription drug plans, as well as all Part D drug plan sponsors. It would also apply to sponsors entitled to Federal RDS subsidies.

We solicited comment generally on the public release of Part C and Part D payment data. We also specifically solicited comment on whether commenters believed that any of the Part C and Part D payment data we proposed to release contained proprietary information, and asked commenters to suggest, if they believed proprietary data were implicated, safeguards that might appropriately protect those data.

Comment: We received numerous comments on this provision of the proposed rule from beneficiary advocacy groups, researchers, PDPs, PBMs, associations, and MA organizations. The beneficiary advocacy group comments supported our proposal to release payment data. One beneficiary advocacy group supported release of all payment data, to the extent it could be done without compromising beneficiary personally identifiable health information, and recommended we codify release in regulation text.

Response: We accept the comment from the beneficiary advocacy group regarding codifying a process for release of summary payment data in regulation text. We believe that codifying the release in the Code of Federal Regulations will permit interested parties to have a better understanding of exactly what summary payment data to expect CMS to release and when to expect to be able to access it. As we indicated in the proposed rule, the Secretary has the authority to include in MA organization and Part D sponsor contracts any terms and conditions the Secretary deems necessary and appropriate. (See sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, which incorporates section 1857(e) into Part D.) As we also stated in the proposed rule, our regulations at sections § 422.504(j) and § 423.505(j) permit us to include other terms and conditions in these contracts that we find necessary and appropriate to implement the Part C and D programs. Similarly, we stated that under § 423.884(c)(3)(i), RDS sponsors agree to comply with the terms and conditions for eligibility for a subsidy payment in our regulations and in related CMS guidance. Accordingly, we are codifying in our regulations at § 422.504(n) our intent to release Part C summary payment data as proposed, at § 423.505(o) our intent to release Part D summary payment data as proposed, and at § 423.884(c)(3)(ii) our intent to release summary RDS payment data as proposed. We will also modify MA organization and Part D sponsor contracts as well as RDS sponsor agreements to account for the release of summary payment data. As we discuss in more detail, below, in our response to comments opposed to our release of summary payment data, we believe we have the authority to promulgate these regulations providing for the routine release of these data.

Finally, in response to the statement from a beneficiary advocacy group that supported release only in the event that personally identifiable beneficiary health information could be protected, we will only release summary data to the extent individually identifiable information is protected—consistent with existing CMS policy. Thus, for instance, to the extent that less than 11 MA plan members of a specific MA plan type reside in a county, we will not release summary payment information or average Part C risk scores for that plan type in that county.

Comment: Some MA organizations supported release of payment data as proposed, while many of them recommended limiting data release in varying ways. Two recommended releasing only average monthly payments and rebates, while others suggested plans should have the right to veto release of any payment information prior to public dissemination. Another MA organization suggested aggregating data at a higher level, for instance by plan type, thus masking plan-specific data. A commenter stated that reporting or releasing payment data at the plan benefit package level is not aggregating or summarizing payment data at all and that such a release would be inconsistent with our stated intent to only release summary payment data. Some Part D plan sponsors recommended releasing Part D payment data on only an aggregate basis—where individual plan payment data would not be revealed. Some health plan associations also recommended releasing payment data on a more aggregated, non-plan-specific basis—for instance, releasing only aggregated Part C or D payment data at the county level with no plan identifiers.

Response: We do not believe it is appropriate to provide veto power to MA organizations regarding release of payment data. If we were to allow some MA organizations to withhold data, the value of the remaining, released data would be diminished and would potentially become useless to researchers and the public. Similarly, were we to aggregate payment data at a higher level prior to release, the public would know very little about what payments were being received by specific CMS contractors—which would undermine a specifically stated goal of release which was to inform the public on how their tax dollars are spent. Researchers would also be hampered in their ability to conduct meaningful studies that analyze the Medicare program and Federal expenditures. We believe we have identified the appropriate level of aggregation such that researchers and the public will have specific enough information to meet their needs, while we will continue to shelter from disclosure bidding and provider contracting information both MA organizations and Part D plan sponsors want protected.

Comment: Some MA organizations contended that proprietary plan payment information related to providers could be deduced from the payment data we proposed to release. Some Part D plan sponsors and associations stated that competitors would be able to reverse engineer bids. One commenter stated that the data we proposed to release could be used with other Part D data currently released by CMS, such as PDP enrollment information, plan premiums, and generic dispensing rates, to reverse engineer bid data and other sensitive information relevant to Part D sponsors' bidding and business strategies.

Response: We do not agree. The bid pricing tool (BPT) document that MA organizations and Part D plan sponsors submit to CMS as part of the annual bidding process asks the plans to provide detailed information on their costs to furnish Part C and D services. In the case of MA organizations, over a dozen initial values related to Part C costs are further broken out by costs for services, administrative costs, expected utilization and member cost sharing. These costs and others are trended from the base year (derived from costs from the calendar year before the bid is submitted) to the year for which plans are bidding. Thus, the input values in the bids are already composed of aggregated cost and utilization information. Information provided on the BPT is aggregated in a number of ways—across providers, beneficiaries, and sites of service. Additionally, the different components of cost—direct

medical, indirect medical, administrative, profit, *etc.* are also aggregated. Thus, to suggest that a competitor would be able to derive or disaggregate specific bidding information from the aggregated payment data we proposed to release, or, much less, that a competitor would be able to derive payment information related to any specific provider, is simply not credible.

A similar argument applies to Part D bid submissions in the sense that dozens of input values representing type of drug (generic, preferred brand, specialty, etc.), expected utilization and cost information aggregated over a number of provider types, and a multitude of contracting entities ensures sufficient protection for plan bidding information. While the payment data proposed for release will be very helpful in understanding the payments received by Part D sponsors and their ability to estimate their revenue needs in their Part D bids, we do not believe that this information will be sufficient for others to determine sensitive components of the Part D bids, such as expected manufacturer rebates and profits. The Part D data to be released do not provide information about administrative costs and drug costs incurred by Part D sponsors in sufficient detail for other parties to determine the sensitive components of bid data. In the few numbers we will release, no specific provider contractual information is in danger of being exposed. Those viewing and using the aggregated data will have no way to disaggregate the data since there are dozens, if not hundreds, of individual components that are used to build up the few data elements that will be released.

Comment: Some commenters stated that by reviewing 2 or more years of payment data, an MA organization of Part D sponsor would be able to determine the cost trends of their competitors. The commenters stated that these entities would be able to determine where their competitors are heading, which would jeopardize the fairness and competitive dynamics of the bidding process. The commenters also stated that competitors would gain information about business strategies that could undermine the bidding process and the competitive nature of the Part C and D programs. Other commenters stated that release would undermine the integrity of the bid process and alter the competitive marketplace.

Response: We do not agree that release of summary payment data as we proposed would affect the integrity of the bidding process in either the Part C or D programs. First of all, as we described briefly in response to an earlier comment, bids are built up of costs related to a multitude of components (plan costs for health care services, administrative activities, utilization, and profits). Further, such costs must be trended from the base year—the calendar year before the bid—to the year for which the bid is submitted—the year after the year in which bids are submitted in June. Utilization, costs, and trends must be certified by a qualified, independent actuary prior to bid submission. Since we will continue to require actuarial certification, integrity is unaffected. Second, the MA and Part D programs are not competitive in the way that term is normally understood. Although Part C and D plans do compete for members, primarily through the benefits offered and the cost (member cost sharing and premium) of those benefits, they do not directly compete for the payments that CMS makes. Rather, we approve all sustainable bids that are otherwise qualified without preference for the lowest bidder. The fact that MA-eligible Medicare beneficiaries can, on average, select from over 2 dozen MA and Part D plans in every county of the nation is ample evidence that competition is robust. As we mentioned in the preamble of the proposed rule, we believe the availability of the summary payment data we proposed to release will permit potential plan sponsors to better evaluate their participation in the Part C and D programs, as well as facilitate the entry into new markets by existing plan sponsors. In other words, we believe competition, if anything, will be enhanced by release rather than harmed in any way. Further, although trends from one year to the next might be revealed through release of payment data for sequential years, the fact remains that such trends will be stale (at least 2 years old) and reveal little about competitive strategies in future years. Finally, where plans are free to modify the actual competitive components that are used to build up bids, such as benefit offerings and member cost-sharing, little is left of the argument that revealed cost trends will have an impact on the competitive nature of the programs.

Comment: One commenter stated that payment data release would work to the programs' detriment.

Response: We do not agree. We believe that a more extensive knowledge of summary payment data will not only not harm competition in the Part C and D programs, but rather that it will permit both existing and potential plan sponsors to better assess the business opportunities available to them.

Comment: Many commenters stated release of summary payment data was prohibited under Exemption 4 of the Freedom of Information Act (FOIA), others cited a prohibition on release based on Exemption 6, still others cited both Exemptions 4 and 6 as prohibiting release under the FOIA. Some provided extensive arguments, citing case law to support their positions. These, and other commenters, also invoked the Trade Secrets Act and argued that there was a strong potential for compromising proprietary information of both Part C and D plan sponsors. Still others stated that the Privacy Act is implicated because release of risk scores might allow someone to identify the health status of an individual enrollee or enrollees.

Response: In response to comments arguing that the Trade Secrets Act (18 U.S.C. 1905) or FOIA exemptions prohibit release of this information or citing past practices of this agency with respect to FOIA requests, as noted previously, we do not believe that the release of the data at issue necessarily would be subject to the FOIA exemption for information protected by the Trade Secrets Act, because we do not believe the data we would be releasing could be used to obtain proprietary information. However, with respect to the data we are proposing to release, we believe the merits of such arguments are moot in light of the fact that we have decided through this rulemaking to require the disclosure of data at issue. Section 1106(a) of the Act (42 U.S.C. 1306(a)) provides authority to enact regulations that would enable the agency to release information filed with this agency. (*See Parkridge Hospital, Inc.* v. *Califano,* 625 F.2d 719, 724–25 (6th Cir. 1980). We have engaged in notice-and-comment rulemaking to promulgate regulations to enable the disclosure of the summary payment information. The Trade Secrets Act permits government officials to release otherwise confidential information when authorized by law. A substantive regulation issued following notice-and-comment rulemaking, such as this one, provides the authorization of law required by the Trade Secrets Act. Because the Trade Secrets Act would allow disclosure, Exemption 4 (5 U.S.C. 552(b)(4)), which is as co-extensive with the Trade Secrets Act, would also not preclude disclosure with respect to the information that would be released under this final rule. This conclusion would not apply to other payment data with respect to which a Trade Secrets Act argument might be made.

With respect to the commenters, who argued that FOIA Exemption 6 (5 U.S.C. 552(b)(6)) protects information that would cause a clearly unwarranted invasion of an individual's personal privacy and argued that releasing plan payment and risk score data could lead to the disclosure of the name or health status of an individual enrollee, we disagree, because the concerns expressed are too speculative to lead to a legitimate privacy interest. Furthermore, there is a substantial public interest in the release of this summary payment data which can be used to shed light on the government's operation of the Part C and D programs, outweighing the speculative privacy interest.

Finally, with regard to protection of individually identifiable data through the release of risk scores, as we stated previously, we will not release summary payment information or average Part C or D risk scores when the small number of enrollees in a plan or in an area might reasonably permit disaggregation such that individually identifiable information could be revealed.

Comment: Some commenters stated release of payment data would harm business partners and thus, the Part D program.

Response: We do not agree. As we have already explained, we are not releasing payment data at a sufficient level of granularity to permit extrapolation of specific contract terms or purchase information. Rather, we will only be releasing summary payment and risk score data that is sufficiently aggregated to prevent extrapolation to any individual provider's or manufacturer's terms with any plan sponsor.

Comment: Some Part D sponsors and one association cited Congressional Budget Office (CBO) and Federal Trade Commission (FTC) letters warning that release of rebate information could lead low bidders to increase their bids compared to the bids they would have submitted without such information on competitor prices. They argued that release of rebate data might foster collusion or otherwise undercut vigorous competition on drug pricing.

Response: These commenters seem to be conflating the release of summary data on the component of savings in the Part C payment calculation known as the Part C rebate with the release of Part D drug manufacturer rebate information. In the CBO and FTC documents we were able to review, warnings were provided solely related to the release of the latter. In the proposed rule we did not propose the release of any Part D drug manufacturer rebate information. The Part C rebate information we proposed to release is solely related to Part C and represents 75 percent of the difference between the plan risk-adjusted statutory non-drug monthly bid amount and the plan risk-adjusted area-specific non-drug monthly benchmark amount—when the bid is below the benchmark. (See § 422.264(ff).) Revealing this Part C rebate information is little different than revealing the Part C plan basic beneficiary premium amount (see § 422.262), release of which is already required by regulation. (See § 422.111(f)(6).)

Comment: Some commenters cited past practices by CMS where CMS specifically denied release of similar data by invoking Exemptions 4 and 6 of the FOIA.

Response: As we previously indicated, the data that would be released under this rule have been specifically limited in nature, and as to the year involved to avoid proprietary data issues. It thus is not necessarily the case that previous denials of FOIA requests would apply to these data. Also, as noted previously, the issue of whether these data would be withheld from release in response to a FOIA request absent this final rule is moot in light of the fact that we have now engaged in notice-and-comment rulemaking to promulgate regulations which clearly enable the disclosure of this information regardless of whether it would have been disclosable in the absence of this final rule.

Comment: Some commenters stated that release of this summary payment data would have limited value to researchers. One researcher cited more than 20 scholarly articles that he and colleagues had written using data on MA payments and enrollment since 2000 and urged us to release the type of MA payment data discussed in the proposed rule for years between 2006 and 2010. An additional commenter also urged the release of the same payment data for years prior to 2010, and argued that this notice and comment process would apply equally to such prior year data.

Response: First, we would note that researchers have informed us that they believe the data we proposed releasing does have value to them. With respect to 2006 through 2009 payment data, while the proposed rule referenced 2010 data in discussing the timing of our release of payment data, we agree that the same analysis and rationale would apply equally to data for prior years as well, and that through our publication of a proposed rule and our response to comments, we have satisfied the requirements in section 1106(a) of the Act (42 U.S.C. 1306(a)) for a regulation that authorizes release of this information for any year. Given the interest of these commenters in such prior year data, we will release data for these prior years as well as 2010, and will release data for future years on the schedule set forth in the proposed rule.

Comment: One commenter stated that we had not stated what public policy goal was being served by releasing payment data at the plan level. Another commenter stated that currently available data are sufficient to CMS' stated purposes for release.

Response: We do not agree that currently available data are sufficient to accomplish the broad public policy purposes supporting release of this information, which we discussed in the proposed rule. In the preamble of the proposed rule we explained that other publicly available data are not, in and of themselves, sufficient for the studies and operations that researchers want to undertake to analyze the Medicare program and Federal expenditures, and to inform the public on how their tax dollars are spent. This is so because currently available data do not provide researchers a means of analyzing payment data at a granular enough level to draw conclusions about regional variations in CMS payment—such as rural/urban differences or the payment variances between MSAs. We also cited the President's January 21, 2009, Memorandum on Transparency and Open Government. Finally, we stated that additional purposes underlying release included allowing public evaluation of the MA, prescription drug benefit, and RDS programs, including their effectiveness, and reporting to the public regarding expenditures and other statistics involving these programs.

Comment: Some commenters stated that release would not help beneficiaries select the MA or Part D plan that is best for them. Others stated that release would adversely impact beneficiaries due to related impacts on MA and Part D plan offerings. Still others stated that release of payment data would be misinterpreted by MA enrollees.

Response: The intent of releasing summary payment data and risk score information is not necessarily to help Medicare beneficiaries to select the right plan for them. When the data are published we will provide appropriate disclaimers to ensure the greatest likelihood of understanding by researchers, enrollees, and other interested parties. As far as the potential for adverse impacts on beneficiary offerings, we have already addressed the issues of competition and collusion and explained our belief that release will

neither limit competition nor engender collusion.

Comment: One commenter noted that release of this information was not authorized by the Social Security Act.

Response: We do not agree. Section 1106(a) of the Act (42 U.S.C. 1306(a)) provides authority to enact regulations that enable the agency to release information filed with this agency.

Comment: One commenter stated that there was a unique situation in their State where they are the largest MA organization offering MA plans. This commenter stated that its primary competition is from Medicare Cost HMOs/CMPs and Medigap insurers—neither of which are impacted by this regulation. The commenter stated it was unfair that its aggregate payment information would be released, while that of Cost HMOs/CMPs with which it was competing would not be released.

Response: While it might be true that in some markets a single MA organization is predominant, it is also true that a valid public policy goal related to the release of summary payment data is to encourage competition. Although Cost HMOs/CMPs and Medigap insurers are not subject to this rulemaking, information on medical loss ratios for Medigap insurers should be available from the State Insurance Department. Thus, while the payment data we release will be available with respect to MA plans but not Cost HMOs/CMPs or Medigap plans, Medigap MLR data will be available with respect to Medigap plans but not MA plans.

Comment: A commenter recommended that when CMS modifies the MA organization contracts, as it proposed in the proposed rule, it should modify them *only* to say that CMS will release the specifically described payment data. The commenter suggested that the new contractual language should not simply reference MA data, as this could be construed to permit CMS to release data that was not the subject of this notice and comment process.

Response: We agree with the commenter and when modifying MA plan contracts, we will limit language regarding payment data disclosure to only the items discussed in the proposed rule. In a similar manner we have limited the regulatory language we are adding to sections § 422.504(n), § 422.505(o) and § 423.884(c)(3)(ii) to provide for disclosure of only those items specifically proposed in the rule.

Comment: One commenter argued that section 1860D–12(b)(3)(D) of the Act, as amended by section 181 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), specifically prohibited release of payment data since the only authorized release would be under the conditions enumerated in that section of the law. The commenter argued that the law authorizes release *only* when one of the following conditions is met: (1) To carry out Part D; (2) to improve public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services; or (3) to release the data to Congressional support agencies for Congressional oversight purposes.

Response: The summary payment data that CMS proposed to release are not data that are provided by Part D sponsors—either under section 1860D–12 or under section 1860D–15 of the Act. Rather, the data that CMS proposed to release are CMS data. The data are compiled and derived solely from CMS internal payment files.

Further, we do not agree with the commenter's interpretation of law. In reviewing the House Ways and Means summary of section 181 of MIPPA, we find that Congressional intent in adding the matter after the first sentence in section1860D–12(b)(3)(D) of the Act was to provide a directive to the Secretary to release claims data to appropriate Congressional support agencies. The Ways and Means summary of section 181 reads, in full: "Clarifies the use of Part D data collected under section 1860D–12 of the Act for research and other purposes. Requires the Secretary to release Part D claims data to Congressional support agencies to the extent that the agencies have authority to request the data in their respective authorizing statutes." In effect, the legislation was intended to require the Secretary to release claims data to Congressional support agencies and not to prohibit its release to any others. Section 1860D–12(b)(3)(D)(i) of the Act reads, in full: "[Information provided to the Secretary] may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate;)" Thus, the law provides discretion to the Secretary to use the data broadly for these purposes, "as the Secretary determines appropriate." Although it is clear to us that the provision was narrowly intended and meant to cover release of only PDE data—"Part D claims data"–because that language only appears in the Ways and Means summary, and not in the statute, we must assume broad application. However, the statutory language, provides discretion to the Secretary, "as the Secretary determines appropriate," to use the data for the purpose of "research on the efficiency of health care." In our proposed rule we cited research and analysis of the Medicare program as one of the reasons for our proposed disclosure of Part C and D summary payment data and risk scores. We stated, "the Secretary believes these data should be made available * * * for the studies and operations that researchers want to undertake to analyze the Medicare program and Federal expenditures." We believe studies related to the efficiency of Part D services are coextensive with our stated purposes for release. As explained earlier, by engaging in notice-and-comment rulemaking to promulgate regulations, proactive disclosure of summary Part C and D payment data is now permitted.

Comment: Some commenters stated that CMS should not release retiree drug subsidy (RDS) payment data. Some stated that RDS plans are not public plans and therefore no payment data should be released for them. Others stated that RDS data should not be released because data would be based on member utilization in commercial prescription drug plans. One commenter stated that RDS plans are private plans in the private market and release of the subsidy amount is tantamount to release of private payment data since the former is a simple 28 percent of the latter. This commenter went on to say that they were unaware of any precedent for releasing private plan data and that they knew of no public policy data analysis that could be conducted using such data. Finally, one commenter stated that they opposed release of RDS data because RDS is a competitive commercial program and there is no basis for release.

Response: We do not agree that RDS summary payment data should not be released. In the proposed rule we stated we would release the gross dollar amount paid to eligible sponsors and the total number of unduplicated Medicare eligible retirees. While we agree that RDS sponsors are private plans, we do not agree that no data should be released. Taxpayers and interested parties should be apprised of how their tax dollars are being spent. To the extent the RDS is a "simple 28 percent of private payment data, "this is merely a consequence of the way the RDS payment is authorized in statute. Knowing that 28 percent of a specific *portion* of the cost of such plans is being paid by CMS does not reveal the final cost of the plan for a number of reasons, not the least of which is that we are not publishing member months, but only

the number of unduplicated Medicare eligible retirees. There are other factors that confound the relationship between the RDS subsidy CMS pays and the cost of a private plan, including the fact that CMS only pays 28 percent of the allowable retiree costs—which are defined in § 423.882. Further, we note that all MA and Part D plans are private plans and the release of summary data regarding payments to RDS plan sponsors is no different than the release of MA and Part D plan summary payment data. As we have noted earlier in this section in our response to other comments, having engaged in notice-and-comment rulemaking to promulgate regulations, disclosure of summary RDS payment data is now permitted.

Comment: Some commenters stated that the 2008 Part D Data rule regarding the release of PDE data should be followed and that no additional payment data should be released. They stated that CMS needs to protect commercially sensitive data and that the threat of release is just as great today as it was in 2008. Others stated that release of summary Part D payment data is contrary to the 2008 Medicare Part D Claims Data final rule regarding limited release of PDE data.

Response: We do not agree. The Part D Data rule (73 FR 30664) published in the **Federal Register** on May 28, 2008, addressed limits on release of Part D claims data—so called PDE (prescription drug event) data. In the proposed rule, we did not propose any changes to the process finalized in the Part D Data rule with respect to release of PDE data. Rather, we proposed to release summary Part D payment data and risk scores. As we have explained in our responses to previous comments, we do not believe that the summary payment data we will be releasing can be disaggregated in such a way as to gain granular knowledge of PDE data. Therefore, while we will continue to follow the guidelines we set out in the Part D Data rule with respect to PDE data, we will also proceed with the release of summary Part D payment and risk score data, consistent with our proposed rule.

For the reasons outlined in our responses to comments and consistent with our proposed rule, we are finalizing our proposal to release summary Part C and D payment data and average risk scores and are codifying this policy in our regulations at § 422.504(n), § 423.505(o) and § 423.884(c)(3)(ii).

4. Required Use of Electronic Transaction Standards for Multi-Ingredient Drug Compounds; Payment for Multi-Ingredient Drug Compounds (§ 423.120)

As provided under section 1860D–4(b)(2)(A) of the Act and codified in § 423.120(c) of the regulations, Part D sponsors must issue (and reissue, as appropriate) a card or other technology that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d) of the Act. Under section 1860D–4(b)(2)(B) of the Act we must provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology that are compatible with the HIPAA administrative simplification requirements of part C of Title XI of the Act and consult with the NCPDP and other standard setting organizations, as appropriate.

In our November 2010 proposed rule, we noted that the NCPDP Telecommunications Standard Version D.0 (Version D.0), which was adopted as the HIPAA standard that must be used by HIPAA covered entities for retail pharmacy drug claims on and after January 1, 2012, standardizes claims processing for compounded drugs. Unlike the current version, in 2012 the pharmacy claim will reflect all ingredients of a drug compound. Since under § 423.120(c)(2), Part D sponsors will be required to adhere to the new standard, we proposed adding a new paragraph (d) to § 423.120 to clarify how Part D sponsors must treat compounded products under the Part D program.

Our preamble observed that a compounded product as a whole generally does not satisfy the definition of a Part D drug; only costs associated with ingredients of a compounded product that satisfy the definition of a Part D drug are allowable costs under Part D. Since pharmacy transactions prior to the new standard have not captured all ingredients of a billed compounded drug, under our current policy Part D plans generally pay for the most expensive Part D drug ingredient in a compound and submit that ingredient on the prescription drug event record for Part D payment reconciliation purposes. Our guidance to date has been limited to clarifying that the dispensing fee may include the labor costs associated with mixing the compounded product (provided that at least one ingredient of the compound is a Part D drug) and providing direction regarding appropriate cost-sharing.

Given that the new standard, Version D.0, will provide plan sponsors with access to information regarding ingredients, we thought it appropriate to clarify the treatment under Part D of compounds in general and, in particular, those that contain non-Part D ingredients. We proposed to codify our existing guidance that only compounded products that contain at least one ingredient that independently meets the definition of a Part D drug may be covered under Part D. Consistent with our current policy, we proposed to clarify that—subject to the exception for compounds containing Part B ingredients—sponsors may cover the Part D ingredients even if the compounded product as a whole does not satisfy the definition of a Part D drug.

We further explained that the aforementioned exception for Part B ingredients is based both on current Part B payment policy and section 1860D–2(e)(2)(B) of the Act, and proposed codifying the following: if a compound includes a Part B drug ingredient, no ingredients of the compound may be covered under Part D, even if one or more ingredients of the compound would individually meet the definition of a Part D drug.

In our November 2010 proposed rule, we proposed that Part D sponsors determine cost-sharing for Part D ingredients of Part D compounds and, in so doing, apply either a flat copayment amount equal to the copayment of the tier for the most expensive Part D ingredient or a coinsurance amount based on the tier of the most expensive Part D ingredient. In both cases, we proposed applying cost-sharing to the whole amount of the Part D claim. In the case of low income subsidy (LIS) beneficiaries, we recommended that sponsors select the cost-sharing amount based on whether the most expensive Part D ingredient is a generic or brand-name drug.

In our preamble, we identified an underlying premise of our policy: if a compound as a whole is considered by a Part D sponsor to be on-formulary at the time of adjudication, for the sake of consistency, then all Part D ingredients of that compound would be considered on-formulary, even if any individual Part D ingredients would be considered off-formulary as single drug claims. Accordingly, we proposed that if a Part D sponsor considers a Part D compound as a whole to be on-formulary, it must adjudicate the Part D ingredients as formulary drugs.

Stating in our November 2010 proposed rule that the government could not require Part D sponsors to reimburse pharmacies for non-Part D drugs in Part D compounds, we

proposed three options for a sponsor: Contract with the pharmacy to pay for the non-Part D ingredients without reporting these costs to us; deny payment, but allow the pharmacy to balance bill the beneficiary; or both deny payment and prohibit balance billing. Noting that limiting reimbursement of ingredients in Part D compounds might deter pharmacies from compounding services and subsequently affect beneficiary access to drugs, we invited comment.

Comment: One commenter requested that we clarify that Part D compounds could include certain non-Part D ingredients such as over-the-counter (OTC) products or excluded Part D drugs that may or may not be covered under a supplemental benefit.

Response: As proposed in § 423.120(d)(1), a compound is considered a Part D compound if it contains "at least one Part D drug that independently meets the definition of a Part D drug" and does not contain any ingredients covered under Part B as prescribed and dispensed or administered. As long as a Part D compound satisfies these two requirements, we clarify that it also may include other non-Part D ingredients such as OTC products and excluded Part D drugs.

Comment: One commenter questioned if there will be additional new reporting requirements for purposes of validating Part D coverage of compounds.

Response: We are not proposing any new reporting requirements specific to Part D compounds in this rule.

Comment: One commenter contended that the policy of allowing coverage for only Part D ingredients of a Part D compound is inconsistent with and contradicts our combination drug product policy. It stated that the combination drug product policy provides a product is covered under Part D if it contains at least one Part D drug ingredient even if one of its ingredients would separately be covered under Part B.

Response: We disagree with the commenter. The combination drug product policy does not apply to Part D compounds. As stated in Chapter 6, section 10.3 of the Prescription Drug Benefit Manual, the combination drug product policy applies to commercially available combination prescription drug products. Part D compounds are extemporaneously compounded by pharmacies and not otherwise commercially available. Nevertheless, neither commercially available combination prescription drug products nor extemporaneously compounded prescription drug products can be covered under Part D if payment is available for these products under Part B as prescribed and administered or dispensed.

Comment: One commenter requested that CMS clarify when an ingredient is considered covered under Medicare Part B so that the compound cannot be covered under Part D.

Response: This rulemaking is intended to address when Part D covers a multi-ingredient compound and is not intended to address coverage rules under Part B. For purposes of determining Part D coverage of a compound, we consider a compound to be covered under Part B (for purposes of § 423.120(d)(1)(i)) if, as prescribed and dispensed or administered, it meets the definition of a drug in section 1861(t) of the Act, fits within a Part B benefit category, and otherwise meets Part B coverage requirements. However, the fact that a compound meets the criteria in § 423.120(d)(1)(i) does not guarantee coverage of that compound under Part B. That stated, we will revise § 423.120(d)(1)(i) to clarify that the criteria applies when an ingredient in the compound is covered under Part B "as prescribed and dispensed or administered."

Comment: One commenter asked us to waive the 60 day notice when individual Part D ingredients within the compound change formulary or tier status.

Response: We decline to adopt this recommendation. We do not see a compelling reason to deny beneficiaries notice of changes in formulary status for Part D drugs they take simply because they take those drugs in a compounded form. However, if a Part D sponsor's formulary includes Part D compounds (that is, identified as such rather than by Part D ingredient), and the formulary status of the compound as a whole remains unchanged, then it follows that there would be no formulary change with respect to that compound about which beneficiaries would need to be notified.

Comment: Most commenters supported the proposed policy that if a Part D compound as a whole is considered by a Part D sponsor to be on-formulary, then all Part D ingredients within the Part D compound must be considered on-formulary even if a specific Part D ingredient would be considered off-formulary if it were provided separately. However, a few commenters recommended that CMS give Part D sponsors the option to determine formulary status not only by the Part D compound as a whole, but also Part D ingredient by Part D ingredient for purposes of meeting transition fill requirements.

Response: We appreciated the comments that supported the proposed policy to consider Part D compounds as a whole as either on-formulary or off-formulary. However, we disagree that Part D sponsors should determine formulary status of a compound on an ingredient-by-ingredient basis. We believe such an approach would be confusing for beneficiaries.

Comment: While strongly supporting the classification of compounds as either on-formulary or off-formulary, one commenter requested that CMS require Part D plans both to include commonly used compounds on their formularies to ensure adequate access and to provide criteria to pharmacy and therapeutic committees in making the formulary classification, for instance, tailored separately for parenteral nutrition.

Response: We did not propose to make any changes with respect to which drugs plans must include on their formularies and, therefore, we believe this comment is beyond the scope of this regulation.

Comment: One commenter asked that CMS clarify whether compounded drugs would still be eligible for the generic drug cost-reduction in the coverage gap in 2013 when, under the ACA, the brand drug cost-sharing will be reduced in the coverage gap.

Response: We believe this commenter is asking if our existing policy with respect to determining the cost-sharing of a compound will change in 2013 and, therefore, we confirm that at this time we have no plans to change the existing policy.

Comment: A few commenters stated that CMS should not require Part D sponsors to base Part D compound cost-sharing on the most expensive Part D ingredient and instead allow Part D sponsors to determine which cost-sharing tier (copayment or coinsurance) under the benefit plan applies to a Part D compound. One commenter recommended that Part D sponsors have the option to base Part D compound cost-sharing on the highest unit cost or a specific copayment/coinsurance that would apply to all Part D compounds because this would allow for a more consistent beneficiary experience since beneficiaries are not aware of the individual ingredients within a Part D compound. Another commenter asked us to clarify that Part D cost-sharing cannot apply to or be based on non-Part D ingredients. One commenter supported the proposal to base the low-income subsidy (LIS) cost-sharing on the most expensive ingredient, while

another commenter recommended that the LIS cost-sharing should be brand cost-sharing when compounds contain both generic and brand name Part D ingredients (that is, when not all Part D ingredients are generic).

Response: We agree with the commenters' recommendation not to require Part D sponsors to establish Part D compound cost-sharing based upon the tier associated with the most expensive Part D drug ingredient. We recognize that there are reasonable alternative methods for determining which cost-sharing tier should apply to Part D compounds and believe that each Part D sponsor should have the discretion to determine the cost-sharing for Part D compounds within its existing benefit design and in accordance with CMS tier requirements (for example, specialty tier cost threshold).

While we have decided that a Part D sponsor can determine which existing cost-sharing tier (copayment or coinsurance) applies to Part D compounds under its benefit design, CMS maintains that the cost-sharing for low-income subsidy (LIS) beneficiaries (as described in § 423.782) must be based on whether the most expensive Part D ingredient is a generic or brand-name drug regardless of which cost-sharing tier the Part D compound is placed on for non-LIS beneficiaries. We believe that this will ensure the LIS cost-sharing for Part D compounds will be consistent across all Part D plans regardless of benefit design in the same manner that LIS cost-sharing is consistent across Part D plans for non-compounded Part D drugs. Therefore, based on the comments, we are revising § 423.120(d)(ii) to remove the requirement to base non-LIS cost-sharing on the most expensive Part D drug ingredient.

Comment: Several commenters asked CMS to clarify that the most expensive Part D ingredient refers to the highest line item computed Part D ingredient cost (unit cost multiplied by quantity) and not the unit cost alone.

Response: We agree with these commenters and clarify that by most expensive Part D ingredient we mean the Part D ingredient with the highest line item computed ingredient cost (unit cost multiplied by the quantity) of that ingredient.

Comment: A few commenters supported the flexibility proposed for addressing non-Part D ingredients included in a Part D compound. However, a number of commenters did not support the proposed approach for several reasons. Some recommended that we require Part D sponsors to cover all Part D and non-Part D ingredients in a Part D compound or always allow balance billing. These commenters reasoned that the proposed approach would deter pharmacies from continuing to provide compounding services because they might not be paid for all ingredients. Others suggested that CMS should not allow Part D sponsor pharmacy contracts to allow pharmacies to balance bill for non-Part D ingredients because it could substantially increase beneficiary cost-sharing and create access problems for beneficiaries who could not afford the additional costs for any unpaid ingredients. Another commenter stated that current Part D sponsor pharmacy contracts generally do not allow member billing for anything other than what is specified as beneficiary cost-sharing on the paid response returned by the Part D sponsor on the pharmacy claim. These commenters also wrote that balance billing would confuse beneficiaries because they would not know which ingredients were not covered and the amounts listed on the explanation of benefits would differ from what the beneficiaries actually paid at the pharmacies. Another commenter stated that balance billing for only some ingredients in the compound would be difficult if secondary payers were involved.

Response: Based on the comments, we have reconsidered this issue, and we now agree with the commenters that recommended that Part D sponsors not allow their network pharmacies to balance bill beneficiaries above and beyond the Part D beneficiary cost-sharing specified on the paid response returned by the Part D sponsor on the pharmacy claim. The proposed policy would have allowed for balance billing based upon the premise that only a portion of some Part D compounds are covered because non-Part D ingredients included within the compound might not be directly paid for by the Part D sponsor and cannot be reported as Part D ingredient costs on PDEs, and we recognize that some commenters are concerned that pharmacies simply will stop preparing Part D compounds if they believe they are insufficiently compensated for that service. However, after considering the comments, we believe a better approach to this issue is one that is more straightforward for beneficiaries, Part D sponsors, and pharmacies. Thus, we are amending our final regulation to prohibit balance billing for non-Part D ingredients of Part D compounds.

Further, in response to concerns about pharmacy reimbursement, we wish to clarify that Part D sponsors and pharmacies are able to negotiate prices for covered Part D compounds that account for non-Part D ingredients. We believe they can accomplish this in one of two ways: (1) Part D sponsors can directly pay for non-Part D ingredients on the pharmacy claim (without charging the beneficiary or reporting these costs on the PDE to CMS); or (2) Part D sponsors can reimburse pharmacies for these ingredients as part of the dispensing fee. In addition, we note that, in our view, our definition of dispensing fees supports the proposition that pharmacies already are reimbursed by the plan for those ingredients of a Part D compound that do not independently meet the definition of Part D drug. For these reasons, we further do not believe that the billing and payment of specific line items on a pharmacy claim for a Part D compound determines whether a Part D sponsor has paid the full negotiated price for the entire Part D compound. Instead, we believe that Part D sponsors and pharmacies have negotiated how Part D compounds are priced in general and that such prices adequately account for any non-Part D ingredients, which usually account for a small portion of the overall cost, regardless of how an individual paid claim represents payment for individual ingredients. Consequently, because the plan's payment to the pharmacy represents payment in full, there are no remaining unpaid amounts to be balance billed. We believe this policy appropriately protects beneficiaries by ensuring that they only pay Part D negotiated prices for Part D compounds without interfering with the ability of pharmacies to negotiate prices that provide adequate reimbursements for Part D compounds. Based on the comments, we are revising § 423.120(d) to prohibit Part D sponsors from balance billing (or permitting pharmacies to balance bill) beneficiaries for non-Part D ingredients in Part D compounds.

Comment: Several commenters stated separately that the proposed approach for covering Part D compounds might increase Medicare costs significantly and noted that CMS did not estimate the savings, if any, this policy would bring to the beneficiary or the Medicare Part D program.

Response: We disagree with the commenters that the proposed approach might significantly increase Medicare costs. The proposed approach to allow reimbursement only for ingredients that independently meet the definition of a Part D drug is not new policy but rather a clarification of existing policy in light of the changing pharmacy billing standard that makes pharmacy claims for compounded drugs more

transparent. We also note that Part D compounds represent significantly less than one percent of the PDEs submitted to CMS. Additionally, as noted previously, CMS revisited its policies in light of a new industry standard rather than to achieve specified savings per se. For these reasons, we do not believe any further action is necessary.

Comment: A number of commenters disagreed with the preamble discussion on PDE reporting for compounds. Specifically, these commenters stated that the quantity reported on the PDE should not reflect only the quantity of the most expensive Part D ingredient national drug code (NDC) submitted on the PDE, but rather should reflect the total quantity of the Part D compound as a whole.

Response: We agree with the commenters that our preamble incorrectly suggested the current PDE guidance requires Part D sponsors to submit the quantity for the most expensive Part D ingredient NDC only. In fact, current PDE guidance does not specify whether the PDE should reflect the quantity of the most expensive NDC only or the total quantity of the Part D compound as a whole. Until further PDE guidance is issued, we will allow Part D sponsors to submit either quantity. However, given the industry consensus for reporting total quantity as reflected in the comments, we recommend that Part D sponsors submit the total quantity of the Part D compounds as a whole.

The final provision, amended as discussed in this section, will apply to plan years on and after January 1, 2012.

5. Denial of Applications Submitted by Part C and D Sponsors With Less Than 14 Months Experience Operating Their Medicare Contracts (§ 422.502 and § 423.503)

Each year, as part of the application evaluation process, we conduct a comprehensive review of each Part C and D sponsor's past performance in the operation of its Medicare contract(s). Current regulations provide that organizations with current or prior contracts with CMS are subject to CMS denial of any new applications for additional or expanded Part C or D contracts if they fail during the preceding 14 months to comply with the requirements of the Part C or D programs, even if their applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the absence of 14 months of performance, however, this leaves a gap whereby CMS must either assume full compliance and exempt the entity from the past performance review, or deny additional applications from such entities until the applicant has accumulated 14 months' experience, during which it complied fully with the requirements of the Part C and/or Part D programs.

Our interest in protecting Medicare beneficiaries and limiting program participants to the best performing organizations possible strongly suggests that we take the latter approach. Our justification for proposing this change was two-fold. First, we would ensure that new entrants to the Part C or Part D program could fully manage their current contracts and books of business before further expanding. Second, this change would require that entities rightfully focus their attention on launching their new Medicare contracts in a compliant and responsible manner, rather than focusing attention almost immediately on further expansions.

Therefore, we proposed modifying § 422.502(b) and § 423.503(b) by adding additional language at § 422.502(b)(2) and § 423.503(b)(2) that in the absence of 14 months' performance history, we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D program, respectively.

Comment: Several commenters requested that CMS clarify at what organizational level this provision would apply. Specifically, to determine whether an applying organization met the 14-month performance history threshold, would CMS review—(1) its experience in offering a particular plan benefit package (PBP); (2) its experience in operating a particular Part C or D contract it holds with CMS; (3) its experience in operating all contracts it holds with CMS; or 4) the experience of its parent organization's operation of all of the Medicare contracts held by its subsidiaries?

Response: These provisions only pertain to applying entities that currently operate Part C or Part D contract(s) but have done so for less than 14 months, and further, are unrelated (by virtue of being subsidiaries of the same parent) to any other contracting entity with at least 14 months' experience. So long as a contracting entity or another subsidiary of its parent organization has operated one or more Medicare contracts for the requisite period of time, applications for new contracts or service area expansions submitted by a current contracting entity will not be subject to denial under § 422.502(b)(2) and § 423.503(b)(2). Rather, these contracting entities will be subject to the past performance review under § 422.502(b) and § 423.503(b), which CMS will conduct according to the "2012 Application Cycle Past Performance Review Methodology" document CMS issued in December 2012 and expects to update each year.

Comment: One organization requested that CMS specify approval criteria for service area expansion.

Response: We have already published our criteria for approving applications, including service area expansions. This information can be found within the Part C and Part D application solicitation materials, and in the memo published on December 12, 2010 entitled, "2012 Application Cycle Past Performance Review Methodology." All of these documents are posted on CMS' Web site (*http://www.cms.gov*).

Comment: CMS received two comments concerning its application of the past performance methodology generally. One organization urged CMS to limit denials based on past performance to instances where the extent and intent of the plan's non-compliance amounts to consistent and willful inappropriate behavior or misrepresentation by a particular plan to beneficiaries. Another organization expressed concern that the past performance review CMS conducts on all applying organizations pursuant to § 422.502(b) and § 423.503(b) (that is, including those with more than 14 months' Part C or D experience) creates an uneven playing field for existing and new sponsors, giving new carriers a competitive advantage since they do not undergo a past performance review.

Response: These comments concern our general authority to deny applications based on an applicant's past Medicare contract non-compliance pursuant to § 422.502(b) and § 423.503(b). The latter comment, in particular, concerns the application of the past performance methodology to entities with established relationships with CMS versus those entities with no prior Part C or Part D relationship with CMS. Neither comment addresses the issue of how CMS should treat entities with less than 14 months experience (neither long-established nor brand new). As such, these comments fall outside the scope of this proposal.

In summary, for the reasons stated in the proposed rule, and after consideration of the comments received in response to the proposal, we are finalizing this provision without modification.

F. Other Clarifications and Technical Changes

We have identified seven technical changes in this section, affecting as

noted in Table 8, cost contract plans, MA plans, or Part D plans.

TABLE 8—Provisions on Other Clarifications and Technical Changes

PROVISION	PART 417/422		PART 423	
	Subpart	Section	Subpart	Section
Clarification of the Expiration of the Authority to Waive the State Licensure Requirement for Provider-Sponsored Organizations	Subpart A	§422.4	N/A	N/A
Cost Plan Enrollment Mechanisms	Subpart K	§417.430	N/A	N/A
Fast-track Appeals of Service Terminations to Independent Review Entities (IREs)	Subpart M	§422.626	N/A	N/A
Part D Transition Requirements	N/A	N/A	Subpart C	§423.120
Revision to Limitation on Charges to Enrollees for Emergency Department Services	Subpart C	§422.113	N/A	N/A
Clarify Language Related to Submission of a Valid Application	Subpart K	§422.502	Subpart K	§423.503
Modifying the Definition of Dispensing Fees	N/A	N/A	Subpart C	§423.100

1. Clarification of the Expiration of the Authority To Waive the State Licensure Requirement for Provider-Sponsored Organizations (§ 422.4)

We clarified in our November 2010 proposed rule (FR 75 71242) that we will no longer waive the State licensure requirement for organizations seeking to offer a provider-sponsored organization (PSO) because, under section 1855(a)(2)(A) of the Act and § 422.370 of our regulations, we had the authority to waive the State licensure requirement for PSOs only for requests for waivers submitted prior to November 1, 2002. While we currently contract with organizations that have previously met the conditions for becoming a PSO and will continue to contract with these organizations, organizations that do not meet State licensure requirements can no longer offer new PSOs because waiver of State licensure laws is necessary in order to offer a PSO. A PSO is defined in section 1855(d) of the Act, and that definition is codified in § 422.350.

Even though the authority to waive the State licensure requirement for PSOs expired on November 1, 2002, and we have not granted waivers of State licensure requirements since that time, we took the opportunity to clarify this policy in our November 2010 proposed rule because of questions we have received. Accordingly, we proposed to revise paragraph (a) of § 422.4 to clarify that we no longer have the authority to waive the State licensure requirement for PSOs. We received no comments on this proposal; therefore, we are finalizing this provision without modification.

2. Cost Plan Enrollment Mechanisms (§ 417.430)

As part of the enrollment process, § 417.430 requires that application forms be submitted to an HMO or CMP and must include a beneficiary's signature. The organization must provide the beneficiary with written notice of acceptance or rejection of the application. We proposed changes to § 417.430(a)(1) to allow us to approve other enrollment mechanisms for cost plans in addition to paper forms, such as electronic enrollment. We also proposed to streamline § 417.430(b)(3) and § 417.430(b)(4)(i) to allow for notice delivery options other than the traditional mailing of documents. These changes take into consideration the advancement of communication technology and comport with revisions we made with respect to the MA program under § 422.50(a)(5) and § 422.60(e).

Comment: Commenters voiced support for this proposal. They believed that alternative enrollment mechanisms provide easier access for beneficiaries to cost plans and lower plan administrative costs.

Response: We appreciate the commenter's support of our proposal and are finalizing this provision without modification.

3. Fast-Track Appeals of Service Terminations to Independent Review Entities (IREs) (§ 422.626)

To correct a typographical error in § 422.626(g)(3), we proposed to remove the word "to" after the word "may" in the regulation text. However, in the proposed rule, we erroneously referred to § 422.626(f)(3) as containing the typographical error rather than § 422.626(g)(3). We are correcting both of these errors in the final rule.

Although we did not include this change in the proposed rule, we are using this opportunity to make a technical correction to a cross-reference in § 422.622 (Requesting immediate QIO review of the decision to discharge from the inpatient hospital). Specifically, we are amending paragraph (g)(1) to refer to § 422.626(g) rather than § 422.626(f).

We did not receive any comments on these proposed revisions and are finalizing these technical corrections with the modifications previously noted.

4. Part D Transition Requirements (§ 423.120)

We explained in our November 2010 proposed rule that as a result of section 3310 of the ACA and the proposed rule at § 423.154, we proposed revising the existing transition policy for enrollees residing in LTC facilities to be more consistent with 7-day-or-less dispensing. We proposed a revised transition fill supply from 93 days to 91 days to accommodate multiple dispensing events associated with 7-days-or-less dispensing in LTC facilities whenever § 423.154(a) applies to drugs dispensed in 7-day-or-less supplies. We explained that the proposed change to a 91-day supply will permit exactly 13 weeks of 7-day transition fills. Under this proposed requirement, a Part D sponsor would be required to provide a LTC resident enrolled in its Part D plan a temporary supply of a prescription when presenting in the first 90 days of enrollment up to a 91-day supply, with supply increments consistent with § 423.154 (unless the prescription is written for less), with refills provided, if needed.

We also proposed amending § 423.120(b)(3)(iii) to clarify the transition notice requirements. Under this requirement, notices must be sent to beneficiaries within 3 business days of adjudication of a temporary fill. We proposed that a written notice be sent to each affected enrollee, and in the case of a LTC enrollee impacted by the dispensing requirement in § 423.154, the written notice be sent within 3 business days after adjudication of the first transition fill. We explained that we were persuaded by feedback from the LTC industry that beneficiaries may be confused when receiving multiple transition notices within 7 to 10 days of each 7-day-or-less dispensing event. We solicited comments on this provision in our proposed rule.

As described earlier in this final rule, we modified the proposed rule at § 423.154 to reflect a 14-day-dispensing requirement. The responses below reflect that modification. As a result of comments received, in this final rule, we are modifying the proposed rule at § 423.120(b)(iii)(B) to state that the temporary supply of non-formulary drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days, and up to 98 days, consistent with the dispensing increment, for beneficiaries residing in a long-term care setting.

Comment: We received comments requesting that we change the transition fill supply requirement in the LTC setting to 91 days across all claims submitted in that setting. Commenters stated that two different systems (91 days for 7-day-or-less-dispensing and 93 days for 31-day dispensing) would be confusing and add unnecessary complexity.

Response: We believe that commenters want a transition requirement that is straightforward, and we believe a transition requirement that is consistent with the way drugs are dispensed will address the commenters' concerns. Therefore, we will modify the proposed rule to require Part D sponsors provide a temporary supply of up to 91, and up to 98 days if the plan desires to have the transition supply mirror the dispensing increment, with refills provided, if needed, unless a lesser amount is actually prescribed by the prescriber. For ease of dispensing, plans can require that the temporary supply be evenly divisible by the quantities dispensed (for example, up to 93 days for a 31-day dispensing increment, up to 91 for a 7-day dispensing increment, or up to 98 days for a 14-day dispensing increment). As long as the beneficiary who is receiving a transition fill can obtain at least 91 days of medication (unless a lesser amount is actually prescribed by the prescriber), plan sponsors will have the flexibility to implement the transition to match the dispensing increment if desired.

We encourage Part D sponsors to establish policies and procedures that will assist in the effectuations of meaningful transitions prior to the exhaustion of a transition fill. However, also consistent with previous guidance, we encourage Part D sponsors to make arrangements to continue to provide necessary drugs to an enrollee by extending the transition supply period, on a case-by-case basis, if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

Comment: Several commenters supported our proposal to send one transition notice at the start of the transition period. Some commenters urged us to require another transition notice prior to conclusion of the transition period to ensure that enrollees have access to medication beyond the transition period.

Response: As stated in the proposed rule, beneficiaries may be confused if they were to receive multiple transition notices for a drug dispensed in multiple increments consistent with § 423.154. As such, we believe that an additional notice sent prior to the end of the transition period may lead to confusion.

We require Part D sponsors to send a transition notice to inform enrollees (and their caregivers) about the options for ensuring that the enrollee's medical needs are safely accommodated within the Part D sponsor's formulary. We require that transition notices be sent within 3 business days of the transition fill to allow for sufficient time for the enrollee to be switched to a therapeutically equivalent drug that is on the formulary or for time to process an exceptions request. Based on previous Part D experience, we believe that one notice sent within 3 business days of the first temporary fill is adequate notice to effectuate a meaningful transition.

Comment: A commenter recommended that the transition notices be sent to the pharmacies as well as beneficiaries residing in long-term care facilities.

Response: Beginning in contract year 2010, we permitted Part D sponsors the option of sending the required transition fill notices to network LTC pharmacies. For more details, see Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage.* We decline to require Part D sponsors to do this, however, because the pharmacy is not directly involved with effectuating a meaningful transition. As stated in previous guidance, the purpose of a transition supply is to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. Pharmacies may assist in the process, but cannot effectuate a meaningful transition by switching the enrollee to a therapeutically equivalent medication or by requesting an exception under § 423.578(b).

As a result of comments received, in this final rule, we are modifying the proposed rule at § 423.120(b)(iii)(B) to state that the temporary supply of non-formulary drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days, and up to 98 days, consistent with the dispensing increment, for beneficiaries residing in a long-term care setting. This provision will be effective January 1, 2012.

5. Revision to Limitation on Charges to Enrollees for Emergency Department Services (§ 422.113)

As provided under section 1852(d)(1) of the Act and codified at § 422.113(b)(2)(v). MA organizations are financially responsible for emergency and urgently needed services. Under § 422.113(b)(2)(v), charges to enrollees for emergency department services may not exceed $50, or what an MA organization would charge an enrollee if he or she obtained the services through the MA organization, whichever is less. This limit on cost sharing was first included in the regulations at § 422.112(b)(4) in the June 26, 1998 interim final rule (63 FR 35081) as the cost sharing limit for emergency services received out-of-network. Subsequently, new section § 422.113 was added to the regulations in the June 29, 2000 final rule (65 FR 40322) and required that same limit on cost sharing for emergency services regardless of whether they were received in- or out-of-network.

In our proposed rule, we explained that because we believe the current limit on cost sharing is outdated and has constrained MA organizations' ability to control unnecessary use of emergency departments we proposed to revise § 422.113(b)(2)(v) to remove the $50 amount and replace it with language indicating that we will evaluate and annually determine the appropriate enrollee cost sharing limit for emergency department services. We would inform MA organizations of any changes to the limit in annual guidance, such as the Call Letter.

Comment: We received many comments expressing support for our proposal to eliminate the $50 maximum for emergency department services and CMS' annual evaluation and determination of the appropriate limit on enrollee cost sharing. However, a few commenters who were generally supportive of our proposal also expressed their interest in CMS providing notice of the methodology that would be used annually to determine the cost sharing limit and to specify what services are to be included in that cost sharing. In addition, we received one comment that supported our proposal but suggested the limit for ER services be no more than $100.

Response: We thank the commenters for their support. CMS' methodology for developing the cost share limit for CY 2012 would be based on CY 2010 total costs for emergency department services visits under Original Medicare. We would calculate a weighted average for these visits and then determine the cost sharing limit to ensure that MA plans would be responsible for at least 50 percent of the total cost of the visit. Although we would not specifically limit the cost sharing to $100 as requested by a commenter, we believe our method takes into account plans' desire to manage utilization and beneficiary access and protections from high out-of-pocket costs to result in appropriate and affordable care.

After consideration of all the public comments received on this proposal, we are finalizing our proposal to amend § 422.113 by revising paragraph (v) to replace the $50 amount with language indicating that CMS will evaluate and determine an appropriate enrollee cost sharing limit annually and that the enrollee would be required to pay the lesser of that amount or the amount the plan would charge the enrollee if he or she obtained the services through the MA organization.

6. Clarify Language Related to Submission of a Valid Application (§ 422.502 and § 423.503)

Since we began our contracting efforts under the MMA in 2005 in preparation for the statute's 2006 effective date, we have established strict deadlines for the initial submission of applications for qualification for contracts to operate as Medicare Part C or D sponsoring organizations and the resubmission of materials needed to cure identified deficiencies. Consistent with that policy, we do not review applications that are submitted after the established deadline, meaning that an organization that misses the deadline would not receive a Part C or D sponsor contract for the following benefit year. Because we do not review such applications, we do not provide a notice of intent to deny under § 422.502(c)(2) or § 423.503(c)(2), nor is the organization entitled to a hearing under § 422.660 or § 423.650.

To avoid the consequences of missing the initial submission deadline, some organizations have submitted applications that we considered so lacking in required information or correct detail as to fail to constitute a valid, timely submission. We suspect that in many instances, these organizations expected to take advantage of our policy of affording applicants two later opportunities during the review process (including the 10-day cure period following the issuance of a notice of intent to deny an application issued under § 422.502(c)(2) and § 423.503(c)(2)) to make their applications complete by providing information that had been omitted from the initial submission. Organizations that provide substantially incomplete applications are effectively submitting "placeholders" designed to save their eligibility to participate in the application review process until they can produce all the required materials. We find this practice to be an abuse of the application review process that defeats the purpose of the established deadline.

We believe that confusion about our authority to enforce the application deadline may be created by the provisions of § 422.502(c)(2)(i) and § 423.503(c)(2)(i), which state that we will provide an applicant a notice of intent to deny when the organization "has not provided enough information to evaluate the application." We intended this language to afford an organization that had made a good faith effort to complete a contract qualification application the opportunity to provide the materials necessary to cure a discrete application deficiency. As noted in our November 2010 proposed rule, it appears that this language could provide an unintended protection to an organization that circumvented our established application deadline by submitting a "placeholder" application.

We believe that the language in § 422.502(c)(2)(i) and § 423.503(c)(2)(i), stating that the agency will issue a notice of intent to deny if CMS finds that the applicant does not appear qualified to contract as a Part C or D sponsor, combined with the language of § 422.502(c)(2)(ii) and § 423.503(c)(2)(ii) allowing the organization to "revise its application to remedy any defects CMS identified" is sufficient to authorize us to consider additional curing materials submitted by a good faith applicant. Therefore, to remove all ambiguity that may exist concerning our authority to decline to accept or review substantially incomplete applications, we proposed to revise the provisions of § 422.502(c)(2)(i) and § 423.503(c)(2)(i) to delete the phrase, "and/or has not provided enough information to evaluate the application."

Comment: Several commenters expressed their general opposition to the proposed regulatory provision as they were concerned that CMS would be arbitrary in determining whether an organization had submitted an invalid application. They also stated that should CMS adopt the provision in the final rule, we should create exceptions that would require us to accept applications where the applicant had a good reason for failing to complete the application and could demonstrate a good faith effort to submit a valid application. Another commenter advised that CMS should establish

objective criteria for determining whether an application is so incomplete as to constitute an invalid submission.

Response: We do not believe that any modification of the proposed regulatory provision is necessary to address the commenters' concerns. With respect to the recommendation that we provide guidance to applicants on our criteria for identifying an invalid application, we already provide instructions in the annual solicitation for applications where we make clear our expectation that organizations submit a complete application by the established deadline and provide guidance on how sponsors can achieve that goal. To provide guidance on how to submit successfully something less than a complete application would undercut our existing direction and undermine the meaning of the application deadline. Also, we do not hold applicants to an unreasonable standard of perfection as our regulations provide organizations that met the deadline an opportunity to submit curing information during the application review process.

We accept contract qualification applications in all instances where there is evidence that the applicant made a good faith effort to submit a substantially complete application by the established deadline. For example, we already make exceptions to the application deadline when there has been a technical systems error on our part that prevented the submission of a valid application. Beyond that limited circumstance, we cannot foresee any other legitimate reason for which we should grant a waiver of our application deadline.

Simply put, this authority is not applicable to applications that are missing only a few required elements but otherwise demonstrate that the submitting organization has completed the arrangements necessary to operate a Part C or D contract. As we noted in our proposed rule, we intend to declare an application invalid when it is so incomplete as to constitute little more than a placeholder submission that the applicant is attempting to use to meet the application deadline and then use the cure period to complete work that should have done prior to the deadline. To illustrate our point, we provide here examples, but not an exhaustive list, of characteristics of an invalid application.

To complete a Part C or D contract qualification application, an organization must execute electronically a series of attestations and provide documentation demonstrating its financial wherewithal and relationships with first tier or downstream entities with which it has contracted to provide required services on its behalf under its contract with CMS. While the attestations are important to the application process, it is the documentation concerning elements such as the applicant's authority to operate as a risk bearing entity, its relationships with first tier and downstream entities (including fully executed contracts), and the extent of its contracted provider network that most clearly substantiate an applicant's ability to administer Medicare benefit plans. These elements also require the most effort on the part of the applicant as each completed document represents the culmination of extensive work with regulators and other business partners. Failure to provide these kinds of documents would be the most likely reason that we would determine that the organization has not submitted a valid application by the stated deadline. Further, if these documents are submitted but are either: (1) Blank or substantially blank, such as a retail pharmacy network list missing data in more than one required column; (2) a Part C document submitted for a Part D application and vice versa, in the absence of the correct documents; or (c) otherwise incorrect attachments, in the absence of other correct documents, CMS may consider the application incomplete.

An example of an application we have received in past years that would have been excluded from further consideration is one where the applicant provided no information concerning its Part D pharmacy network; that is, no list of contracted pharmacies, no pharmacy contract templates, and no report demonstrating the network's compliance with Part D pharmacy access requirements. Further, the applicant presented no evidence of licensure as a risk bearing entity and no executed contracts with the first tier and downstream entities the applicant had identified in the body of its application as providing Medicare-related services on its behalf. In this instance, it was clear that the deficiencies were not the result of an honest mistake on the part of the applicant, but instead indicated that it had not finished the work necessary to submit a substantially complete application before the deadline. We should not grant such an organization the opportunity to continue with the application review process when its work shows that it ignored a deadline that other organizations made their best effort to meet.

We already have significant experience, through our administration of the annual bid and formulary review processes, in assessing the validity of submissions for the purposes of determining compliance with a submission deadline. Since 2005, we have declined to accept a handful of bid and formulary submissions that were so lacking in detail that we could not consider the submitting organizations to have met the deadline. None of our decisions in those cases has been successfully challenged, and we intend to apply the same level of judgment and analysis used in those decisions to our determinations concerning valid contract qualification applications.

Comment: A commenter urged that CMS provide appeal rights to those organizations whose applications CMS excludes from consideration pursuant to this proposed regulatory provision.

Response: The point of the proposed provision is to document our authority to determine when an organization has even qualified for further consideration of its application, including the rights that attach to that process, such as the opportunity to cure deficiencies and appeal a denial, by meeting the submission deadline. To afford appeal rights in instances where we have determined that an organization submitted an invalid application would re-create the very program vulnerability this provision is intended to eliminate.

Having addressed the comments in the previous discussion, we are finalizing this provision without modification.

7. Modifying the Definition of Dispensing Fees (§ 423.100)

In the November 2010 proposed rule, we proposed a simplified and clarified definition of "dispensing fees" under § 423.100. We explained in our proposed rule that "dispensing fees," as defined in the final rule issued January 28, 2005, implied that the salaries of pharmacists and other pharmacy workers were reasonable pharmacy costs only for pharmacies owned and operated by a Part D plan itself. We proposed to clarify that the salaries of pharmacists and other pharmacy workers may be reasonable pharmacy costs for any pharmacy. We also proposed to modify the definition of "dispensing fees" under § 423.100 to include costs associated with the acquisition and maintenance of technology to maintain reasonable pharmacy costs. We proposed adding to the definition of "dispensing fees" a restocking fee associated with return for credit and reuse in long-term care pharmacies when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsor and the pharmacy.

We explained in the proposed rule that it was not our intent to include all activities that are "reasonable costs" in the definition of "dispensing fees," but in light of the statutory requirements regarding LTC pharmacy dispensing, we believed that it was particularly important to highlight the potential pharmacy costs aimed at reducing the volume of unused Part D drugs and increasing efficiency of dispensing. We also stated that we believe dispensing fees should differentiate among the costs associated with different dispensing methodologies and appropriately address costs that are incurred to offset the amount of unused Part D drugs.

We proposed to clarify the definition of "dispensing fees" by modifying § 423.100 and eliminating the distinction between pharmacies owned and operated by a Part D plan itself and all other pharmacies. We also proposed to modify § 423.100 by adding to the definition that dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of drugs that go unused. Additionally, we proposed adding that dispensing fees may also take into account restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsor and the pharmacy. As a result of comments, in this final rule, we further modify the definition to account for costs associated with data collection on unused Part D drugs in LTC facilities.

Comment: Commenters supported our proposal to modify the definition of dispensing fees. Some commenters requested that we amend the definition of dispensing fees to include other costs associated with the dispensing requirement under § 423.154. Some of the commenters requested that we add costs associated with the return and report requirement described in § 423.154(f)(1) and § 423.154(a)(2).

Response: In the proposed rule, we modified the definition of "dispensing fees," in part, to highlight the potential pharmacy costs aimed at reducing the volume of unused Part D drugs and increasing the efficiency of dispensing. As we stated in the proposed rule, it is not our intent to provide a comprehensive list of all activities that are "reasonable costs" in the definition of "dispensing fees." However, in this final regulation, we amend the definition of "dispensing fees" to include costs associated with the data collection on unused Part D drugs.

Comment: Some commenters wanted us to provide assurances that dispensing fees would appropriately reflect the increased costs associated with dispensing requirements under § 423.154 in LTC facilities and to monitor dispensing fees to pharmacies dispensing to enrollees in LTC facilities to ensure that dispensing fees are adequate.

Response: As provided in section 1860D–11(i) of the Act, we are prohibited from interfering with negotiations between Part D plans and pharmacies.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following sections of this document contain paperwork burden but not all of them are subject to the information collection requirements (ICRs) under the PRA for reasons noted.

A. ICRs Regarding Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

Under § 417.454(d) and § 422.100(g) and (h), we clarify that MA organizations may not impose cost sharing that exceeds that required under Original Medicare. We evaluate the following services annually to ensure that MA plans are charging cost sharing in the upcoming contract year that does not exceed cost sharing in Original Medicare. Specifically, chemotherapy administration services that include chemotherapy drugs and radiation therapy integral to the treatment regimen, renal dialysis as defined at section 1881(b)(14)(B) of the Act, and skilled nursing care defined as services provided during a covered stay in a skilled nursing facility would be subject to this limitation. The burden associated with this requirement is the time and effort necessary for MA organizations and section 1876 cost contracts to submit their benefit designs, including cost-sharing amounts, via the Plan Benefit Package (PBP) software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OMB control number (OCN) 0938–0763 with a May 31, 2011, expiration date.

B. ICRs Regarding SNP Provisions (§ 422.101, § 422.107, and § 422. 152)

1. Dual-Eligible SNP Contracts With State Medicaid Agencies (§ 422.107)

Section 422.107(d)(ii) extends the deadline for new and existing dual-eligible SNPs (D–SNPs) to operate without a contract with their respective State Medicaid agency(ies). New D–SNPs and D–SNPs not seeking to expand their service areas can continue to operate without a State contract until December 31, 2012.

For new and existing D–SNPs that are seeking to expand in contract years 2011 through 2013, the burden associated with this requirement is the time and effort put forth by each dual eligible SNP to confer and develop a contract with the State Medicaid agency. While this requirement is subject to the PRA, this burden is already approved, under OCN 0938–0753, with a November 30, 2011, expiration date.

2. ICRs Regarding NCQA Approval of SNPs (§ 422.101 and § 422.152)

Sections 422.101 and 422.152 provide for the approval of all SNPs, existing and new, by NCQA beginning in 2012. The burden associated with this requirement is the time and effort put forth by MA organizations offering SNPs to submit their MOC to CMS for NCQA evaluation and approval as per CMS guidance. Although the submission of the MOC document is already part of the application process, scrutiny of these documents by NCQA for approval is a new requirement. Previously, all SNPs were not required to complete the SNP proposal portion of the application each year. Under the new requirement, we require all SNPs (that is, all of the SNP plans offered by an MA organization) must complete the SNP proposal portion of the application. We estimate that it will take each SNP plan 40 hours to complete the annual application. Within those 40 hours, it will take each SNP plan 6 hours to

complete the SNP portion of the application. For the existing 544 SNPs, we estimate the burden associated with completing the SNP section only is 3,264 hours.

The number of new plans each year will vary and cannot easily be predicted. However, based on the number of new plans that submitted SNP Proposals during the application period in February 2010 for operation in 2011, we estimate that approximately 15 new applications will be submitted annually. Thus, for 15 new plans at 40 hours each, we estimate the total annual burden hours to be 600. The burden associated with the proposed requirement for the new plans is currently approved under OCN 0938–0935 with a January 21, 2011 expiration date.

C. ICRs Regarding Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

Our regulatory modifications pursuant to section 3303 of the ACA ensure that our regulations reflect the new statutory prohibition on reassigning LIS beneficiaries from Part D plans that waive a de minimis amount of their premium on the basis that the premium exceeded the low-income premium benchmark. Further, the regulatory modifications reflect statutory discretion for us to auto-enroll or reassign LIS beneficiaries to Part D plans that waive the de minimis amount of the premium. The modifications to § 423.34 do not by themselves impose any new information collection requirements on any external entity.

However, related proposals to modify § 423.780 do impose new information collection requirements. Specifically, the modifications provide for the process for a Part D plan to volunteer to waive a de minimis amount over the monthly beneficiary premium for certain low income subsidy eligible (LIS) individuals. As specified in proposed changes to § 423.34, we are prohibited from reassigning LIS beneficiaries from Part D plans that waive the de minimis amount of the premium based on the fact that their premiums exceed the LIS benchmark premium amount, and we may choose to auto-enroll or reassign LIS beneficiaries to such plans.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit data to us indicating its decision to volunteer to waive the de minimis amount. Since we will collect this information as part of an already established system, we estimate that it will take an additional 10 minutes annually for plans to read the instructions, select an online check box, and submit the information. The de minimis amount will be established each year, and the amount may vary among years. For purposes of estimating the burden, we assume that the de minimis amount will be $1.00, and that all Part D plans with premiums within the de minimis amount over the regional LIS benchmark will volunteer to waive it. We estimate 150 Part D plans will qualify for de minimis in a given fiscal year. For 150 plans at 10 minutes each fiscal year, we estimate the total annual burden hours to be 25. We assume an hourly wage of $23.92 for a compliance officer, resulting in a total annual labor cost of $598.

D. ICRs Regarding Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (Part D—IRMAA) (§ 423.44)

Section 423.44(e)(4) requires PDPs to provide Part D enrollees with a notice of termination in a form and manner determined by CMS. We estimate that approximately 1.05 million of the 29.2 million Medicare beneficiaries enrolled in the Part D program will exceed the minimum income threshold amount and will be assessed an income related monthly adjustment amount. We also estimate that approximately 80,000 beneficiaries will be directly billed for the Part D—IRMAA because they are not receiving monthly benefit payments from SSA, the OPM, or the RRB, or the monthly benefit payment is not sufficient to have the Part D—IRMAA withheld.

Of the 80,000 Part D enrollees who will be directly billed for the Part D—IRMAA, CMS cannot estimate how many might accrue Part D—IRMAA arrearages and be subsequently terminated. However, in the event that the 80,000 Part D enrollees who pay the Part D—IRMAA through direct billing become delinquent, PDPs would be required to send all 118,000 enrollees a notice of termination in accordance with § 423.44(e)(4), and the burden associated with this requirement would be the time and effort that it takes a PDP to populate the notice with a beneficiary's information. Termination notices are generally automated; therefore, CMS estimates that it will take 1 minute to generate a termination notice. As such, the total maximum annual hourly burden associated with this requirement is 1,333 hours (1 minute multiplied by 80,000 enrollees, divided by 60 minutes). We estimate that the hourly wage paid to an individual tasked with generating the automated letters is $40 (based on U.S. Department of Labor statistics for hourly wages for administrative support). The associated burden amount for this work is $53,320. Additionally, Part D plan sponsors will have to retain a copy of the notice in the beneficiary's records. We estimate 5 minutes multiplied by 80,000 enrollees divided by 60 minutes. This equates to 6,666 hours at approximately $40 an hour (based on U.S. Department of Labor statistics for hourly wages for administrative support). This associated burden amount is $266,640. We estimate the total maximum annual burden for all Part D plan sponsors resulting from this proposed provision to be $319,960.

E. ICRs Regarding Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

We are amending § 423.772 and § 423.782 in accordance with section 3309 of the ACA. Specifically, the changes provide for a definition of an individual receiving home and community based services, and for zero cost-sharing for Medicare Part D prescriptions filled by full-benefit dual eligible beneficiaries receiving such services.

To carry out these provisions, we require State Medicaid Agencies to submit data at least monthly identifying these individuals. There is already an established data exchange for States to identify their dual eligible individuals to CMS at least monthly. We will leverage that data exchange by adding a new value for the existing institutional status field, which will prompt CMS to set a zero copayment liability for full-benefit dual eligible beneficiaries who qualify for HCBS zero cost-sharing, as set forth under section 3309 of the ACA. The estimated size of the population to be reported as being full benefit dual eligible and receiving home and community-based services is 600,000.

We estimate the burden associated with the requirement for States to provide CMS with the specified information including a one-time development cost and ongoing annual costs. The startup development effort is estimated at 20 hours per State, or an additional 1,020 hours for all 51 State Medicaid Agencies (50 States and the District of Columbia), in the fiscal year prior to the effective date of this provision. Assuming an hourly salary of $34.10 for computer programmers, this results in a development cost of $34,782. Once implemented, the information collection burden is estimated to be 1 hour each month, or 612 hours in each fiscal year for 51 State

Medicaid Agencies. Assuming an hourly salary of $34.10 for computer programmers, we estimate an ongoing cost of $20,862 per fiscal year.

F. ICRs Regarding Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

Under § 423.154 (a), we implement provisions of section 3310 of the ACA, which require Part D sponsors to use specific, uniform dispensing techniques such as weekly, daily, or automated dose dispensing when dispensing covered Part D drugs to enrollees who reside in long-term care facilities in order to reduce waste associated with 30-day fills. The collection burden associated with this proposed provision is the reporting requirement and re-negotiation of contracts.

We are introducing a new requirement under § 423.154 (a)(2) for Part D sponsors to collect and report to CMS the method of dispensing technique used for each dispensing event described under § 423.154 (a) and on the nature and quantity of unused brand and generic drugs. We anticipate a billing standard that incorporates the collection of the method of dispensing technique. So, pharmacies and plans will not have to create unique data collection processes to collect that data. We estimate that 40 sponsors-contractors (28 drug claim processors and 12 sponsors that process their drug claims and data collection) will be subject to this requirement. For the collection of data on unused drugs, we estimate that it will take a total of 2400 hours for 10 vendors (software vendors plus pharmacies with proprietary systems) to develop the programming for this requirement. The estimated total cost associated with the software development is equal to the number of software vendors plus the number of pharmacies with proprietary systems (10) times an hourly rate of $145.37 (this includes $43.35 in direct wages and an additional $102.02 in fringe benefits/overhead/general and administrative costs/fee) times 240 (estimated number of hours to design and program one system; the cost is $348,888. The aforementioned burden will be included in a revision of the collection currently approved under OMB Control No 0938–0992.

The requirements will necessitate the renegotiation of contracts between Part D sponsors and the pharmacies servicing LTC facilities. We anticipate dispensing fees will increase, consistent with our proposed change in the definition of dispensing fees (§ 423.100), with the relative investment in the dispensing technologies and corresponding dispensing efficiencies associated with the dispensing technologies used in § 423.154.

We estimate that the total annual hourly burden for negotiating a contract between the Part D sponsors and entity contracting with the pharmacies servicing long-term care facilities (for example, PBM) to be equal to the number of Part D sponsors (731) multiplied by the average estimated hours per sponsor (10), equaling 7,310 hours. We estimate the number of entities contracting with pharmacies servicing long-term care facilities to be 40 (28 processors and 12 other entities). We estimate the total annual hourly burden for negotiating a contract between an entity described previously and the pharmacies servicing LTC facilities to be the number of entities (40) multiplied by the average estimated hours per entity (80), which is 3,200 hours. The total number of hours for contract renegotiation is estimated to be 10,510 hours (7,310 hours + 3,200 hours). The estimated hourly labor cost for reporting is $150.20. The total estimated cost associated with these contract negotiation requirements is $1,578,602. We estimate that the total burden cost associated with this provision is $1,927,490.

Comment: We received comments regarding the burden associated with the reporting requirements. Many commenters believed that the Controlled Substance Act, hazardous waste laws, and State laws would be a barrier to LTC facilities returning unused drugs to pharmacies. Commenters stated that manual reporting of unused drugs would create a burden on the pharmacy and sponsor and require additional staffing to accommodate the increased workload.

Response: In response to the comments, we will eliminate the requirement that unused drugs be transferred to the pharmacy and instead retain only the requirement that Part D sponsors collect information from the network LTC pharmacies to determine the amount of unused drugs. We believe that this information can be collected by the pharmacies from the LTC facilities or determined by calculating the difference between the quantity dispensed and the quantity consumed which can be used to calculate the amount of unused medication. We are revising the PRA package for the Part D Reporting Requirements (OMB Control No. 0938–0992) to reflect this approach. Please comment on our approach in the Part D Reporting Requirement PRA package.

G. ICRs Regarding Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

Under § 422.504(a) and § 423.505(b) we would require MA organizations and Part D sponsors to address and resolve all complaints in the CMS complaint tracking system and to include a link to the electronic complaint form at *http://www.medicare.gov* on their main Web page. This requirement would allow thorough monitoring of complaints through the tracking system by identifying how plan sponsors resolve and close complaints and allow members to access complaint forms electronically on *http://www.medicare.gov.*

The burden associated with this proposed provision is the time and effort of the MA organizations and Part D sponsors in recording complaint closure documentation in the CTM and training staff, as well as posting and maintaining a link from their Web site to the electronic complaint form at the Medicare.gov Internet Web site. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). That is, the time, effort, and financial resources necessary to comply with the requirement would be incurred by the Part D sponsors in the normal course of their business activities.

Comment: We received comments from one commenter expressing support for the use of a drop-down checklist of complaint closure reasons. However, the commenter was concerned that a new electronic complaint form that could be accessed through the plan's Web site as well as *http://www.medicare.gov* would be seen as a substitute for beneficiaries' current avenues for issue resolution. The commenter additionally recommended that CMS establish a strict process for monitoring and reviewing how these complaints are resolved.

Response: Sections 422.504(a) and 423.505(b) require MA organizations and Part D sponsors to address and resolve all complaints in the CMS complaint tracking system and to include a link to the electronic complaint form at *http://www.medicare.gov* on their main Web page. The requirement allows complaint monitoring through the tracking system by identifying how plan sponsors resolve and close complaints, and allows enrollees to access complaint forms electronically on *http://www.medicare.gov.* We are therefore not modifying the burden estimate in our proposed rule in this final rule.

H. ICRs Regarding Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128 and § 423.562)

In accordance with the new section 1860D–4(b)(3)(H) of the Act, we proposed revising § 423.128 at paragraphs (b)(7) and (d) in our proposed rule to specifically provide three mechanisms that plan sponsors must have in place in order to meet the uniform appeals requirements of 1860D–4(b)(3)(H) of the Act.

We proposed adding paragraph (i) to § 423.128(b)(7) to require that plan sponsors make available standard forms to request coverage determinations and redeterminations (to the extent that standard request forms have been approved for use by CMS). In this final rule, we modify the language of the proposed rule to instead require plan sponsors to make available uniform model forms for requesting coverage determinations and appeals, and we clarify that we intend to revise our existing model forms.

We also proposed adding paragraph (ii) to § 423.128(b)(7), requiring sponsors to develop a Web-based electronic interface that allows an enrollee (or an enrollee's prescriber or representative) to immediately request a coverage determination or redetermination via a plan's secure Web site. The interface would be the "electronic equivalent" of the paper coverage determination and appeals forms referenced at § 423.128(b)(7)(i). Based on comments we received, we are finalizing the language related to instant access to coverage determinations and appeals processes via the plan's Web site, but have clarified in the preamble that we are interpreting instant access to mean, at a minimum, the ability of Part D plan sponsors to accept e-mail requests. Similarly, we are revising § 423.128(d) to require sponsors to provide a toll-free telephone line for requesting coverage determinations and redeterminations. The burden associated with these requirements involves collecting the coverage determination request information submitted through the various processes.

We estimated that all 731 plan sponsors would receive a total of 484,468 coverage determination requests submitted by mail, with some using the standardized coverage determination request form, if available. We further estimated that it would take 10 minutes to enter the information submitted from each request into a claims processing system, for a potential total annual burden of 80,745 hours. Although this final rule modifies the proposed language to include a reference to a model coverage determination request form, we do not expect this modification to impact our estimated burden for coverage determination requests submitted by mail. In the proposed rule, we estimated that all plan sponsors would receive a total of 52,086 coverage determination requests submitted through secure websites, but that this process would not create an additional burden for plan sponsors beyond that required for requests submitted by mail because enrollees would enter information into a claims processing system themselves. In this final rule, we scale back the Web site requirement to mean, at a minimum, the ability to accept requests via e-mail. We expect plan sponsors to process the e-mail requests in the same manner as requests received by mail, and estimate that it will take 10 minutes to enter the information submitted from each request into a claims processing system, for a potential total annual burden of 8,681 hours. Finally, we estimated that all plan sponsors would receive a total of 690,064 coverage determination requests submitted by telephone, and it would take 10 minutes to enter the information submitted by phone into the claims processing system, for a total annual burden of 115,011 hours. The burden associated with the redetermination process is exempt under 5 CFR 1320.4(a)(2) because a redetermination is an administrative action. Information collected when conducting an administrative action is not subject to the PRA.

Our final rule requires Part D sponsors to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the POS. That is, pharmacies and processors will be required to program their systems to relay the message at the pharmacy to distribute the POS pharmacy notice that instructs the enrollee to contact the plan sponsor to request a coverage determination. In cases when a prescription cannot be filled as written, Part D sponsors would be required under § 423.562(a)(3) to arrange with their network pharmacies to distribute a pharmacy notice that advised the enrollee of his or her right to contact the plan to request a coverage determination. We estimate that the burden on processors will be the programming to send the code or billing response to the pharmacy, as well as revisions to the contract requirement with the pharmacy. We estimate that the number of hours for each processor (28 PBMs and 12 plan organizations) to perform these tasks will be 40 hours per processor or plan organization, for a total one-time burden of 1600 hours. The estimated one-time cost associated with the processor or plan organization tasks is $64,000 (1600 hours × $40). Each pharmacy will need to program to receive the code and print the response. Programming by the pharmacies (40 pharmacy software vendors) in order to receive the code will be 10 hours, for a total of 400 hours. The estimated one-time cost associated with the processor tasks is $16,000 (400 hours × $40).

We estimate that the average time to process a coverage determination is 10 minutes (0.167 hours), and that an average of 734 coverage determination requests received by mail or secure Web site (e-mail) will be processed for each respondent (n=731). Therefore, we estimate that requiring plan sponsors to process the information submitted in model coverage determination request forms (§ 423.128(b)(7)(i)) will result in an annual burden of 89,605 hours (731 entities × 734 contracts per entity × .167 hours per contract to process). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $3.58 million. We estimate that processing coverage determination requests that are received by telephone (§ 423.128(d)) will take an average of 10 minutes (0.167 hours) per request and that entities (n=731) would process on average 944 coverage determination requests. We expect this to result in an annual burden of approximately 115,240 hours (731 entities × 944 determination requests per entity × 0.167 hours per determination request). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $4.6 million (115,240 hours × $40.00 per hour). We estimate that contracting entities (n=731) will distribute an average of 2,200 pharmacy notices.

Therefore, requiring plan sponsors to arrange with their network pharmacies to distribute pharmacy notices at the point-of-sale when prescriptions cannot be filled as written (§ 423.562(a)(3)) is estimated to result in an annual burden of 53,071 hours (2 minutes or 0.033 hours at point-of-sale × 731 contracts × 2200 pharmacy notices per contract). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change is $2.1228 million.

Comment: One commenter believed that our estimate of $40 an hour was too low for processing coverage determinations and redeterminations.

Response: We disagree with the commenter. The estimated hourly rate of $40 is a composite rate based upon

the Bureau of Labor Statistics National Compensation Survey.

Comment: One commenter asked CMS if the agency expects the pharmacy to maintain a copy of the POS notice according to the 10-year record retention requirement. If so, the commenter believed that this requirement would increase dispensing fees and present an additional hurdle for pharmacies and PBMs in response to CMS audit requests, thereby increasing the burden estimate.

Response: Part D sponsors are responsible for determining which pertinent documents they must retain. CMS does not specify which specific records Part D sponsors must require their network pharmacies to retain for audit purposes. Therefore, the burden estimate associated with the POS notice does not account for record retention requirements provided at § 423.505.

I. ICRs Regarding Including Costs Incurred by AIDS Drug Assistance Programs and the Indian Health Service toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

Revising the definition of "incurred cost" at § 423.100 to include the costs associated with IHS/ADAPs towards the TrOOP does not impose new information collection for CMS' COB contractor or ADAPs. The COB contractor currently collects data-sharing agreements from ADAPs under the MSP information collection process. The burden associated with this collection is accounted for under OMB 0938–0214.

J. ICRs Regarding Improvements to Medication Therapy Management Programs (§ 423.153)

This final rule amends § 423.153(d)(1)(vii) to require Part D sponsors to use a standardized format for the action plan and summary resulting from the annual comprehensive medication review, and permit the use of telehealth technology in the conduct of the CMR.

The burden associated with a number of the new MTM program requirements in the ACA, including the requirement for a written summary of the CMR, was summarized in our April 2010 final rule (75 FR 19678 through 19826) and approved under OCN 0938–0964 with an expiration date of September 30, 2012. We believe the burden associated with the requirement in § 423.153(d)(1)(vii)(D) to provide an action plan and summary in a standardized format is generally part of that burden. Therefore, we do not estimate an additional burden for this requirement in this final rule. Further, since the use of telehealth technology to conduct the CMR is permitted but not required, there is no burden associated with this change.

In our proposed rule, we estimated an ICR burden associated with the proposed requirement for Part D sponsors to coordinate MTM program quarterly medication reviews with LTC consultant pharmacist monitoring for Part D enrollees in LTC facilities. We are not finalizing this requirement and are eliminating this burden from our estimates. As a result, there is no burden associated with this provision.

K. ICRs Regarding Changes to Close the Part D Coverage Gap (§ 423.104 and § 423.884)

Section 423.104(d)(4) requires the approximately 40 pharmacy claims processors currently responsible for adjudication of pharmacy benefits to identify the applicable Part D covered drugs in their systems and apply a different cost-sharing percentage when processed in the coverage gap than the percentage applied to non-applicable drugs. We estimate a one-time burden to be 12,000 hours per processor to make the initial coding changes necessary to implement this requirement and an annual burden of 250 hours per processor to perform periodic updates of the applicable drugs in their systems. There are an estimated 40 processors. At an average labor cost of $105 per hour for a senior computer programmer, we estimate the first fiscal year annual burden associated with this requirement to be 480,000 hours (12,000 hours × 40 processors) at an estimated total cost of $50.4 million. After the first fiscal year, the estimated burden associated with this requirement would be 10,000 hours (250 hours × 40 processors) at an estimated total annual cost of $1,050,000.

L. ICRs Regarding Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate (§ 422.252, § 422.258 and § 422.266)

Under § 422.258(d)(6) we base the 5-star rating system for quality bonus payments on a modified version of the plan ratings published each fall on *http://www.medicare.gov.* The 5-star rating system for quality bonus payment will require no additional burden. The data collection for the 5-star rating is currently approved under the following OCNs:

OCN	Expiration Date
0938-1028	November 30, 2011
0938-0732	November 30, 2010
0938-0701	August 31, 2010

We have included new calculations for the benchmarks and rebates in § 422.252, § 422.258, and § 422.266. The burden associated with the bid data used in these calculations is included in the burden estimate associated with the Bid Pricing Tool which is currently approved under OCN 0938–0944 with a May 31, 2011, expiration date.

M. ICRs Regarding Quality Bonus Appeals (§ 422.260)

We add a new § 422.260 to state that each MA organization is afforded the right to request an administrative review of CMS' determination concerning the organization's qualification for a quality bonus payment. The burden associated with this proposed provision is MA organizations' time and effort in developing and presenting their case demonstrating that they should qualify for the quality bonus payment to a CMS official and, ultimately, to the CMS Administrator. Eligibility for quality bonus payments will be based largely on CMS' application of a publicized methodology for assigning star ratings to MA organizations. These star ratings will be calculated using a combination of the MA organization's performance scores across a variety of quality assessment measures. MA organizations will have the opportunity to challenge

CMS' application of the methodology to their performance.

We estimate that the total hourly burden in a fiscal year for developing and presenting a case to us for review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing MA organization to research, draft, and submit their arguments to CMS. Based on the star rating distributions of previous contract years, out of the approximately 350 MA contracts that are subject to star rating analysis (that is, those not excluded from analysis because of low enrollment, contract type not required to report data, or new contract with no performance history), approximately 250 may receive less than a four-star rating. We estimate that 10 percent of those contracts (25) will request an appeal of their rating under the proposed rule. We further estimate that one attorney working for 8 hours could complete the documentation to be submitted to CMS for each contract, resulting in a total burden estimate of 200 hours (8 hours × 25 contracts = 200 hours). The estimated fiscal year cost to MA organizations associated with this provision (assuming an attorney billing rate of $250 per hour) is $50,000 (200 hours × $250).

N. ICRs Regarding Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

In this final rule, we are amending § 423.509 to state that when CMS terminates a contract with a Part D plan sponsor, the Part D plan sponsor must ensure the timely transfer of any data or files. Our intent is to ensure that terminated Part D plan sponsors transfer to CMS the necessary data to provide a smooth transition for beneficiaries into a new Part D plan similar to when the Part D sponsor terminates the contract or CMS and the Part D plan sponsor mutually terminate the contract. The burden associated with this proposed provision is the time and effort that Part D plan sponsors must undertake to transfer the requisite data and files to CMS. We have not developed a burden estimate for this requirement because we do not believe that we will exceed the PRA threshold of 9 organizations per any 12-month period.

O. ICRs Regarding Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Sections 422.2274(b) and (c) and 423.2274(b) and (c) would require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program. We are considering implementing this requirement through a RFP competitive process. The burden associated with this requirement is the time and effort put forth by plan sponsors and/or third party vendors to submit their proposals for CMS review. We estimate that about 12 entities (plan sponsors and/or third party vendors) will submit a proposal and the average estimated hours per entity to complete the proposal is 100 hours. The total estimated hourly burden associated with this requirement is equal to the estimated number of entities (12) multiplied by the estimated hours per entity (100) resulting in a total of 1200 hours. We estimate the hourly labor cost of $59.20 for the preparer (based on hourly wages for management analysts reported by the U.S. Department of Labor Bureau of Labor Statistics). We estimate that the total annual labor cost of this proposal preparation is $71,040 ($59.20 × 1200 hours) per fiscal year.

Also at § 422.2274 and § 423.2274, we clarify that the annual agent and broker training requirements apply to all agents and brokers selling Medicare products and not just independent agents and brokers. The burden associated with this requirement is the time and effort put forth by the MA organization or Part D sponsor to ensure all agents and brokers selling Medicare products are trained and tested annually. While this requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their business activities.

P. ICRs Regarding Call Center and Internet Web site Requirements (§ 422.111 and § 423.128)

At § 422.111(g)(1)(2)(3) (redesignated as § 422.111(h)(1) through (3)), we require MA organizations to operate a toll-free customer call center that is open during usual business hours and provides customer telephone service in accordance with standard business practices, as well as to provide current and prospective enrollees with information via an Internet Web site and in writing (upon request). In § 422.111(g)(1)(iii) and § 423.128(d)(1)(iii) (redesignated as (h)(1)(iii)) we codify provisions from the Medicare Marketing Guidelines (August 15, 2005 version and all subsequent versions) that require plan sponsors to provide call center interpreters for non-English and LEP beneficiaries. The burden associated with this requirement is the time and effort necessary to maintain a customer call center and Internet Web site, to provide information to beneficiaries in writing upon request, and to provide call center interpreters. While this requirement is subject to the PRA, we believe this burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their business activities.

Q. ICRs Regarding Requiring Plan Sponsors to Contact Beneficiaries to Explain Enrollment by an Unqualified Agent/Broker (§ 422.2272 and § 423.2272)

Sections 422.2272(e) and 423.2272(e) require MA organizations and Part D sponsors, respectively, to notify Medicare beneficiaries upon discovery that they were enrolled in a plan by an unqualified agent. While this requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their business activities.

R. ICRs Regarding Customized Enrollee Data (§ 422.111 and § 423.128)

As discussed in our November 2010 proposed rule (75 FR 71249 through 71250), proposed § 422.111(b)(11) and § 423.128(b)(12) authorize CMS to require MA organizations and PDP sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the annual notice of change/evidence of coverage, or ANOC/EOC).

Plan sponsors already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In our proposed rule, we stated that the burden associated with this proposed requirement would be the time and effort necessary for a plan sponsor to complete program development and testing, and to disclose (print and mail) this information to each beneficiary. We anticipated that it would take 30 hours per MA organization and 20 hours per Part D sponsor to develop and submit the required information. This included 2 hours for reading CMS' published

instructions, 20 hours per MA organization and 10 hours per Part D sponsor generating the document or documents, and 8 hours printing and disclosing to enrollees. We developed this burden estimate using our burden estimates for the ANOC/EOC documents under OCN 0928–1051 as a baseline, then expanded on that baseline, and factored in expected programming and development costs to provide beneficiary specific information. We estimated that 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. We proposed that the total annual burden associated with this requirement would be 18,620 hours in a fiscal year.

In our proposed rule, we estimated the subsequent annual burden associated with this proposed requirement by the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We anticipated that it would take 20 hours per MA organization and 15 hours per Part D sponsor to develop and submit the required information. This included 1 hour for reading CMS' published instructions, 10 hours per MA organization and 5 hours per Part D sponsor generating the document or documents, and 6 hours printing and disclosing to beneficiary. We estimated that 564 MA organizations and 85 Part D sponsors would be affected annually by this requirement. We estimated the total annual burden associated with this proposed requirement would be 12,555 hours in a fiscal year (20 hours for each of the 564 MA organizations + 15 hours for each of the 85 Part D sponsors). Based on the comments we received on our proposed rule, we are modifying our burden estimate as described below.

Comment: As discussed in section II.D.4 of this final rule, we received many comments on our proposal to authorize CMS to require MA organizations and Part D drug sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Commenters were particularly concerned with the administrative and cost burdens associated with providing beneficiaries with customized enrollee data that included an estimate of future costs. Several of the commenters stated that our analysis of the burden associated with this proposed requirement, which we developed by expanding on the baseline burden estimates for the ANOC/EOC documents under OCN 0928–1051, was undervalued. One commenter stated that the estimate did not take into account the size of organizations' memberships, sophistication of IT systems, variances in benefit designs or delivery systems. Several commenters stated that creating systems to compile current year information as well as to calculate future year information would require many more hours of IT and staff time than we estimated. Commenters offered estimates such as "more than 30 hours per plan option per product" and "thousands of hours."

Response: As discussed in section II.D.4 of this final rule, we are modifying our original proposal to authorize CMS to require that MA organizations periodically provide each enrollee with enrollee specific data. We are finalizing § 422.111(b)(12) to state that we may require an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under part 422. As discussed in section II.D.4 of this final rule, we intend to work with MA organizations, Part D sponsors and beneficiary advocates to develop an explanation of benefits for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e). We plan to continue the research and development process through a small pilot program with volunteer organizations in CY 2012 with the hope of implementing an EOB requirement for all MA plans beginning in the future.

Based on the comments received, and our modified final policy, we have recalculated our estimate of the burden, based on the annual burden to Part D plan sponsors to furnish enrollees with an EOB for prescription drug benefits under OMB 0938–0964. MA organizations already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In the first year that the pilot program is implemented, the burden associated with this proposed requirement would be the time and effort necessary for 564 MA organizations to complete program development and testing of an explanation of benefits when Part C benefits are provided, and to disclose (print and mail) this information to each beneficiary. Given that stand alone PDPs already produce an EOB in accordance with § 423.128(e), the revised burden estimate includes only MA organizations. We estimate that in the first year it will require each entity 200 hours on an annual basis to disseminate the required materials, for a total annual burden of 112,800 hours. We calculate the total labor cost estimate based on the hourly rate of $34.92 for a GS–11/step 6 analyst. This first year estimate builds from the estimated annual burden for the Part D EOB. Our revised estimate increases the number of hours organizations will need to initiate and complete program development and testing of an EOB.

In subsequent years, the burden associated with this requirement will be the time and effort necessary for about 564 MA organizations to provide an EOB when Part C benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis to disseminate the required materials, for a total annual burden of 90,240 hours. We calculate the total labor cost estimate based on the hourly rate of $34.92 for a GS–11/step 6 analyst. The decreased estimate of burden hours relative to the first year reflects the completion of program development in the first year and brings the estimated hours in line with the current estimated number of hours for the Part D EOB.

S. ICRs Regarding Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100(f) and § 422.101(d))

In this final rule, we are extending the mandatory MOOP and catastrophic limit requirement to RPPO plans at § 422.100(f) and § 422.101(d). Each RPPO plan will establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services. We will set the dollar amount of the MOOP limit annually. RPPO plans' MOOPs will include all cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services. These requirements will not result in an additional data collection burden for RPPOs since they already collect this data to establish their own in-network MOOP and catastrophic limits under § 422.101(d)(4). While this requirement is subject to the PRA, the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement is incurred by persons in the normal course of their business activities.

T. ICRs Regarding Prohibition on Use of Tiered Cost Sharing by MA Organizations (§ 422.100 and § 422.262)

Section § 422.262 clarifies that MA organizations may not impose cost sharing that varies across enrollees for any reason, including provider group,

hospital network or enrollees' utilization of services. The burden associated with this proposed revision is the time and effort necessary for MA organizations and section 1876 cost contracts to submit their benefit designs, including cost-sharing amounts, via the Plan Benefit Package (PBP) software. While this requirement is subject to the PRA, the burden associated with it is currently approved under OCN 0938–0763 with a May 31, 2011 expiration date.

U. ICRs Regarding Translated Marketing Materials (§ 422.2264 and § 423.2264)

This clarification at § 422.2264(e) and § 423.2264(e) does not impose any additional burden upon MA organizations because they have been required to provide translated marketing materials pursuant to § 422.2264(e) and § 423.2264(e) (previously numbered § 422.80(c)(5) and § 423.50(d)(5)). We believe the burden associated with these proposed requirements is exempt from the requirements of PRA as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

V. ICRs Regarding Expanding Network Adequacy Requirements to Additional MA Plan Types (§ 422.112)

Our amendment to § 422.112(a)(10) ensures that any MA plan that meets Medicare access and availability requirements through direct contracting network providers does so consistent with the requirements at § 422.112(a)(10). We do not include MA MSAs in § 422.112(a)(10) because MSA plans historically have not had networks and enrollees in MSA plans may see any provider. However, MSA plans are not prohibited from having networks as long as enrollee access is not restricted to network providers. While there are currently no MA MSA network plans, we are aware of possible interest in offering such plans.

The burden associated with this requirement is the time and effort required by MA organizations to submit network adequacy data to CMS for review and approval as part of the application process. This burden is already accounted for under OCN 0938–0935. However, since this amendment will extend the current network adequacy requirements only to Medicare MSA plans, and there is currently only one Medicare MSA contract (which does not use a network of providers), we believe that fewer than 10 applications would be subject to this proposed requirement in each fiscal year.

W. ICRs Regarding Maintaining a Fiscally Sound Operation (§ 422.2, § 422.504, § 423.4, and § 423.505)

Sections 422.504(a) and 423.505(b) add a contract term under which an MA organization or PDP sponsor agrees to maintain a fiscally sound operation by at least maintaining a positive net worth. A determination of whether there is a positive net worth will be made from the financial reports submitted under the current financial reporting requirements. The burden associated with this requirement is the time and effort necessary to submit these financial reports. While this requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0469 with an expiration date of April 30, 2013.

X. ICRs Regarding Release of Part C and Part D Payment Data (Parts 422 and 423, Subpart K)

This provision permits the Secretary to release Part C and D summary payment data for research, analysis, and public information functions. The Secretary believes these data should be made available because other publicly available data are not, in and of themselves, sufficient for the studies and operations that researchers want to undertake to analyze the Medicare program and Federal expenditures, and to inform the public on how their tax dollars are spent.

These data will be routinely released on an annual basis in the year after the year for which payments were made. The data release will occur after final risk adjustment reconciliation has been completed for the payment year in question and, for Part D, after final payment reconciliation of the various subsidies. Thus, we will release data for payment year 2010 in the fall of 2011. This timeframe will not apply to the release of RDS data, since we do not reconcile RDS payment amounts until 15 months following the end of the plan year. The majority of our sponsors provide retiree drug coverage on a yearly basis. If an applicable plan year ended December 31, 2010, the payment reconciliation is not due until March 31, 2012, which would be after the fall 2011 target for other Part C and D payment data. We will release the most current RDS payment data available at the time Part C and D payment reconciliation has been completed and those data are compiled and released.

Since we are not seeking additional information from MA organizations or from Part D sponsors, there are no PRA implications. Payment data are quite different than the bid data plans submit and for which we have existing OMB authority for collection (OCN 0938–0944). The gross payment data we are proposing to disclose are not derived from information plans submit to us, but rather are compiled and derived solely from CMS internal payment files.

Comment: One commenter argued that CMS should release MA payment data in accordance with the Freedom of Information Act (FOIA) and the current administration's FOIA policy. The commenter believed that these data were necessary to assess the impact and operation of the MA program, requested immediate release of 2006–2009 data, and asked CMS to release 2010 data as soon as possible.

Response: We disagree with the commenter's argument that we must proactively release MA payment data in accordance with FOIA. Accordingly, we have engaged in notice and comment rulemaking pursuant to our authority under section 1106(a) of the Social Security Act to authorize the proactive release of data from 2010 and beyond. We are therefore finalizing our burden estimate as proposed.

Y. ICRs Regarding Revision to Limitation on Charges to Enrollees for EmergencyDepartment Services (§ 422.113)

At § 422.113(b)(2)(v) we eliminate the current $50 cost-sharing limit on emergency department services and, instead, to require CMS to evaluate and determine the appropriate enrollee cost sharing limit for emergency department services on an annual basis. The burden associated with this proposed requirement is the time and effort necessary to for MA organizations to submit their benefit designs, including cost-sharing amounts, via the Plan Benefit Package (PBP) software. While this proposed requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0763 with an expiration date of May 31, 2011.

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Table 9—Estimated Fiscal Year Reporting Recordkeeping and Cost Burdens

Regulation Sections	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting[1] ($)	Total Labor Cost	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§422.101 and §422.152	0938-0935	544	544	6	3,264	55.46	181, 021	0	181, 021
§423.780(f)	0938-New	150	150	0.167	25	23.92	598	0	598
§423.44	0938-New	80,000 731	80,000 80,000	0.017 0.083	1,333 6,666	40.00 40.00	53,320 266,640	0	53,320 266,640
§423.772 and §423.782 (Start-up)	0938-New	51	51	20	1020	34.10	34,782	0	34,782
§423.772 and §423.782 (Annual)	0938-New	51	51	12	612	34.10	20,869	0	20,869
§423.154 and §423.100	0938-0992	731 40 40	731 40 10	10 80 240	7,310 3,200 2,400	150.20 150.20 145.37	1,097,962 480,640 348,888	0 0	1,097,962 480,640 348,888
§423.128(b)(7)(i)	0938-New	731	536,554	0.167	89,605	40.00	3,584,200	0	3,584,200
§423.128(d)	0938-New	731	690,064	0.167	115,011	40.00	4,600,440	0	4,600,440
§423.562(a)(3)	0938-New	731 40 40	1,608,200 40 40	0.033 40 10	53,071 1,600 400	40.00 40.00 40.00	2,122,840 64,000 16,000	0 0 0	2,122,840 64,000 16,000

[1] Bureau of Labor Statistics, U.S. Department of Labor, **National Compensation Survey: Occupational Earnings in the United States, 2009**. United States Government Printing Office. July 2009. Retrieved from http://www.bls.gov/ncs/ncswage2009.htm

Regulation Sections	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting[1] ($)	Total Labor Cost	Total Capital/ Maintenance Costs ($)	Total Cost ($)
§423.104(d) (Start-up)	0938-New	40	40	12,000	480,000	105.00	50,400,000	0	50,400,000
§423.104(d) (Annual)	0938-New	40	40	250	10,000	105.00	1,050,000	0	1,050,000
§422.260	0938-New	25	25	8	200	250	50,000	0	50,000
§422.2274 and §423.2274	0938-New	12	12	100	1,200	59.20	71,040	0	71,040
§422.111 and §423.128 (Start-up)	0938-New	564	564	200	112,800	34.92	3,938,976	0	3,938,976
§422.111 and §423.128 (Annual)	0938-0964	564	564	160	90,240	34.92	3,151,181	0	3,151,181
Total		81,485	2,997,720		979,957		71, 352,376	0	71,352,376

[1] Bureau of Labor Statistics, U.S. Department of Labor, **National Compensation Survey: Occupational Earnings in the United States, 2009**. United States Government Printing Office. July 2009. Retrieved from http://www.bls.gov/ncs/ncswage2009.htm

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IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an "economically" significant rule under section 3(f)(1) of Executive Order 12866, and a major rule under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.0 million to $34.5 million in any 1 year; for details, see the Small Business Administration's Web site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2465b064ba6965cc1fbd2eae60854b11&rgn=div8&view=text&node=13:1.0.1.1.16.1.266.9&idno=13).* Individuals and States are not included in the definition of a small entity.

MA organizations and Part D sponsors, the entities that will largely be affected by the provisions of this rule, are not generally considered small business entities. They must follow minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. HHS uses as its measure of significant economic impact on a substantial number of small entities, a change in revenue or costs of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because this final rule will have minimal impact on small entities. Therefore, an analysis for the RFA will not be prepared because the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This final rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Based on CMS Office of the Actuary estimates, we do not believe that this final rule imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We note that we have estimated that our provision to eliminate, pursuant to section 3309 of the ACA, Medicare Part D cost-sharing for full-benefit dual eligible individuals receiving home and community based services at § 423.772 and § 423.782 will have a very small cost impact on States resulting from the need to identify eligible individuals and provide data to CMS. As discussed elsewhere in this RIA, we estimate the annual cost associated with the requirement for States to provide CMS with this data to be $34,782 in the first year and $20,869 for subsequent years.

B. Statement of Need

The purpose of this final rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D), to implement provisions specified in the ACA and make other changes to the regulations based on our continued experience in the administration of the Part C and Part D programs. These latter revisions are necessary to, (1) clarify various program participation requirements, (2) make changes to strengthen beneficiary protections, (3) strengthen our ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers, and (4) make other clarifications and technical changes.

C. Overall Impact

The CMS Office of the Actuary has estimated savings and costs to the Federal government as a result of various provisions of this final rule. As detailed in Table 11, we expect savings to the Federal government of approximately $82.42 billion for fiscal years (FYs) 2011 through 2016 as a result of the implementation of the following provisions:

Payment Changes Related to MA benchmarks, Quality Bonus Payments, Rebates, and Application of Coding Adjustment	$76.47 billion
Increase in Part D premiums Due to Income Related Monthly Adjustment Amount (D-IRMAA)	$4.77 billion
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities under PDPs and MA-PD plans and Dispensing Fees	$1.00 billion
Elimination of the Stabilization Fund	$181 million

In Table 10, we estimate total costs to the Federal government, States, Part D sponsors, MA organizations, and other private sector entities as a result of various provisions of this final rule. As detailed in Table 10, we expect costs of approximately $5.35 billion for FYs 2011 through 2016 as a result of the implementation of various additional provisions of this final rule. Following are the provisions with the most significant costs (that is, costs greater than $100 million between FY 2011 and FY 2016) in this final rule:

Changes to Close the Part D Coverage Gap	$3.67 billion
Determination of Part D Low-Income Benchmark Premium	$770 million
Including Costs Incurred by AIDS Drug Assistance Programs (ADAPs) and the Indian Health Service (IHS) Toward the Annual Part D Out-of-Pocket Threshold	$460 million
Voluntary De Minimis Policy for Subsidy Eligible Individuals	$170 million
Cost-Sharing for Medicare Covered Preventive Services	$148 million

Tables H2, H3, and H4 detail the breakdown of costs by cost-bearing entity. Specifically, Table 11 describes costs and savings to the Federal government, Table 12 describes costs to MA organizations and/or PDP sponsors and third party entities, and Table 13 describes costs to States.

Taking into account both costs and savings estimated in this RIA, we estimate a net savings of $76.17 billion as a result of the provisions in this final rule over FYs 2011 to 2016. Therefore, this final rule is "economically significant" as measured by the $100 million threshold, and is a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that details anticipated effects (costs, savings, and expected benefits), and alternatives considered by this requirement. For collection of information burden associated with our requirements and the bases for our estimates, refer to the collection of information section of this final rule.

1. Expected Impact on States, Plans and the Medicare Program

a. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

We estimate that our implementation of section 3202 of the ACA will result in no additional program costs. In our November 2010 proposed rule (75 FR 71250) we had proposed cost sharing limits for in-network home health services provided under MA plans in addition to the ACA-required limits on cost sharing in MA plans for chemotherapy services, renal dialysis services, and skilled nursing facility care. We are not finalizing our proposed requirement to requiring cost sharing limits for in-network home health services provided by MA plans. We estimate that the Federal fiscal year 2012 (FY 2012) costs to Medicare of limiting cost sharing in MA plans for the service categories specified in the ACA (that is, chemotherapy and radiation services, renal dialysis, and skilled nursing facility care) will be zero because we already require plans to charge in-network cost sharing for these three service categories that does not exceed cost sharing under Original Medicare. In fact, we believe that Congressional intent was to require that CMS maintain the limits on in-network cost sharing that we had already implemented for SNF care, renal dialysis services, and Part B chemotherapy services. Thus, we expect that there will be no effect on plans or beneficiaries as a result of our implementation of the cost sharing limits specified in section 3202 of the ACA. We believe MA organizations will continue to have adequate flexibility to design plan benefits that are responsive to beneficiary needs and preferences while providing access to high quality and affordable health care.

b. Approval of SNPs by NCQA (§ 422.4, § 422.101, and § 422.152)

The burden associated with this requirement is the time and effort put forth by MA organizations offering SNPs to submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance. Although the submission of the MOC is already part of the application process, review of this document by NCQA for approval is a new requirement. This requirement is for all new and existing SNPs. We estimate that it will take each SNP plan 40 hours to complete the annual application. Within those 40 hours, we estimate it will take SNP plans 6 hours to complete the SNP proposal portion of the MA application. Currently, there are 544 existing SNP plans. We estimate of the 6 hours, it will take existing SNPs 2.5 hours to complete the MOC for the SNP approval process. For the existing 544 SNPs, we estimate the burden associated with completing the MOC for the SNP approval process only is 1,360 hours. For the existing plans to complete the SNP sections only, the burden associated with this new requirement is 3,264 hours.

The number of new plans each year will vary and cannot easily be predicted. However, based on the number of new plans that submitted SNP Proposals during the application period in February 2010 for operation in 2011, we estimate that approximately 15 new applications will be submitted annually. For the estimated 15 new plan

applications, we estimate of the 6 hours to complete the SNP portion of the application it will take new SNPs 2.5 hours to complete the MOC for the SNP approval process. For the 15 new plan applications, we estimate the burden associated with completing the MOC for the SNP approval process only is 38 hours. Thus, for 15 new plans at 40 hours each, we estimate the total annual burden hours to be 600.

The estimated costs associated with the burden hours are summarized in Tables 10 through 12. Table 10 summarizes the estimated total costs for the Federal government and MA SNP plans from FYs 2011 to 2016. The costs in Table 11 reflect the contract award to NCQA for $1 million and a contract award at the level of $500,000 for years 2012 to 2016. The additional costs incurred in this table are for the Federal salaries for two GS–13 step 10 analysts and a GS–15 manager. Table 12 contains the projected costs to the SNPs for preparing the SNP sections of the application. These costs are primarily labor costs for staff employed by the plans to complete the required materials. The salaries are equivalent to that of one GS–13 step-10 analyst at a salary of $55.46 an hour.

c. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

Beginning in 2011, section 1860D–14(b)(3)(B)(iii) of the Act requires CMS to calculate the LIS benchmarks using basic Part D premiums before the application of Part C rebates each year. This final rule updates our regulations at § 423.780(b)(2)(ii)(C) to codify this provision. This provision will decrease the number of reassignments of low-income beneficiaries from plans that are above the low-income benchmark because it will increase the benchmark, thereby producing more zero-premium plans. We believe this provision will lead to additional costs to the Federal government of approximately $90 million for FY 2011.

The estimated cost to the Federal government between FY 2011 and FY 2016 is $770 million. The year-by-year impacts in millions of dollars are shown in Tables 10 through 12. Table 11 shows that the bulk of this total cost is due to increased Federal premium subsidy payments, which are the result of generally increasing the low-income benchmarks. The higher benchmarks allow a greater number of low-income beneficiaries to remain in their current plan, rather than reassigning them to a lower cost plan. In each region, the low-income benchmark essentially functions as a ceiling for the Federal premium subsidy for low-income beneficiaries. That is, the Federal premium subsidy covers the full cost of the plan's basic Part D premium for a full-subsidy beneficiary, up to the low-income benchmark amount.

This approach maintains a strong incentive to bid low to keep and possibly add LIS beneficiaries. Absent the provision, there may be a "winner take all" outcome in certain regions with one organization acquiring all of the LIS beneficiaries in the region. It is difficult to predict what will happen in the absence of this provision, but we expect some organizations will be induced to bid even lower, while other organizations will give up on this population and bid higher.

We expect this rule to reduce the administrative costs for plan sponsors associated with the reassignment of LIS beneficiaries. These costs include the production of new member informational materials by the new plan, increased staffing of call centers to field beneficiary questions, and costs associated with implementing transition benefits for new enrollees. The cost estimate for the LIS benchmark methodology change in Table 10 does not include a projection for administrative savings.

We believe this final rule will have an effect on the number of reassignments, and the number of zero-premium plans available to full-subsidy eligible individuals in each region. This final rule will reduce the number of reassignments and increase the number of zero premium organizations available to beneficiaries. This is because, under the higher benchmarks, more PDPs are likely to have premiums that are equal to or less than the low-income benchmark and, as a result, will be fully covered by the premium subsidy. Low-income subsidy beneficiaries will be able to remain in these PDPs and will not be reassigned to other lower-premium PDPs. Under the current framework we would expect 1.9 million reassignments. Under the formula for calculating benchmarks we will expect 900,000 reassignments, or approximately one million fewer reassignments. We expect the formula to increase the number of zero premium organizations available to beneficiaries in 21 of the 34 PDP regions.

Although there is no quantifiable monetary value to CMS to reducing reassignments, we believe this benefit is important, as it will increase program stability and continuity of care.

d. Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

The new voluntary de minimis provisions in § 423.34(d) and § 423.780(f) permit Part D plans to volunteer to waive a de minimis amount of the Part D premium above the LIS benchmark. We expect that the only Part D plans that will volunteer to do so are those PDPs that would otherwise lose LIS beneficiaries to reassignment. We will establish a new de minimis amount in August of each year, and the de minimis amount may vary by year. For purposes of illustration, if the de minimis amount were $1.00, we would estimate 800,000 LIS beneficiaries would have an average of $0.50 per month waived by Part D plans, resulting in a total annual cost to all de minimis plans of $5 million per year. Table 12 shows that this would result in a total cost of $30 million to PDPs from FY 2011 to 2016. If the de minimis amount were $2.00, we would estimate that 1,200,000 LIS beneficiaries would have an average of $0.93 per month waived by Part D plans, resulting in a total annual cost to all de minimis plans of $10 million per year.

Our voluntary de minimis provisions are estimated (based on the assumption of a $1.00 de minimis amount) to cost the Medicare Trust Fund $140 million over the 6-year period from FY 2011 to FY 2016. Tables 11 and 12 illustrate how these costs are borne by the Federal government and PDPs, respectively. PDPs that volunteer to waive a de minimis amount will not have their LIS beneficiaries reassigned to a zero premium plan. The additional costs are attributable to low-income beneficiaries staying in higher cost plans. The result of staying in higher costs plans is that Medicare's low-income premium and cost-sharing subsidy and reinsurance payments will be greater than would have been the case if CMS reassigned these beneficiaries to lower-cost plans.

e. Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (D–IRMAA) (§ 423.44)

Section 423.44(e)(3) requires PDPs to provide Part D enrollees with a notice of disenrollment in a form and manner determined by CMS. PDPs will provide disenrollment notices to enrollees who were required to pay the Part D—IRMAA because their modified adjusted gross income exceeded the income threshold amounts set forth in 20 CFR 418, but failed to pay it after a grace period and appropriate notice has been provided.

Consistent with data from individuals paying the Part B IRMAA (1.8 million) and enrolled in a Part D plan, we estimate that approximately 1.05 million of the 29.2 million Medicare beneficiaries enrolled in the Part D program will exceed the minimum income threshold amount and will be assessed an income related monthly adjustment amount. Out of the 1.05 million affected beneficiaries, we estimate that 0.22 million will drop the Part D coverage in 2011. Under Part B, approximately 122,000 (14.8 percent) of the 1.8 million beneficiaries assessed an IRMAA are billed directly. This constitutes 5.17 percent of the Medicare population. We estimate that approximately 80,000 (7.6 percent) of the 1.05 million beneficiaries enrolled in Part D who must pay the Part D—IRMAA will be directly billed for the Part D—IRMAA either because they are not receiving monthly benefit payments from SSA, OPM, or the RRB, or the monthly benefit payment is not sufficient to have the Part D—IRMAA withheld.

Of the 80,000 Part D enrollees who will be directly billed for the Part D—IRMAA, we cannot estimate how many might accrue Part D—IRMAA arrearages and be subsequently terminated. However, in cases where the PDP is required to send an enrollee a notice of termination in accordance with § 423.44(e)(4), the burden associated with this requirement would be the time and effort it takes the PDP to populate the notice. Termination notices are generally automated; therefore, assuming all 80,000 Part D enrollees that have a Part D—IRMAA become delinquent, we estimate 1 minute × 80,000 enrollees divided by 60 minutes. This equates to an annual burden for PDP sponsors of 1,333 hours at approximately $40/hour (based on U.S. Department of Labor statistics for hourly wages for administrative support). The associated burden amount for this work is $53,320. Additionally, Part D plan sponsors would have to retain a copy of the notice in the beneficiary's records. We estimate 5 minutes × 80,000 enrollees divided by 60 minutes. This equates to 6,666 hours at approximately $40/hour (based on U.S. Department of Labor statistics for hourly wages for administrative support). This associated burden amount is $266,640. We estimate the total maximum annual burden for all Part D plan sponsors resulting from this provision to be $319,960. Therefore, as shown in Table 12, we estimate this provision to result in a maximum burden cost, to PDP sponsors, in the amount of $1.92 million for FYs 2011 through 2016. During calendar year 2011, we expect that implementation of the Part D—IRMAA provisions, at § 423.286(d)(4) and § 423.293(d), will increase the Medicare Trust Fund by $270 million, with a net Federal government savings of approximately $4.77 billion from FY 2011 through FY 2016 from increased premium payments by Medicare beneficiaries. We describe these savings to the Federal government in Table 11, and describe total year-by-year impact for the Federal government and Part D sponsors in Table 10. Also, because the income thresholds do not increase between 2011 and 2019, we anticipate that more beneficiaries will be affected by the IRMAA provision over time and this, in turn, will produce significant growth in the savings associated with this program.

f. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

We are amending § 423.772 and § 423.782 pursuant to section 3309 of the ACA. Specifically, the changes provide for a definition of an individual receiving home and community based services, and for zero cost-sharing for Medicare Part D prescriptions filled by full-benefit dual eligible beneficiaries receiving such services. As illustrated in Table 12, this provision will not increase costs for MA organizations or PDP sponsors. The affected beneficiaries already have LIS as full duals and are, therefore, low-income individuals. Their Part D copayment level is likely to be low prior to the elimination of copayments. The elimination of copayments will allow them additional disposable income for other expenses. The reduction in the copayments to zero will be fully offset by increasing low income subsidy cost sharing subsidy payments we make to their Part D plans. The formal elimination of the fund will have little or no impact on the current operation of the MA program. We believe the impact on the Federal government will be minimal given that most of the impacted individuals are already at a low copayment level and the shift from the low copayment level to zero copayment is small.

This provision will impact States, as they will have to identify eligible individuals and provide data to CMS. They will send the new data on an existing monthly data exchange already used to identify dual eligible beneficiaries. We estimate the cost for States to comply with this requirement to include a one-time development cost of $34,782 in FY 2011, and as well as an ongoing annual cost of $20,869 starting in FY 2012.

g. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities Under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

We are adding a new regulation at § 423.154 to require Part D sponsors to utilize uniform dispensing techniques in increments of 14-days-or-less when dispensing covered brand name Part D drugs to enrollees who reside in long-term care (LTC) facilities. Based on our discussions with industry, we estimate that 75 percent to 80 percent of the cost related to drug waste arises from 20 percent of the drugs. That 20 percent is made up of brand name medications. In an effort to target the drugs resulting in the most financial waste and to lessen burden for facilities transitioning from 30-day supplies to 14-day-or-less supplies, we are initially limiting the requirement for 14-day-or-less dispensing to brand name drugs as defined in § 423.4.

Pharmacies servicing LTC facilities may have upfront costs associated with software upgrades, packaging and hardware changes, and ongoing costs of transaction fees, and additional deliveries. These costs were not reflected in Table 10 of the proposed rule; instead, we solicited comments on these costs. We expect some of these expenses to be offset by an increase in dispensing fees consistent with § 423.100. In addition, a decrease in volume of drugs dispensed may result in lower revenues and rebates.

We expect most pharmacies to initially convert from a 30-day punch card system to a 14-day punch card system. Our conversations with manufacturers of the 30-day punch card systems have indicated that there is minimal capital investment conversion needed for the transition from 30-day to 14-day packaging. We expect only a relatively small number of pharmacies will convert to an automated dose dispensing system in the very short-term due to the acquisition costs of the technology. We anticipate costs associated with the change in software and training of pharmacy staff associated with the change. We also expect a few pharmacies to incur a small additional expense related to the number of deliveries required to service a facility with a 14-day-or-less dispensing technique.

We anticipate that dispensing fees will be developed to take into account the marginal costs associated with additional dispensing events in a single billing cycle for a single prescription

and consider costs undertaken to acquire and maintain technology aimed at reducing waste. We would expect dispensing fees to be greater when a Part D drug is dispensed using automated dose dispensing technology, as opposed to a Part D drug dispensed via a 14-day blister pack, due to substantially greater marginal costs of acquiring and implementing automated dose technology than in adjusting current systems and workflows to dispense in 14-day rather than 30-day quantities. For purposes of scoring this final rule, we project that the current aggregate level of dispensing fees will double. It is not at all clear that negotiated dispensing fees must or will increase directly in proportion to the number of dispensing events per month as some, but not all, commenters assert. Nonetheless, in order to be as conservative as possible in projecting cost increases, we have assumed a doubling of the current aggregate level of dispensing fees. In addition, the information we have to work with in projecting potential savings reflects widely divergent estimates. The variation in savings estimates range from as low as approximately 3 percent to as high as 17 percent for 7-day supplies, and as high as 20 to 25 percent for automated dose dispensing. Given the divergence in estimates and the uncertainty in the rate of conversion to the more efficient methodologies, we have elected to be very conservative in estimating savings in this final rule in order to ensure that savings do result from the implementation of this provision.

We estimate the total yearly burden for negotiating a contract between the Part D sponsor and the entity (for example, PBM) contracting with the pharmacies servicing LTC facilities to be equal to the number of the Part D sponsors (731) × the average estimated hours per sponsor (10). This equals 7,310 hours. We estimate the number of entities contracting the pharmacies servicing LTC facilities to be 40 (28 processors and 12 sponsors). We estimate the total yearly hourly burden for negotiating a contract between the entity described previously and the pharmacies servicing LTC facilities to be the number of entities (40) × the average estimated hours per entity (80). This is 3200 hours. The total number of hours for contract negotiation is estimated to be 10, 510 hours. The estimated hourly labor cost for reporting is $150.20. Hourly rates in the RIA include fringe benefits and overhead. This estimate is a compilation of the hourly rate for a lawyer and support staff from the Bureau of Labor Statistics. The total estimated cost associated with these contract negotiation requirements is $1,578,602 ($150.20 × (3,200 + 7,310 hours) = $1,578,602) and is described in Table 12. This is a one-time contract negotiation cost.

We are introducing a new requirement under § 423.154 (a)(2) for Part D sponsors to collect and report to CMS the method of dispensing technique used for each dispensing event described under § 423.154 (a) and on the nature and quantity of unused brand and generic drugs. We anticipate a billing standard that incorporates the collection of the method of dispensing technique. So, pharmacies and plans will not have to create unique data collection processes to collect that data. We estimate that 40 sponsors-contractors (28 drug claim processors and 12 sponsors that process their drug claims and data collection) will be subject to this requirement. For the collection of data on unused drugs, we estimate that it will take a total of 2,400 hours for 10 vendors (software vendors plus pharmacies with proprietary systems) to develop the programming for this requirement. The estimated total cost associated with the software development is equal to the number of software vendors plus the number of pharmacies with proprietary systems (10) times an hourly rate of $145.37 (this includes $43.35 in direct wages and an additional $102.02 in fringe benefits/overhead/general and administrative costs/fee) times 240 (estimated number of hours to design and program one system; the cost is $348,888. The total cost associated with this provision is $1,927,490 and is described in Table 12.

We anticipate that the initial upfront costs to convert to a 14-day-or-less dispensing technique will eventually be more than offset by the savings to the Federal government associated with dispensing (see Table 10 for estimates of the year-by-year savings). We expect this provision to reduce in Part D program expenses, pharmaceutical waste, environmental disposal costs impact, and the risk of pharmaceutical diversion associated with unused drugs in 30-day fills.

Comment: Several commenters believed that we failed to adequately analyze the financial impact of the 7-day-or-less dispensing requirement. Some commenters also stated that we failed to consider the increased costs associated with hiring pharmacists and pharmacy technicians that would be needed to keep up with the 7-day-or-less dispensing requirement.

Response: As discussed earlier in this final rule, we modified the proposed rule at § 423.154 to reflect 14-day-or-less dispensing as opposed to 7-day-or-less dispensing. Given that the requirement is for 14-day-or-less dispensing and is limited to brand name drugs only (which make up only 20 percent of the drugs dispensed), we do not believe there will be a significant increase in pharmacy staff. In addition, this final rule modifies our proposed rule in such a way as to reduce the burden associated with this provision. As previously discussed, we eliminated the requirement for Part D sponsors' pharmacies to collect unused Part D drugs the pharmacies had originally dispensed to enrollees, and we simplified the reporting requirements associated with this provision by allowing pharmacies to calculate the number of doses that go unused by enrollees in LTC facilities by utilizing the discontinuation dates of the prescription and the quantities dispensed to the enrollee. Also, by changing the requirement from 7-day-or-less dispensing to 14-day-or-less dispensing, we reduce the burden associated with filling the prescriptions by the pharmacies and checking-in prescriptions by the LTC facilities. The burden reduction should translate into a reduction in costs associated with this provision because, for example, fewer additional staff will be needed to implement the requirements of § 423.154. We also believe that at least some of the costs associated with implementing this requirement will be offset by the increase in dispensing fees. We have, however, modified our impact estimate to reflect the assumption that dispensing fees will double and to take into consideration that the implementation date is January 1, 2013.

Comment: Several commenters stated that we failed to take into consideration the costs associated with collecting unused drugs from the LTC facilities and the costs associated with disposal of those unused drugs.

Response: We have eliminated the requirement for Part D sponsors contracted pharmacies to collect unused Part D drugs from LTC facilities. Therefore, the pharmacies will not incur increased costs associated with the collection of unused drugs or the disposal of those drugs as a result of this final rule.

h. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504 and § 423.505)

The burden associated with this provision is the time and effort of the MA organizations and Part D sponsors in training staff and recording complaint closure documentation in the CTM, as

well as posting and maintenance of a link from their Web site to the electronic complaint form at *http://www.medicare.gov.* We estimate that the total annual hourly burden for training staff and recording complaint closure in the CTM is equal to the average estimated hours per sponsor for documentation for each complaint closure (.25) × the average number of complaints per sponsor (102) plus the average estimated hours per sponsor for training (8 hours), multiplied by the average cost of a technical health care worker ($15) × the number of Part C and D contracts (757). We also estimate that the total annual hourly burden for posting and continued maintenance of a link is 20 hours × the average cost of a Web site developer ($34) × the number of Part C and D contracts (757). We estimate the annual burden associated with all these changes equals 40,500 hours. The average cost per hour is approximately $22.10. The estimated annual cost associated with these requirements is $895,160.

i. Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128 and § 423.562)

We are modifying our proposal in our November 2010 proposed rule (75 FR 71250) to include a reference to the availability of model forms for requesting coverage determinations and appeals, as opposed to requiring use of a standardized form. We are finalizing the language related to instant access to the coverage determination and appeals process via the plan's Web site, but have clarified in the preamble that we are interpreting instant access to mean, at a minimum, the ability of Part D plan sponsors to accept e-mail requests. We expect that streamlining the appeals and exceptions process will allow beneficiaries to access appeals more quickly and will ensure beneficiaries have access to covered medications in a timely manner. MA organizations and Part D sponsors will be required to process coverage determination requests submitted by mail or via an Internet Web site (§ 423.128(b)(7)(i) and (ii)), which is estimated to result in an annual burden of 80,745 hours. At an estimated cost of $40.00 per hour, the estimated total annual cost of this requirement is $3.23 million. Also, processing coverage determination requests that are received by telephone (§ 423.128(d)) is estimated to result in an annual burden of 115,010 hours. At an estimated cost of $40.00 per hour, the estimated total annual cost of this requirement is $4.6 million.

In cases when a prescription cannot be filled as written, Part D sponsors are required under § 423.562(a)(3) to arrange with their network pharmacies to distribute a pharmacy notice advising the enrollee of his or her right to contact the plan to request a coverage determination. Under this provision, Part D sponsors are required to modify their electronic transactions to pharmacies so that they can transmit codes instructing pharmacies to distribute notices at the POS. That is, pharmacies and PBMs are required to program their systems to relay the message at the pharmacy to distribute the POS pharmacy notice that instructs the enrollee to contact the plan sponsor to request a coverage determination.

We estimate the burden on plan processors will be the programming to send the code or billing response to the pharmacy, as well as revising the terms of their contracts with pharmacies. We estimate that the number of hours for each processor (28 PBMs and 12 plan organizations) to perform these tasks will be 40 hours per processor or plan organization, for a total one-time burden of 1,600 hours. The estimated one-time cost associated with the processor or plan organization tasks is $64,000 (1600 hours × $40). Each pharmacy will need to program to receive the code and print the response. Programming by the pharmacies (40 pharmacy software vendors) in order to receive the code by each pharmacy will be 10 hours, for a total of 400 hours. The estimated one-time cost associated with the processor tasks is $16,000 (400 hours × $40).

We estimate that the 731 contracting entities would distribute an average of 2,200 pharmacy notices. Therefore, requiring plan sponsors to arrange with their network pharmacies to distribute pharmacy notices at the point-of-sale when prescriptions cannot be filled as written (§ 423.562(2)(3)) would result in an annual burden of 53,071 hours (2 minutes or 0.033 hours at point-of-sale × 731 contractors × 2,200 pharmacy notices per contract). At an estimated cost of $40.00 per hour, the estimated total annual cost of this change would be $2.12 million.

Comment: One commenter believes that our estimate of $40 an hour was too low for processing coverage determinations and redeterminations.

Response: We disagree. The estimated hourly rate of $40 is a composite rate based upon the Bureau of Labor statistics National Compensation Survey.

Comment: One commenter asked CMS if we expect the pharmacy to maintain a copy of the POS notice according to the 10 year record retention requirement. The commenter argued that this would increase the burden estimate since it would likely increase dispensing fees and present an additional hurdle for pharmacies and PBMs in response to CMS audit requests.

Response: We do not specify which specific records must be retained by Part D sponsors for audit purposes. Part D sponsors are responsible for determining which pertinent documents their network pharmacies must retain. Therefore, the burden estimate associated with the POS notice does not account for the record retention requirements provided under § 423.505.

j. Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

As provided under § 423.100 and § 423.464, Part D sponsors are required to count ADAP and IHS costs towards a beneficiary's TrOOP costs, allowing the beneficiary to move through the coverage gap portion of the benefit and into catastrophic coverage phase. There is no burden on IHS facilities since claims will be identified as IHS provider claims by the National Provider Identifier (NPI). However, ADAPs will be requested to submit information to CMS Coordination of Benefits (COB) contractor via a voluntary data sharing agreement (VDSA), which will be sent to the TrOOP facilitator to ensure proper calculation of the TrOOP amounts. Several ADAPs already participate in the COB file exchange and have submitted their VDSAs. The approximate cost associated with this submission is 30 minutes to complete the VDSA per entity. We estimate a negligible one-time annual cost to 50 ADAPs that require VDSAs.

The burden associated with this provision is not expected to impact sponsor organization costs, with the exception of up-front programming costs, which we estimate will be 1 hour per sponsor for an approximate cost of $40 per sponsor. Including these costs toward TrOOP impacts how fast a beneficiary will reach the catastrophic limit, triggering Federal reinsurance payments. Sponsors will not incur additional costs due to this requirement. The Federal cost impact is estimated at $460 million from FY 2011 to FY 2016. The additional cost to the Federal government (Medicare program) is due to more individuals reaching the catastrophic coverage phase under the Part D benefit. Overall, we expect this provision to reduce the costs to ADAPs and IHS.

k. Cost Sharing for Medicare Covered Preventive Services (§ 417.454 and § 422.100)

We estimate that our implementation of sections 4103, 4104, and 4105 of the ACA will result in additional program costs as beneficiaries will pay no portion of the costs for the Personalized Prevention Plan Services, the Initial Preventive Physical Exam and Medicare-covered preventive services for which cost sharing is waived under Original Medicare (§ 417.454 and § 422.100). We estimate that the FY 2012 costs to Medicare for increasing access to clinical preventive services in accord with sections 4103, 4104, and 4105 of ACA will be $410 million.

Although slightly less than 30 percent of Medicare expenditures for Parts A and B are for MA enrollees, we estimate that the cost to the MA program of increasing access to clinical preventive services as described by sections 4103, 4104, and 4105 of the ACA will be significantly less than 30 percent of the estimated cost to the Medicare program for implementation of these provisions. In contrast to the Original Medicare program, most MA plans already provide some in-network preventive services without charging beneficiary cost sharing. In contract year 2010, at least 78 percent of plans provide many, or all, of the Medicare-covered preventive services without charging beneficiary cost sharing. In fact, almost all MA plans currently provide a few of the Medicare-covered preventive benefits without cost sharing. Therefore, we estimate that our requirement for MA plans to provide the Medicare-covered preventive services without beneficiary cost sharing will not increase plan costs by a significant amount.

Based on our finding that 78 percent of plans provide some preventive benefits without cost sharing in contract year 2010, we estimate that for FY 2012 plans will incur approximately $27.1 million in costs by providing in-network Medicare preventive services without charging beneficiary cost sharing as provided under § 417.454 and § 422.100. Over time, we estimate that the relative cost to the MA program for provision of improved access to Medicare-covered preventive services will be consistent with the estimated cost for Medicare, which increases with growth in the Medicare population. We estimate the total cost of this provision to be $147.9 million between FYs 2011 and 2016.

Further, although not included in our estimates, we believe that the increased emphasis on provision of preventive services may also result in improved beneficiary well-being and subsequently decrease their need for, and utilization of, more costly medical and surgical interventions and may decrease overall program costs.

l. Elimination of the Stabilization Fund (§ 422.458)

Section 10327(c) of the ACA repealed section 1858(e) of the ACA, eliminating the stabilization fund. Therefore, we are deleting paragraph (f) from § 422.458, since the statutory basis for the Fund no longer exists. The elimination of the stabilization fund will have the effect of savings for the Federal government, but will also result in a loss of financial incentives for regional plans to operate in regions with no or low MA penetration.

We expect the Federal government to save approximately $181.2 million for the fiscal years 2011 through 2016 from the implementation of this provision. The savings are a result of the elimination of the national bonus payment and recruitment and retention bonus payments to MA plans that would operate in regions with no or low MA penetration.

The fund will no longer offer a financial incentive for regional organizations to offer plans in regions with low or no MA penetration. The funds have never been accessible, however, because, since the fund's inception, payments have been delayed through legislation. Therefore, the formal elimination of the fund will have little or no impact on the current operation of the MA program.

m. Improvements to Medication Therapy Management Programs (§ 423.153)

Our proposed rule estimated first year costs associated with the requirement for Part D sponsors to contract with all LTC facilities in which their Part D enrollees reside to provide appropriate MTM services in coordination with independent consultant pharmacist evaluation and monitoring was $96,709,680 ($402,957 estimated cost per parent organization or sponsor × 240 parent organizations or stand alone sponsors with Part D LTC residents = $96,709,680 estimated cost). Annual costs for updating the contracts for subsequent years were estimated to be $32,236,560 ($134,319 estimated cost per parent organization or sponsor × 240 parent organizations or sponsors with Part D LTC residents = $32,236,560 estimated cost). After considering comments on our proposal, we are not finalizing the proposed requirement that Part D sponsors contract with LTC facilities for appropriate MTM services in coordination with LTC consultant pharmacist evaluation and monitoring, and, therefore, are not finalizing our original cost estimate associated with this proposal.

Comment: Two commenters requested that we include in our costs estimate include all costs related to the provision of MTM services in LTC settings and not merely those costs associated with Part D sponsor contracting.

Response: We are not finalizing the proposed requirement for Part D sponsors to coordinate MTM with LTC consultant pharmacist evaluation and monitoring, and are, therefore, not finalizing our original impact estimate. We plan to work with the industry to develop an alternate proposal and a more inclusive estimate of the associated costs.

n. Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

With the implementation of provisions related to closing of the Part D coverage gap, Medicare beneficiaries will have improved access to the prescription drugs in the coverage gap. They will likely enter the catastrophic phase of the benefit earlier in the benefit year as a result of our changes to close the Part D coverage gap, because they will be more likely to obtain necessary drugs in the coverage gap, thereby bringing them to the catastrophic phase sooner. Beneficiary cost sharing in the coverage gap would be determined on the basis of whether the covered Part D drug is considered an applicable drug under the Medicare coverage gap discount program. Different cost sharing levels will apply during the coverage gap to the drugs that are applicable and not applicable under the coverage gap discount program. In addition to the cost sharing changes, the rate of growth of the annual Part D out-of-pocket threshold would be reduced from FY 2014 to FY 2016. Further, in attesting to the actuarial equivalence of qualified retiree prescription drug plans to the standard Medicare Part D coverage, sponsors would not take into account the value of any discount or coverage provided during the coverage gap.

For changes associated with closing the Part D coverage gap, we estimate a one-time total cost of $50,400,000 (12,000 burden hours for each processor × 40 processors × $105 for the average labor cost of a senior programmer based on data from the Bureau of Labor Statistics) in the first year for the 40 pharmacy claims processors to implement systems changes. In subsequent years, the estimated total annual cost is $1,050,000 (250 burden hours per processor × 40 processors ×

$105 for the full cost of labor of a senior programmer) to identify changes to the applicable drugs under the Medicare coverage gap discount program and update systems with this information each month. The total estimated costs to the Medicare program for the adjustments to beneficiary cost sharing in the coverage gap are $130,400,000 in the first year (FY 2011), increasing in subsequent years as the coverage gap closes and the Part D enrollment increases. The estimated annual cost to the Medicare program associated with decreasing the rate of annual growth in the Part D out-of-pocket threshold is $40,000,000 in FY 2014, increasing in subsequent years as the Medicare Part D enrollment increases and the coverage gap closes.

o. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment (§ 422.252, § 422.258, § 422.266, and § 422.308)

Prior to enactment of the ACA, MA payment benchmarks (county rates) were established only partially in relationship to average fee-for-service costs in a county. Section 1102 of reconciliation amendments links all county benchmarks to FFS costs, effective 2012. As a transition, the ACA sets the 2011 MA benchmarks equal to the benchmarks for 2010; for subsequent years it specifies that, ultimately, the benchmarks will be equal to a percentage (95, 100, 107.5, or 115 percent) of the fee-for-service rate in each county. During a transition period, the benchmarks will be based on a blend of the pre-ACA and post-ACA benchmarks. The phase-in schedule for the new benchmarks will occur over 2 to 6 years, with the longer transitions for counties with the larger benchmark decreases under the new method.

The ACA, as amended, also introduces MA bonuses and rebate levels that are tied to the plans' quality ratings. Beginning in 2012, benchmarks will be increased for plans that receive a 4-star or higher rating on a 5-star quality rating system. The bonuses will be 1.5 percent in 2012, 3.0 percent in 2013, and 5.0 percent in 2014 and later; these bonuses increase the new benchmark portion of the blended benchmark until all transitions are complete. An additional county bonus, which is equal to the plan bonus, will be provided on behalf of beneficiaries residing in specified counties. The percentage of the "benchmark minus bid" savings provided as a rebate, which historically has been 75 percent, will also be tied to a plan's quality rating. In 2014, when the provision is fully phased in, the rebate share will be 50 percent for plans with a quality rating of less than 3.5 stars; 65 percent for a quality rating of 3.5 to 4.49; and 70 percent for a quality rating of 4.5 or greater. This provision will provide incentives for plan quality to increase. Plans will be paid based on quality performance rather than just the specific services they provide. However, the rules for determining quality bonus payments for CY 2012 through 2014 will be modified under the terms of the national quality bonus payment demonstration project.

The ACA amended the statutory provision that requires us to make an adjustment to MA risk scores for differences in coding patterns between MA and FFS. The ACA made four modifications to this requirement: The analysis must be conducted annually; the data used in the analysis is to be updated as appropriate; the results of the analysis are to be incorporated into risk scores on a timely basis; and the application of an adjustment for differences in coding patterns was extended past 2010 indefinitely. Further, the ACA provides for minimum adjustments for MA coding in future years.

Our changes to § 422.252, § 422.258, and § 422.266 codify section 1102 of the ACA, which links county benchmarks to FFS costs and provides eligible plans with a quality bonus. These provisions will lower payments from us, bringing MA payments in line with FFS payments. The new provisions will also generally reduce MA rebates and benchmarks for plans and thereby result in less generous benefit packages. We estimate that the Federal government will save approximately $40.56 billion from FY 2011 to FY 2014. The Federal government will save approximately $76.470 billion from the FY 2011 to FY 2016. The year-by-year savings in millions of dollars are shown in Table 10.

p. Quality Bonus Appeals (§ 422.260)

We estimate a minimal overall impact as a result of this provision, as we expect only a minority of MA organizations to take advantage of the opportunity to appeal CMS' annual quality rating. Of those organizations that do appeal their rating, a minimal number of professional staff working over a short period of time would be required to prepare and present an organization's appeal.

We estimate that the total annual hourly burden for developing and presenting a case to us for review is equal to the number of organizations likely to request an appeal multiplied by the number of hours for the attorneys of each appealing MA organization to research, draft, and submit their arguments to CMS. Based on the star rating distributions of previous contract years, out of the approximately 350 MA contracts that are subject to star rating analysis (that is, those not excluded from analysis because of low enrollment, contract type not required to report data, or new contract with no performance history), approximately 250 may receive less than a four-star rating. We estimate that 10 percent of those contracts (25) will request an appeal of their rating under the final rule. We further estimate that one attorney working for eight hours could complete the documentation to be submitted to us for each contract, resulting in a total burden estimate of 200 hours (8 hours × 25 contracts = 200 hours). The estimated annual cost to MA organizations associated with this provision (assuming an attorney billing rate of $250 per hour) is $50,000 (200 hours × $250 = $50,000). Our intent in finalizing this provision is to ensure that MA organizations are afforded the benefit of reasonable opportunity to challenge CMS determinations that ultimately affect an organization's payments from the Medicare Trust Fund. Granting organizations an avenue to challenge CMS' determinations will enhance the transparency and credibility of the process CMS uses to determine the recipients of quality bonus payments.

q. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

We anticipate minimal financial impact from our requirement that terminated Part D plan sponsors help to effectuate a smooth transition for their enrollees by providing CMS with Medicare beneficiary data including information to identify each affected beneficiary, pharmacy claims files, true out-of-pocket (TrOOP) cost balances, and information concerning pending grievances and appeals.

We estimate that the total annual burden for this provision to be the cost of maintaining sufficient staff to transfer the data required under § 423.509. As a result, we estimate the total annual burden to be the number of Part D sponsors we anticipate terminating in a contract year (2) × the hourly rate of staff to transfer the required data ($75/hour) × the number of hours required to provide data to us (20 hours). Therefore, the estimated annual cost associated with these requirements is $3,000. We do not anticipate that this provision will

result in a financial benefit to the terminated Part D sponsor.

r. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

We are modifying the language in the proposed rule with respect to the requirement for a physician or other health care professional to review initial determinations involving medical necessity. Under this final rule, if the plan expects to issue a partially or fully adverse decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request for medical necessity before the plan issues its decision.

We are finalizing our modifications to § 422.562, § 422.566, § 423.562, and § 423.566 to require MA organizations and Part D plan sponsors to employ a medical director. We estimate that 95 percent of MA organizations and Part D sponsors already have a medical director overseeing decisions of medical necessity. Therefore, we believe that there will be no increase in cost for the majority of MA organizations and Part D sponsors. We anticipate that 5 percent of MA organizations and Part D sponsors will incur a financial impact as a result of this provision.

Of the 5 percent of MA organizations and Part D sponsors that do not currently employ a medical director, we estimate that the total annual burden for employing a medical director is equal to 5 percent of the number of MA organization and Part D sponsors (757), which equals 38 organizations and sponsors, at a salary of $250,000 per year. Therefore, the estimated annual cost associated with these requirements is $9,500,000.

We believe this approach balances the need to ensure proper medical review of initial coverage determinations with the ability of MA organizations and Part D plan sponsors to manage health care professional staff resources. We believe these provisions will enhance medical review activities and overall coordination and accountability of plan operations.

s. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Sections 422.2274(b) and (c) and 423.2274(b) and (c) require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS endorsed or approved training program. We are considering implementing this requirement through a Request for Proposal (RFP) competitive process. The burden associated with this requirement is the time and effort put forth by plan sponsors and/or third party vendors to develop and submit their proposals for CMS review. We estimate that about 12 entities (plan sponsors and/or third party vendors) will submit a proposal annually and that the average estimated hours per entity to complete the proposal is 100 hours. The total estimated hourly burden associated with this requirement is equal to the estimated number of entities (12) multiplied by the estimated hours per entity (100) = 1,200 hours. We estimate the hourly labor cost for the preparer of the proposal will be $59.20 (based on the U.S. Department of Labor statistics for hourly wages for management analysts). The annual cost of proposal preparation is estimated to be $71,040 ($59.20 × 1200 hours).

t. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

We estimate the cost for our call center requirements at the parent organization level because most parent organizations have one call center for all of their contracts. For the parent organizations that currently and consistently provide interpreters, their costs will not increase. Organizations that provide interpreters, but not consistently, will need to train their CSRs on how to use the interpreter service, which can be included in regularly scheduled training meetings at no increased cost. Lastly, we expect the cost for each of the two parent organizations that currently do not provide interpreters to increase by $9,933 per year. This estimated cost is based on 1–800–MEDICARE foreign language interpreter use, which is 4.5 percent of all calls. If 4.5 percent of calls could require an interpreter over the course of a standard 12-hour call center day, this would translate into using interpreter services for 33 minutes each day. Over the course of a year for the 301 days a call center is required to be open, and at a rate of $1.00 per minute, based on CMS market research in for interpreter costs, the cost for each of the two parent organizations would increase by $9,933 per year, which is $19,866 for both in FY 2012.

u. Customized Enrollee Data (§ 422.111 and § 423.128)

In proposed rule (75 FR 71261 through 71262), proposed § 422.111(b)(11) and § 423.128(b)(12) would require MA organizations and PDP sponsors to periodically provide each enrollee with enrollee-specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. Plans would disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the annual notice of change and evidence of coverage documents).

We estimated that the initial year burden associated with this requirement would be the time and effort necessary for a plan sponsor to complete program development and testing, and to disclose (print and mail) this information to each beneficiary. We developed this burden estimate using our experience with burden estimates for the ANOC/EOC documents under OMB control number (OCN) 0928–1051as a baseline, then expanding on that baseline, and factoring in expected programming and development costs to provide beneficiary specific information. We estimated the total annual burden hours associated with this provision at 18,620 hours for the 564 MA organizations and 85 Part D sponsors that would be affected annually by this requirement. Using the same wage/cost estimate as the ANOC/EOC documents, we applied an hourly wage cost for GS–10, step 1 analyst at an estimated cost of $27.24 per hour. Therefore, the estimated total initial year cost of this requirement is approximately $507,208.00.

In subsequent years, we estimated that the burden associated with this requirement would be the time and effort necessary for a plan sponsor to disclose (print and mail) this information to each beneficiary. We estimated the total annual burden hours associated with this provision at 12,555 hours for the 564 MA organizations and 85 Part D sponsors that would be affected annually by this requirement. At an estimated cost of $27.24 per hour, the estimated total initial year cost of this requirement would be approximately $342,000.

After considering comments on our proposed policy, we have modified both the final policy and our cost estimate, as described below.

Comment: Many commenters stated that a customized estimate of future costs would create significant administrative, financial, IT resource, and call center burdens on MA plans and Part D sponsors, much more than CMS has anticipated. They stated that the expense and operational burden of

the proposal cannot be justified economically or in value to beneficiaries, considering the potential for beneficiary confusion and dissatisfaction that may result from relying on estimated future costs. One commenter suggested that the significant costs of producing and distributing a custom statement will increase administrative costs that in turn may increase plan bids and result in a negative impact on benefits and or premiums. As discussed in section II.D.4 of this final rule, we received many comments on our proposal to authorize CMS to require MA organizations and Part D drug sponsors to periodically provide each enrollee with enrollee specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year.

Response: Based on the comments received, and our modified final policy, we have also recalculated our estimate of the burden based on the annual burden to Part D plan sponsors to furnish enrollees with an EOB for prescription drug benefits under OMB—0938–0964. MA organizations already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In 2012, the burden associated with this proposed requirement would be the time and effort necessary for 564 MA organizations to complete program development and testing of an explanation of benefits when Part C benefits are provided, and to disclose (print and mail) this information to each beneficiary. Given that stand alone PDPs already produce an EOB in accordance with § 423.128(e), the revised burden estimate includes only MA organizations. We estimate that in the first year it will require each entity 200 hours on an annual basis to disseminate the required materials, for a total annual burden of 112,800 hours. This first year estimate builds from the estimated annual burden for the Part D EOB, expanding the total hour requirement to include additional hours required to initiate and complete program development and testing of an EOB. The estimated first year cost is $3,938,976. This estimate is based upon the hourly rate at the GS–11/step 6 ($34.92) multiplied by the number of burden hours (112,800).

In subsequent years, the burden associated with this requirement will be the time and effort necessary for about 564 MA organizations to provide an explanation of benefits when Part C benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis to disseminate the required materials, for a total annual burden of 90,240 hours. The decreased estimate of burden hours relative to the first year reflects the completion of program development in the first year and brings the estimated hours in line with the current estimated number of hours for the Part D EOB. The estimated annual cost is $3,151,181. This estimate is based upon the hourly rate at the GS–11/step 6 ($34.92) multiplied by the number of burden hours (90,240).

The anticipated effect of our modified provision to require MA organizations to provide an explanation of Part C benefits would be greater access to individualized information for beneficiaries to track their own utilization of services and to use in making decisions about their enrollment and their health care options. While this new EOB requirement will result in less of a cost burden for MA plans than the burden of calculating out-of-pocket costs including an estimate of costs in the next plan year, we continue to believe that plans should already have the systems in place to collect the required out-of-pocket cost information as part of their claims processing operations and for calculating MOOP limits. Therefore, over time, we anticipate that plans would continue to refine and work to make their processes for disclosing this information as well as the annual notice of change, evidence of coverage, and other plan documents more efficient, thereby mitigating the burden in future years.

v. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

Sections 422.100(f) and 422.101(d) extend the mandatory MOOP and catastrophic limit requirements to RPPO plans. Each RPPO plan must establish an annual MOOP limit on total enrollee cost sharing liability for Parts A and B services, the dollar amount of which would be set annually by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts A and B services will be included in RPPO plans' MOOPs. While this change is significant in that it will help beneficiaries to understand and anticipate their possible health care expenditures, as with the requirement to establish a mandatory MOOP for local MA plans, we do not believe that this change would by itself have a significant cost impact on RPPO plan participation or plan costs.

We estimate that any impact on enrollee premiums will be very limited for several reasons. First, since implementation of the MMA, RPPOs have been required to establish a MOOP for in-network cost sharing and a catastrophic limit; however those amounts are currently at the discretion of MA organizations offering RPPO plans. For FY 2011, we encouraged RPPO plans to adopt either the mandatory or voluntary MOOPs established in CMS guidance. For FY 2011, the voluntary MOOP limits for local PPO plans were set at $3,400 in-network and $5,100 catastrophic (in- and out-of-network), and the mandatory MOOP limits for local PPO plans were set for FY 2011 at $6,700 in-network and $10,000 catastrophic (in- and out-of-network). Based on data for FY 2011 approved bids, we found that only 3 regional PPO plans (4 percent of all RPPOs) did not meet or exceed our voluntary or mandatory in-network or catastrophic maximum out-of-pocket limits. Based on this information, it is our expectation that the impact on RPPO plans will be very small.

Second, it is our intention to continue setting both the MOOP and Parts A and B cost-sharing thresholds at levels that, while affording reasonable financial protection for those beneficiaries with high health care needs, do not result in significant new operating costs for MA plans or increased out-of-pocket costs for beneficiaries to the extent that MA plans pass along any increased costs to their enrollees in the form of premium increases. Given a competitive marketplace and Medicare beneficiary sensitivity to premium amounts, we believe that MA plans may choose instead to modify their benefit packages to reduce costs elsewhere. Furthermore, we estimated that beneficiaries in regional PPO plans that currently offer the FY 2011 voluntary or mandatory MOOP limits (about 92 percent of RPPO plans) would experience no cost increases as a result of these provisions. In our April 2010 final rule, we estimated that the maximum impact of these requirements on beneficiary premiums for those plans that currently have no MOOP limit of any kind (8 percent of all prospective FY 2011 RPPO plans) would average $5 in the absence of other adjustments to benefit packages to account for the annual MOOP requirements. However, in this case, the RPPO plans already offer MOOP and catastrophic limits, so we estimated that any premium impact would be less than $5.

By setting the parameters for the annual mandatory MOOP limit, we believe that we will make it easier for plans to compete on a level playing field.

w. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Our final rule slightly modifies existing subregulatory guidance, so the impact to plan sponsors (MA organizations and PDP sponsors) depends upon whether, and to what extent, they are currently translating marketing materials. In the preamble, we indicate that moving to a 5 percent translation standard (from 10 percent) and focusing on the primary language spoken by individuals in the service area who have limited ability to read, write, speak, or understand English will result in a slight burden reduction. For 2011, 321 contract sponsors are required to translate marketing materials at the 10 percent translation standard. Under the 5 percent primary language translation standard, we used 2011 data to determine that sponsors would be required to translate marketing materials for only 305 contracts, which is 16 contracts fewer than under the 10 percent standard. In 2010, sponsors were required to provide translated marketing materials for 307 contracts. Because the number of contracts (307) from 2010 is extremely close to the revised number of contracts (305) that we estimate for 2011, we are not changing our impact estimate from the 2010 estimate. We acknowledge that the original estimates would have been higher if we had used 2011 data when originally compiling these estimates. At the beginning of 2010, we conducted a translated marketing material monitoring study in which preliminary findings revealed that some sponsors had produced a few materials. However, we do not yet know the specific number of sponsors that are providing all translated materials. Our research indicates that the average translation cost is 20 cents per word, and that will cost approximately $18,325 for a sponsor to produce all of the required plan materials in one language for the first year because there are approximately 17 documents containing 91,623 words for translation. In subsequent years, sponsors will only need to edit existing documents with the new data and any changes required by CMS, which could result in approximately 5 percent of the documents being changed. As a result, after the first year of translating all required documents, plan sponsors will need to spend $916 updating translated materials. Because we do not have final data from our translated materials study, we do not know what proportion of sponsors would have to develop a complete set of translated materials for the first year and what proportion would only need to update existing documents. Because not all required translated marketing materials are plan benefit package (PBP) specific, if a plan sponsor translates the document for one PBP, it could use the document for all PBPs offered that year. For the purpose of this analysis, we assume that the sponsors of all 307 contracts would have to translate all materials for the first year at a total cost of $5,625,775. In subsequent years, sponsors will only need to edit existing translated documents, which we estimate will cost a total of $281,212 annually for all sponsors. As mentioned in the preamble, CMS hopes to further reduce burden in the future by providing pretranslated model materials. However, as we do not have funding committed for this effort at this time, we have not changed the burden estimates to reflect this goal.

Comment: One industry commenter identified that this impact analysis did not include the cost of an employee's time involved with coordinating the translated materials effort.

Response: We did not include employee time because, as stated in the Collection of Information Requirements section of this final rule, the requirement to provide translated materials is not a new responsibility for Medicare Part C and D plans. We do not have complete data on which plan sponsors are providing translated materials, and which ones are not. The number of employees that would be involved with coordinating this effort is also unknown. Therefore, to err on the side of caution, we presumed all sponsors would have to develop first year translations. Thus, we believe the overall cost is an over estimate that would more than compensate for not including employee coordination time. We are therefore finalizing our proposed impact estimate without modification.

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Table 10: Estimated Costs and Savings by Provision for Fiscal Years 2011 Through 2016
($ in millions)2

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Approval of SNPs by NCQA	§422.4 §422.101 and §422.152	1.75	1.24	1.24	1.24	1.24	1.24	7.95
Determination of Part D Low-Income Benchmark Premium	§423.780	90.00	120.00	130.00	140.00	140.00	150.00	770.00
Voluntary De Minimis Policy for Subsidy Eligible Individuals	§423.34 and §423.780	25.00	25.00	25.00	25.00	35.00	35.00	170.00
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)3	§423.44	-269.68	-269.68	-649.64	-899.61	-1139.60	-1349.59	-4,767.78
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.03	0.02	0.02	0.02	0.02	0.02	0.14
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	§423.154	1.93	0.00	-10.00	-20.00	-30.00	-40.00	-98.07
Complaint System for Medicare Advantage Organizations and PDPs	§422.504 and §423.505	0.00	0.90	0.90	0.90	0.90	0.90	4.48
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	§423.128(b)(7)(i)	0.00	3.23	3.23	3.23	3.23	3.23	16.15
	§ 423.128(d)	0.00	4.60	4.60	4.60	4.60	4.60	23.05
	§423.562(a)(3)	0.00	2.20	2.12	2.12	2.12	2.12	10.68
Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) toward the Annual Part D Out-of-Pocket Threshold	§423.100 and §423.464	50.00	70.00	70.00	80.00	90.00	100.00	460.00
Cost Sharing for Medicare Covered Preventive Services	§417.454 and §422.100	0.00	27.10	27.10	28.40	31.00	34.30	147.90
Elimination of the Stabilization Fund	§422.458	0.00	0.00	0.00	-43.50	-63.40	-74.30	-181.20
Changes to Close the Part D Coverage Gap	§423.104 and §423.884	130.40	171.05	381.05	601.05	931.05	1,451.05	3,665.65
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment	§422.252 §422.258 §422.266 and §422.308	-5,260.00	-8,570.00	-11,890.00	-14,840.00	-16,860.00	-19,050.00	-76,470.00
Quality Bonus Appeals	§422.260	0.00	0.05	0.05	0.05	0.05	0.05	0.25
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	§423.509	0.00	0.004	0.005	0.006	0.007	0.00	0.02

2 Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2009 wage data from the United States Department of Labor, Bureau of Labor and Statistics.
3 Estimated total savings includes annual cost burden to all Part D sponsors (see section V.B.5. of this final rule).
4 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	§422.562, §422.566, §423.562 and §423.566	0.00	9.50	9.50	9.50	9.50	9.50	47.50
Agent and Broker Training Requirements	§422.2274 and §423.2274	0.00	0.07	0.07	0.07	0.07	0.07	0.36
Call Center Interpreter Requirements	§422.111 and §423.128	0.02	0.00	0.00	0.00	0.00	0.00	0.02
Customized Enrollee Data)	§422.111 and §423.128	0.00	3.94	3.15	3.15	3.15	3.15	16.54
Translated Marketing Materials	§422.2264 and §423.2264	5.63	0.28	0.28	0.28	0.28	0.28	7.03
Total		-5,224.92	-8,590.48	-11,891.33	-14,903.50	-16,840.79	-18,718.38	-76,169.39

5 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
6 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.
7 Costs appear as zero due to rounding. CMS estimates actual costs of 0.003 million.

Table 11: Estimated Costs and Savings to the Federal Government by Provision for Fiscal Years 2011 through 2016 ($ in millions)[8]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Approval of SNPs by NCQA	§422.4 §422.101 and §422.152	1.40	0.89	0.89	0.89	0.89	0.89	5.85
Determination of Part D Low-Income Benchmark Premium	§423.780	90.00	120.00	130.00	140.00	140.00	150.00	770.00
Voluntary De Minimis Policy for Subsidy Eligible Individuals	§423.34 and §423.780	20.00	20.00	20.00	20.00	30.00	30.00	140.00
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	§423.44	-270.00	-459.98	-649.96	-899.93	-1,139.92	-1,349.91	-4,769.70
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	§423.154	0.00	0.00	-10.00	-20.00	-30.00	-40.00	-100.00
Complaint System for Medicare Advantage Organizations and PDPs	§422.504 and §423.505	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	§423.128(b)(7)(i)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	§ 423.128(d)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	§423.562(a)(3)	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) toward the Annual Part D Out-of-Pocket Threshold	§423.100 and §423.464	50.00	70.00	70.00	80.00	90.00	100.00	460.00
Cost Sharing for Medicare Covered Preventive Services	§417.454 and §422.100	0.00	27.10	27.10	28.40	31.00	34.30	147.90
Elimination of the Stabilization Fund	§422.458	0.00	0.00	0.00	-43.50	-63.40	-74.30	-181.20
Changes to Close the Part D Coverage Gap	§423.104 and §423.884	80.00	170.00	380.00	600.00	930.00	1,450.00	3,610.00
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment	§422.252 §422.258 §422.266 and §422.308	-5,260.00	-8,570.00	-11,890.00	-14,840.00	-16,860.00	-19,050.00	-76,470.00
Quality Bonus Appeals	§422.260	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	§423.509	0.00	0.00	0.00	0.00	0.00	0.00	0.00

8 Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2009 wage data from the United States Department of Labor, Bureau of Labor and Statistics.

Provision(s)	Regulation Section(s)	Fiscal Year						Total ($ in millions) (FYs 2011-2016)
		2011	2012	2013	2014	2015	2016	
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	§422.562, §422.566, §423.562 and §423.566	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Agent and Broker Training Requirements	§422.2274 and §423.2274	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Call Center Interpreter Requirements	§422.111 and §423.128	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Customized Enrollee Data)	§422.111 and §423.128	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Translated Marketing Materials	§422.2264 and §423.2264	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total		-5,288.60	-8,621.99	-11,921.97	-14,394.14	-16,871.43	-18,749.02	-76,387.15

Table 12: Estimated Costs to MA Organizations and Part D Sponsors by Provision for Fiscal Years 2011 Through 2016 ($ in millions)[9]

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Approval of SNPs by NCQA	§422.4 §422.101 and §422.152	0.35	0.35	0.35	0.35	0.35	0.35	2.10
Determination of Part D Low-Income Benchmark Premium	§423.780	0.0010	0.0011	0.0012	0.0013	0.0014	0.0015	0.0016
Voluntary De Minimis Policy for Subsidy Eligible Individuals	§423.34 and §423.780	5.00	5.00	5.00	5.00	5.00	5.00	30.00
Increase In Part D Premiums Due to the Income Related Monthly Adjustment Amount (D-IRMAA)	§423.44	0.32	0.32	0.32	0.32	0.32	0.32	1.92
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Appropriate Dispensing of Prescription Drugs in Long-term Care Facilities Under PDPs and MA-PD Plans	§423.154	1.93	0.00	0.00	0.00	0.00	0.00	1.93
Complaint System for Medicare Advantage Organizations and PDPs	§422.504 and §423.505	0.00	0.90	0.90	0.90	0.90	0.90	4.48
Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans	§423.128(b)(7)(i)	0.00	3.23	3,23	3.23	3.23	3.23	16.15
	§ 423.128(d)	0.00	4.60	4.60	4.60	4.60	4.60	23.00
	§423.562(a)(3)	0.00	2.20	2.12	2.12	2.12	2.12	10.68
Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) toward the Annual Part D Out-of-Pocket Threshold	§423.100 and §423.464	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Cost Sharing for Medicare Covered Preventive Services	§417.454 and §422.100	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Elimination of the Stabilization Fund	§422.458	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Changes to Close the Part D Coverage Gap	§423.104 and §423.884	50.40	1.05	1.05	1.05	1.05	1.05	55.65

9 Estimates of costs and savings reflect scoring by the Centers for Medicare and Medicaid Services, Office of the Actuary, and 2009 wage data from the United States Department of Labor, Bureau of Labor and Statistics.

10 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

11 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

12 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

13 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

14 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

15 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0006 million.

16 Costs appear as zero due to rounding. CMS estimates actual costs of 0.0036 million.

Provision(s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment	§422.252 §422.258 §422.266 and §422.308	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Quality Bonus Appeals	§422.260	0.00	0.05	0.05	0.05	0.05	0.05	0.25
Timely Transfer of Data and Files When CMS Terminates a Contract with a Part D Sponsor	§423.509	0.00	0.00	0.00	0.00	0.00	0.00	0.02
Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director	§422.562, §422.566, §423.562 and §423.566	0.00	9.50	9.50	9.50	9.50	9.50	47.50
Agent and Broker Training Requirements	§422.2274 and §423.2274	0.00	0.07	0.07	0.07	0.07	0.07	0.36
Call Center Interpreter Requirements	§422.111 and §423.128	0.02	0.00	0.00	0.00	0.00	0.00	0.02
Customized Enrollee Data	§422.111 and §423.128	0.00	3.94	3.15	3.15	3.15	3.15	16.54
Translated Marketing Materials	§422.2264 and §423.2264	5.63	0.28	0.28	0.28	0.28	0.28	7.03
Total		63.65	31.49	30.62	30.62	30.62	30.62	217.62

Table 13: Estimated Costs and Savings to States by Provision for Fiscal Years 2011 Through 2016 ($ in millions)

Provision (s)	Regulation Section(s)	Fiscal Year 2011	2012	2013	2014	2015	2016	Total ($ in millions) (FYs 2011-2016)
Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services	§423.772 and §423.782	0.03	0.02	0.02	0.02	0.02	0.02	0.14

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2. Expected Effects on Beneficiaries

a. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and 422.100)

We believe that the requirement that MA plan cost sharing may not exceed that required under Original Medicare for chemotherapy services, renal dialysis services, and skilled nursing facility care will provide additional transparency and cost sharing and predictability for beneficiaries as they evaluate their health plan options, and also will strengthen our beneficiary protections against discriminatory cost sharing and benefit designs.

b. Approval of SNPs by NCQA (§ 422.4, § 422.101, and § 422.152)

We believe that our requirement that all SNPs be approved by NCQA based on evaluation of each plan's model of care (MOC) will result in SNP options that are appropriate for special needs beneficiaries and address their targeted populations' particular health care needs. SNP MOCs provide the structure for care management processes and systems that enable SNPs to provide coordinated care for special needs individuals. By ensuring that these documents provide an adequate framework for coordinated care for the vulnerable beneficiaries eligible to enroll in SNPs through the NCQA SNP approval process, we believe the quality of care under SNPs will be positively impacted.

c. Determination of Part D Low-Income Benchmark Premium (§ 423.780)

This final rule supports pharmacy and formulary consistency for the beneficiary. Particularly in regions with high MA–PD penetration, this final rule will reduce the year-to-year volatility in reassignments of LIS beneficiaries and would help avoid the disruption that is inherent anytime a beneficiary is switched from one plan to another.

d. Voluntary De Minimis Policy for Subsidy Eligible Individuals (§ 423.34 and § 423.780)

The voluntary de minimis provisions permit Part D plans to volunteer to waive a de minimis amount of the Part D premium above the low income benchmark and, thus, avoid losing LIS beneficiaries to reassignment. We perform reassignments to ensure that beneficiaries whom we originally assigned to a zero premium plan will not incur a new premium liability when their current plan's premium goes above the LIS benchmark in the following year. The number of reassignments has ranged between 1 and 2 million over each of the past 4 years. While reassignments are effective at avoiding new premium liabilities, they can create confusion and disrupt continuity of care. We expect that the de minimis provisions will reduce reassignments.

e. Increase in Part D Premiums Due to the Income Related Monthly Adjustment Amount (D–IRMAA) (§ 423.44, § 423.286, § 423.293)

Beginning in CY 2011, we estimate that approximately 1.05 million of the 29.2 million Medicare beneficiaries enrolled in the Part D program will exceed the minimum income threshold amount and will be assessed an income related monthly adjustment amount. During calendar year 2011, we expect that implementation of the Part D—IRMAA provisions, at § 423.286(d)(4) and § 423.293(d), will increase the Medicare Trust Fund by $270 million, with a net increase to the Medicare Trust Fund over a 5-year period from FY 2011 through FY 2016 of $4.77 billion. The Part D—IRMAA 2011 income levels and premium adjustment amounts are as follows:

	Beneficiaries who file individual tax returns with income that is:	**Beneficiaries who file joint tax returns with income that is:**	**Part D-Income Related Monthly Adjustment Amount will be:**
Income Threshold Tier 1	Less than or equal to $85,000	Less than or equal to $170,000	$0.00
Income Threshold Tier 2	Greater than $85,000 and less than or equal to $107,000	Greater than $170,000 and less than or equal to $214,000	$12.00
Income Threshold Tier 3	Greater than $107,000 and less than or equal to $160,000	Greater than $214,000 and less than or equal to $320,000	$31.10
Income Threshold Tier 4	Greater than $160,000 and less than or equal to $214,000	Greater than $320,000 and less than or equal to $428,000	$50.10
Income Threshold Tier 5	Greater than $214,000	Greater than $428,000	$69.10

	Beneficiaries who are married but file separate tax returns from their spouses with income that is:	**Part D-Income Related Monthly Adjustment Amount will be:**
Income Threshold Tier 1	Less than or equal to $85,000	$0.00
Income Threshold Tier 2	Greater than $85,000 and less than or equal to $129,000	$50.10
Income Threshold Tier 3	Greater than $129,000	$69.10

Approximately 3.6 percent of Medicare beneficiaries will be impacted. We estimate that the number of beneficiaries impacted per tier will be as follows:

Income Threshold	Estimated number of beneficiaries impacted
Tier 1	0
Tier 2	397,249
Tier 3	340,147
Tier 4	123,002
Tier 5	192,945

f. Elimination of Medicare Part D Cost-Sharing for Individuals Receiving Home and Community-Based Services (§ 423.772 and § 423.782)

The expected benefit of the elimination of the Medicare Part D cost-sharing for individuals receiving home and community based services provision is greater access to prescription drug coverage for a population that traditionally has high medical needs. These individuals are already eligible for the full low income subsidy, and likely qualify for the $1.10/$3.30 copayment level now. The elimination of the copayment will provide financial relief for those who are able to pay at that level and greater access for those who are not.

g. Appropriate Dispensing of Prescription Drugs in Long-Term Care Facilities under PDPs and MA–PD Plans (§ 423.154) and Dispensing Fees (§ 423.100)

We expect that Part D enrollees who use a 14-day supply (or less) of Part D drugs described in the requirements under section 423.154 (a) will benefit from the savings resulting from a reduction in cost sharing that would be associated with a full 30-day supply whenever a Part D drug is discontinued within the first 2 weeks from the start date of the drug. We would expect that many drugs discontinued due to adverse drug reactions or side effects will be discontinued within the first 2 weeks. In addition, Part D enrollees residing in LTC facilities that elect to use more efficient dispensing systems, such as automated dose dispensing, may also benefit from additional interactions with nursing staff a result of decreased medication preparation time associated with automated dose dispensing. Over time, we expect a decrease in drug expenditures in the Part D program will be reflected by a reduction in Part D premiums.

h. Complaint System for Medicare Advantage Organizations and PDPs (§ 422.504(a) and § 423.505(b))

We expect this provision to reduce the volume of calls using 1–800–MEDICARE as members will have online access to the complaint tracking system to file complaints regarding their MA or prescription drug benefit plan. We also expect the provision will benefit Medicare beneficiaries by offering another means for them to file their complaints. Electronic complaint filing should also save time for those beneficiaries who choose to use this method.

i. Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA–PD Plans (§ 423.128, and § 423.562)

We expect that as a result of implementation of this provision, beneficiaries and the health care providers or representatives that assist them will benefit from a more streamlined approach to the exceptions and appeals process than what is in place currently. They will have access to the appeals process via a Web site or a customer call center, if their plan sponsor has not already adopted this approach.

j. Including Costs Incurred by the AIDS Drug Assistance Program (ADAP) and the Indian Health Services (IHS) Toward the Annual Part D Out-of-Pocket Threshold (§ 423.100 and § 423.464)

Prior to implementation of this provision, beneficiaries in both programs had difficulty reaching the catastrophic phase of the Part D benefit. This provision will not only enable beneficiaries to reach the catastrophic limit where they will experience significant reductions to their drug costs, but will relieve the ADAPs and IHS from incurring excessive prescription costs.

k. Cost Sharing for Medicare Covered Preventive Service (§ 417.454 and § 422.100)

We believe that our requirement for MA organizations and section 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing puts MA enrollees on a level playing field with enrollees in Original Medicare. Furthermore, we believe that the increased emphasis on provision of preventives services will result in improved beneficiary well-being and subsequently decrease their need for, and utilization of, more costly medical and surgical interventions, and possibly in decreased overall program costs.

l. Elimination of the Stabilization Fund (§ 422.458)

As previously stated, the formal elimination of the fund will have little or no impact on the current operation of the MA program. Thus, we do not believe this provision will have any impact on beneficiaries.

m. Improvements to Medication Therapy Management Programs (§ 423.153)

We expect that beneficiaries will benefit from this provision. Standardized formats for the action plan and summary resulting from annual Comprehensive Medication Reviews (CMR) will enable beneficiaries to have a better understanding of the CMR review findings and recommendations. Also, the opportunity for sponsors to use telehealth technology will improve access to MTM services for beneficiaries, particularly those in remote locations or unable to travel.

n. Changes To Close the Part D Coverage Gap (§ 423.104 and § 423.884)

Under these provisions to close the Part D coverage gap, beneficiaries would pay less for drugs in the coverage gap, and would reach the out-of-pocket threshold earlier in the benefit year. We expect that, because beneficiaries should find their prescription drugs

more affordable, there would be greater adherence to drug therapies and fewer instances of adverse health outcomes arising from failure to take medications as prescribed.

o. Medicare Advantage Benchmark, Quality Bonus Payments, and Rebate and Application of Coding Adjustment (§ 422.252, § 422.258 and § 422.266, and § 422.308)

We have not determined an impact on beneficiaries as a result of this provision.

p. Quality Bonus Appeals (§ 422.260)

While we expect the QBP system will encourage and incentivize MA plans to transform their delivery systems and processes to provide beneficiaries with high-quality and efficient care, we do not anticipate the QBP appeals process will have any effect on beneficiaries.

q. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

Our intent in implementing this provision is to ensure that terminated Part D plan sponsors transfer to CMS the necessary data to provide a smooth transition for beneficiaries into a new Part D plan similar to when the Part D sponsor terminates the contract or CMS and the Part D plan sponsor mutually terminate the contract. We anticipate that this provision will benefit beneficiaries by ensuring that TrOOP and gross covered drug cost data are transferred from the terminated plan to the beneficiaries' new plan, enabling the members to be correctly positioned in the new plan's benefit.

r. Review of Medical Necessity Decisions by a Physician or other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

We are modifying the language in the proposed rule with respect to the requirement for a physician or other health care professional to review initial determinations involving medical necessity. Under this final rule, if the plan expects to issue a partially or fully adverse decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request for medical necessity before the plan issues its decision. This requirement will favorably impact beneficiaries by ensuring their requests for coverage receive medical review by an individual with appropriate clinical expertise, without imposing any burden on beneficiaries because the requirements for requesting an organization or coverage determination are not modified by this requirement.

s. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Requiring all agents and brokers to receive training and testing via a CMS endorsed or approved training program will further ensure that beneficiaries are educated about Medicare health plan options by plan agents and brokers who are thoroughly and consistently trained on the fundamentals of Medicare regulations. We believe that such thorough and consistent training will help ensure that beneficiaries receive accurate information about their Medicare health care options and make the best choices about their health care coverage options for their particular health care needs.

t. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

The expected benefit of our call center interpreter requirements is that all beneficiaries, regardless of language spoken, will have access to all the information they need to make appropriate decisions about their health care to utilize their Medicare benefits most effectively.

u. Customized Enrollee Data (§ 422.111 and § 423.128)

We believe that our requirement that MA organizations send enrollees an explanation of benefits will ensure that the beneficiaries periodically receive information about their Part C utilization and out-of-pocket costs to help them make the best choices about their health care coverage options for their particular health care needs.

v. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

We believe extending the mandatory MOOP requirement to RPPOs will provide significant protection for MA enrollees from out-of-pocket costs so that beneficiaries will better understand and anticipate their out-of-pocket expenditures. This requirement increases transparency for beneficiaries, and will ensure all RPPO plan enrollees are protected against high out-of-pocket costs and are better able to compare plans by focusing on differences in premium and plan quality.

w. Translated Marketing Materials (§ 422.2264 and § 423.2264)

The expected benefit of our requirement to codify existing subregulatory guidance with respect to translated marketing materials is to help limited-English proficient beneficiaries obtain access to the information they need to make appropriate decisions about their health care to utilize their Medicare benefits most effectively.

Comment: One commenter indicated that the impact analysis in the proposed rule improperly indicated that we would be helping *all* beneficiaries have access to translated materials.

Response: We agree with the commenter, and have revised the impact discussion in this final rule to remove language insinuating that *all* beneficiaries speaking *all* languages will have access to translated materials.

E. Alternatives Considered

The alternatives that were considered are summarized as follows.

1. Cost Sharing for Specified Services at Original Medicare Levels (§ 417.454 and § 422.100)

We considered using the authority granted to the Secretary by section 3202 to limit MA cost sharing for service categories in addition to those specified in the ACA. However, we decided that it is preferable to restrict our implementation of section 3202 of the ACA to the specified service categories, allowing ourselves time to evaluate the effects of those provisions, as well as other recently-established policies before using the new authority to adopt those cost sharing limits for an expanded list of service categories.

Although we proposed to use our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to limit the cost sharing for home health services to Original Medicare levels we have decided not to finalize our proposal, as discussed elsewhere in this final rule.

2. Cost Sharing for Medicare-Covered Preventive Services (§ 417.454 and § 422.100)

We are proposing to implement regulations to require MA organizations and 1876 cost plans to provide in-network Medicare-covered preventive benefits at zero cost sharing, consistent with the new regulations for Original Medicare-covered preventive benefits. More specifically, we are requiring that all MA organizations provide Medicare-covered preventive services, as specified by CMS, without enrollee cost sharing charges.

We considered allowing plans to charge cost sharing for Medicare-

covered preventive services or to voluntarily adopt zero cost sharing for the specified preventive services. We determined that in light of the importance of preventive services in managed and coordinated care, and the requirements at section 1852(a)(1)(A) of the Act (except as provided in section 1859(b)(3) of the Act for MSA plans and in section 1852(a)(6) of the Act for MA regional plans) that each MA plan must provide to its members all Parts A and B benefits included under the Original Medicare fee-for-service program as defined at section 1852(a)(1)(B) of the Act, that requiring the same level of cost sharing for the specified preventive services for enrollees of Medicare health plans as required under Original Medicare would be the more appropriate policy.

3. Quality Bonus Appeals (§ 422.260)

We considered not affording bonus payment appeal rights to MA organizations. We rejected this option partly in recognition of the obligation the law generally imposes on us to afford entities affected by CMS determinations concerning contract performance or payment to have an opportunity to challenge such determinations. We also believe, as noted previously, that the appeals process promotes fairness in and enhances the credibility of the bonus payment determination process.

4. Timely Transfer of Data and Files When CMS Terminates a Contract With a Part D Sponsor (§ 423.509)

We did not consider alternatives to our provision regarding the timely transfer of data and files following the CMS termination of a Part D sponsor's contract. These data are necessary for the proper adjudication of all Part D benefits when a beneficiary changes plans, such as calculating the true out-of-pocket cost and determining whether the beneficiary has any outstanding claims for which the terminating contract is responsible. Because of these important beneficiary protections, we did not consider alternatives to these requirements.

5. Review of Medical Necessity Decisions by a Physician or Other Health Care Professional and the Employment of a Medical Director (§ 422.562, § 422.566, § 423.562, and § 423.566)

We did not consider alternatives regarding review of medical necessity decisions by a physician or other health care professional and employment of a medical director, as a majority of MA organizations and Part D sponsors already employ a medical director to oversee decisions of medical necessity. As noted previously, we are modifying our proposed rule language on the requirement for a physician or other health care professional to review initial determinations involving medical necessity. Under this final rule, if the plan expects to issue a partially or fully adverse decision based on the initial review of the request, a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, must review the request for medical necessity before the plan issues its decision.

6. Agent and Broker Training Requirements (§ 422.2274 and § 423.2274)

Sections 422.2274(b) and (c) and 423.2274(b) and (c) require MA organizations' and Part D sponsors' agents and brokers to receive training and testing via a CMS-endorsed or -approved training program. The alternative we considered was to continue to allow plans to conduct training and testing on their own or through third party vendor(s) and for CMS to continue to review some of these training programs upon request by third party vendors for comprehensiveness and accuracy. However, we believe that it is in the best interest of beneficiaries who are educated about Medicare health plan options by plan agents and brokers that those agents and brokers be consistently and thoroughly trained on the fundamentals of Medicare regulations. We believe the best method to achieve this end is to require agents and brokers to receive training and testing through one or more CMS-endorsed or -approved training programs.

7. Call Center Interpreter Requirements (§ 422.111 and § 423.128)

Compliance with Title VI of the Civil Rights Act of 1964 to serve all individuals regardless of national origin is a contractual requirement for MA and Part D sponsors; therefore, we did not consider any other alternatives to our call center interpreter requirements.

8. Customized Enrollee Data (§ 422.111 and § 423.128)

In our November 2010 proposed rule (75 FR 71249 through 71250), we considered an alternative to require MA organizations and PDP sponsors to provide each enrollee with specific data to use to compare utilization and out-of-pocket costs in the current plan year to projected utilization and out-of-pocket costs for the following plan year. We further considered requiring plans to disclose this information to plan enrollees in each year in which a minimum enrollment period has been met, in conjunction with the annual renewal materials (currently the annual notice of change/evidence of coverage, or ANOC/EOC). However, we are not finalizing this policy alternative in our final rule. Instead, as discussed in section II.D.4 of this final rule, we intend to work with MA organizations, Part D sponsors and beneficiary advocates to develop an explanation of benefits for Part C benefits modeled after the EOB currently required for Part D enrollees at § 423.128(e).

9. Extending the Mandatory Maximum Out-of-Pocket (MOOP) Amount Requirements to Regional PPOs (§ 422.100 and § 422.101)

The alternative we considered was not extending the mandatory MOOP and catastrophic limit requirements to RPPO plans, but instead to permit plans to continue to establish their own in-network MOOP and catastrophic limits without a maximum limit set by CMS while encouraging them to adopt either the mandatory or voluntary MOOPs established in CMS guidance. However, as we discussed in our April 2010 final rule, (75 FR 19711), we believe RPPOs should be subject to the same requirements with respect to a MOOP as local PPO plans. As discussed elsewhere in this preamble, we believe that the alternative chosen will make it easier for beneficiaries to understand and compare MA plans and will provide significant protection for MA enrollees from out of pocket costs.

10. Translated Marketing Materials (§ 422.2264 and § 423.2264)

Compliance with Title VI of the Civil Rights Act of 1964 to serve all individuals regardless of national origin is a contractual requirement for MA and Part D sponsors. Therefore, we did not consider any other alternatives to our translated marketing materials requirements.

Comment: One commenter was concerned that we did not consider any alternatives to codifying the existing population-based translation threshold stated in our subregulatory guidance (that is, the 10 percent translation standard).

Response: In response to numerous comments regarding the translation standard itself, we conducted several analyses using 2011 plan service area data and the most recent American Community Survey datasets. We analyzed the effect of keeping our standard at 10 percent, the effect of

moving to a 10 percent standard focusing on primary language, the effect of moving to 5 percent standard focusing on primary language, the effect of moving to a simple 5 percent standard, and the effect of using a 5 percent or 500 person standard. After reviewing the results from these sensitivity analyses, we determined that a 5 percent threshold that focuses on primary language spoken would be the most appropriate approach for beneficiaries and plans. We are therefore maintaining this 5 percent threshold in the final rule.

11. Increases to the Applicable Percentage for Quality (§ 422.258(d))

The ACA requires a 5-star rating system. We considered whether the 5-star rating system should be consistent with the current 5-star rating system in place for beneficiary choice or should be a separate system. We believe that plans should be rated the same for consumer choice and payment. There should not be two different systems to rate the quality and performance of MA plans. Thus, the plan ratings are the basis for the star rating system for quality bonus payments.

F. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 14, we have prepared an accounting statement showing the classification of the costs, benefits, and transfers associated with the provisions of this final rule. The accounting statement is based on estimates provided in Tables H10 through 13, (our best estimate of the costs, savings, and transfers as a result of the changes) and discounted at the 7 percent and 3 percent for the time period of FY 2011 through FY 2016.

TABLE 14--Accounting Statement: Classification of Estimated Costs, Savings, and Transfers from FY 2011 to FY 2016 ($ in Millions)

Category	TRANSFERS			
	Year Dollar	Units Discount Rate		Period Covered
		7%	3%	
Annualized Monetized Transfers	2011	-$12,193.50	-$12,496.54	FYs 2011-2016
From Whom To Whom?	Federal Government to MA organizations and Part D Sponsors			
	COSTS			
	Year Dollar	Units Discount Rate		Period Covered
Annualized Costs to MA organizations and Part D Sponsors		7%	3%	
	2011	$37.19	$36.63	FYs 2011-2016
Annualized Costs to States	2011	$0.02	$0.02	FYs 2011-2016

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services announces the effective date of June 6, 2011 for amendments to 42 CFR 422.564, 422.624, and 422.626 published April 4, 2003 at 68 FR 16652 and further amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C., 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart J—Qualifying Conditions for Medicare Contracts

■ 2. Section 417.402 is amended by revising paragraph (c) introductory text to read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in § 417.492(b) and § 417.494(a) for any period beginning on or after January 1, 2013, where—

* * * * *

Subpart K—Enrollment, Entitlement, and Disenrollment Under Medicare Contract

■ 3. Section 417.430 is amended as follows:

■ A. Revising the paragraph heading for paragraph (a).

■ B. Revising paragraphs (a)(1), (b)(3), and (b)(4).

§ 417.430 Application procedures.

(a) *Application forms and other enrollment mechanisms.* (1) The application form must comply with CMS instructions regarding content and format and be approved by CMS. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between the HHS and its designees and the HMO or CMP.

* * * * *

(b) * * *

(3) The HMO or CMP gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) The notice of acceptance. If the HMO or CMP is currently enrolled to capacity, explains the procedures that will be followed when vacancies occur.

* * * * *

4. Section 417.454 is amended by adding paragraphs (d) and (e) to read as follows.

§ 417.454 Charges to Medicare enrollees.

* * * * *

(d) *Limit on charges for specified preventive services.* An HMO may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

(e) *Services for which cost sharing may not exceed cost sharing under original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which HMOs' cost sharing may not exceed that required under original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 5. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

■ 6. Section 422.2 is amended by adding the definitions of "fiscally sound operation," "fully integrated dual eligible special needs plan," and "senior housing facility plan" in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

* * * * *

Fully integrated dual eligible special needs plan means a CMS approved MA–PD dual eligible special needs plan that—

(1) Enrolls special needs individuals entitled to medical assistance under a Medicaid State plan, as defined in section 1859(b)(6)(B)(ii) of the Act and § 422.2;

(2) Provides dual eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization;

(3) Has a capitated contract with a State Medicaid agency that includes coverage of specified primary, acute, and long-term care benefits and services, consistent with State policy;

(4) Coordinates the delivery of covered Medicare and Medicaid health and long-term care services using aligned care management and specialty care network methods for high-risk beneficiaries; and

(5) Employs policies and procedures approved by CMS and the State to coordinate or integrate member materials, enrollment, communications, grievance and appeals, and quality improvement.

* * * * *

Senior housing facility plan means an MA coordinated care plan that—

(1) Restricts enrollment to individuals who reside in a continuing care retirement community as defined in § 422.133(b)(2);

(2) Provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that CMS determines is adequate consistent with prevailing patterns of community health care referenced at § 422.112(a)(10);

(3) Provides transportation services for beneficiaries to specialty providers outside of the facility; and

(4) Was participating as of December 31, 2009 in a demonstration established by CMS for not less than 1 year.

* * * * *

■ 7. Section 422.4 is amended as follows:

■ A. Revising paragraphs (a)(1)(iii) and (iv).

■ B. Adding paragraph (a)(1)(vi).

The revisions and additions read as follows:

§ 422.4 Types of MA plans.

* * * * *

(a) * * *

(1) * * *

(iii) Coordinated care plans include plans offered by any of the following:

(A) Health maintenance organizations (HMOs);

(B) Provider-sponsored organizations (PSOs), subject to paragraph (a)(1)(vi) of this section.

(C) Regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section.

(D) Other network plans (except PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS's SNP requirements and exclusively enrolls special needs individuals as defined by § 422.2 of this subpart. All MA plans wishing to offer a SNP will be required to be approved by the National Commission on Quality Assurance (NCQA) effective January 1, 2012. This approval process applies to existing SNPs as well as new SNPs joining the program. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance.

* * * * *

(vi) In accordance with § 422.370, CMS does not waive the State licensure requirement for organizations seeking to offer a PSO.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

■ 8. Add § 422.53 to read as follows:

§ 422.53 Eligibility to elect an MA plan for senior housing facility residents.

(a) *Basic eligibility requirements.* To be eligible to elect an MA senior housing facility plan, the individual must meet both of the following:

(1) Be a resident of an MA senior housing facility defined in § 422.2.

(2) Be eligible to elect an MA plan under § 422.50.

(b) *Restricting enrollment.* An MA senior housing facility plan must restrict enrollment to only those individuals who reside in a continuing care retirement community as defined at § 422.133(b)(2).

(c) *Establishing eligibility for enrollment.* An MA senior housing facility plan must verify the eligibility of each individual enrolling in its plan using a CMS approved process.

■ 9. Section 422.62 is amended as follows:

■ A. Revising paragraphs (a)(2)(i), (a)(2)(iii), and (a)(5).

■ B. Adding paragraphs (a)(2)(iv) and (a)(7).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(2) * * **

(i) For 2002 through 2010, except for 2006, the annual coordinated election

period for the following calendar year is November 15 through December 31.

* * * * *

(iii) Beginning in 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

(iv) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to Original Medicare or to a different MA plan, or from Original Medicare to an MA plan. If an individual changes his or her election to Original Medicare, he or she may also elect a PDP.

* * * * *

(5) *Open enrollment and disenrollment from 2007 through 2010.* (i) Open enrollment period. For 2007 through 2010, except as provided in paragraphs (a)(5)(ii), (iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible in 2007 through 2010 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the third month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(iii) *Single election limitation.* The limitation to one election or change in paragraphs (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section, or during a special election period specified in paragraph (b) of this section.

* * * * *

(7) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* For 2011 and subsequent years, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d).

* * * * *

■ 10. Section 422.68 is amended by adding paragraph (f) to read as follows:

§ 422.68 Effective dates of coverage and change from coverage.

* * * * *

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Beginning in 2011, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(7), is effective the first day of the first month following the month in which the election is made.

■ 11. Section 422.74 is amended by adding paragraphs (d)(1)(v) and (vi) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(1) * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS may reinstate enrollment in the MA plan, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vi) *No extension of grace period.* A beneficiary's enrollment in the MA plan may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 12. Section 422.100 is amended by adding paragraphs (j) and (k) to read as follows.

§ 422.100 General requirements.

* * * * *

(j) *Services for which cost sharing may not exceed cost sharing under Original Medicare.* On an annual basis, CMS will evaluate whether there are service categories for which MA plans' in-network cost sharing may not exceed that required under Original Medicare and specify in regulation which services are subject to that cost sharing limit. The following services are subject to this limit on cost sharing:

(1) Chemotherapy administration services to include chemotherapy drugs and radiation therapy integral to the treatment regimen.

(2) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(3) Skilled nursing care defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under Original Medicare.

(k) *Cost sharing for in-network preventive services.* MA organizations may not charge deductibles, copayments, or coinsurance for in-network Medicare-covered preventive services (as defined in § 410.152(l)).

■ 13. Section 422.101 is amended as follows:

A. Revising paragraphs (d)(2) and (3).

B. Adding paragraph (f)(2)(vi).

The revisions and addition read as follows.

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* MA regional plans are required to establish a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the Original Medicare fee-for-service program (Part A and Part B benefits) that is no greater than the annual limit set by CMS.

(3) *Total catastrophic limit.* MA regional plans are required to establish a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the Original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under Original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section and may be no greater than the annual limit set by CMS.

* * * * *

(f) * * *

(2) * * *

(vi) All MAOs wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

■ 14. Section 422.106 is amended as follows:

■ A. Revising paragraph (d)(1).

■ B. Adding paragraphs (d)(4) through (d)(6).

The revision and additions read as follows.

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

* * * * *

(d) * * *

(1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an employer-sponsored group MA plan (including an MA–PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this part that hinder the design of, the offering of, or the enrollment in, such MA plan.

* * * * *

(4) An employer-sponsored group MA plan means MA coverage offered to retirees who are Medicare eligible individuals under employment-based retiree health coverage, as defined in paragraph (d)(5) of this section, approved by CMS as an MA plan.

(5) Employment-based retiree coverage means coverage of health care costs under a group health plan, as defined in paragraph (d)(6) of this section, based on an individual's status as a retired participant in the plan, or as the spouse or dependent of a retired participant. The term includes coverage provided by voluntary insurance coverage, or coverage as a result of a statutory or contractual obligation.

(6) Group health plans include plans as defined in section 607(1) of ERISA, (29 U.S.C. 1167(1)). They also include the following plans:

(i) A Federal or State governmental plan, which is a plan providing medical care that is established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision of a State (including a county or local government), or by any agency or instrumentality or any of the foregoing, including a health benefits plan offered under 5 U.S.C. 89 (the Federal Employee Health Benefit Plan (FEHBP)).

(ii) A collectively bargained plan, which is a plan providing medical care that is established or maintained under or by one or more collective bargaining agreements.

(iii) A church plan, which is a plan providing medical care that is established and maintained for its employees or their beneficiaries by a church or by a convention or association of churches that is exempt from tax under section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501).

(iv) Any of the following plans:

(A) An account-based medical plan such as a Health Reimbursement Arrangement (HRA) as defined in Internal Revenue Service Notice 2002–45, 2002–28 I.R.B. 93.

(B) A health Flexible Spending Arrangement (FSA) as defined in Internal Revenue Code (Code) section 106(c)(2).

(C) A health savings account (HSA) as defined in Code section 223.

(D) An Archer MSA as defined in Code section 220, to the extent they are subject to ERISA as employee welfare benefit plans providing medical care (or would be subject to ERISA but for the exclusion in ERISA section 4(b), 29 U.S.C.1003(b), for governmental plans or church plans).

■ 15. Section 422.107 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 422.107 Special needs plans and dual-eligibles: Contract with State Medicaid Agency.

* * * * *

(d) * * *

(1) * * *

(ii) Existing dual-eligible SNPs that do not have a State Medicaid agency contract—

(A) May continue to operate through the 2012 contract year provided they meet all other statutory and regulatory requirements.

(B) May not expand their service areas during contract years 2010 through 2012.

* * * * *

■ 16. Amend § 422.111 as follows:

■ A. Adding paragraph (b)(12).

■ B. Removing paragraph (f)(12).

■ C. Adding paragraph (h).

The additions read as follows.

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(12) *Claims information.* CMS may require an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

* * * * *

(h) *Provision of specific information.* Each MA organization must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include all of the following:

(1) A toll-free customer service call center that meets all of the following:

(i) Is open during usual business hours.

(ii) Provides customer telephone service in accordance with standard business practices.

(iii) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(2) An Internet Web site that includes, at a minimum the following:

(i) The information required in paragraph (b) of this section.

(ii) Copies of its evidence of coverage, summary of benefits, and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.

(3) The provision of information in writing, upon request.

■ 17. Section 422.112 is amended by revising paragraph (a)(10) introductory text to read as follows:

§ 422.112 Access to services.

(a) * * *

(10) *Prevailing patterns of community health care delivery.* MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:

* * * * *

■ 18. Amend § 422.113 by revising paragraph (b)(2)(v) to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(b) * * *

(2) * * *

(v) With a limit on charges to enrollees for emergency department services that CMS will determine annually, or what it would charge the enrollee if he or she obtained the

services through the MA organization, whichever is less.

* * * * *

Subpart D—Quality Improvement

■ 19. Amend § 422.152 by revising paragraph (g) introductory text to read as follows:

§ 422.152 Quality improvement program.

* * * * *

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval, in accordance with CMS guidance. A SNP must conduct a quality improvement program that—

* * * * *

■ 20. Amend § 422.156 by revising paragraph (b)(1) to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(1) *Quality improvement.* The deeming process should focus on evaluating and assessing the overall quality improvement (QI) program. However, the quality improvement projects (QIPs) and the chronic care improvement programs (CCIPs) will be excluded from the deeming process.

* * * * *

Subpart E—Relationships With Providers

■ 21. Amend § 422.214 by adding paragraphs (c) and (d) to read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

* * * * *

(c) *Deemed request for Medicare payment rate.* A noncontract section 1861(u) of the Act provider of services that furnishes services to MA enrollees and submits the same information that it would submit for payment under Original Medicare is deemed to be seeking to be paid the amount it would be paid under Original Medicare unless the provider expressly notifies the MA organization in writing that it is billing an amount less than such amount.

(d) *Regional PPO payments in non-network areas.* An MA Regional PPO must pay non-contract providers the Original Medicare payment rate in those portions of its service area where it is providing access to services by non-network means under § 422.111(b)(3)(ii) of this part.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

■ 22. Section 422.252 is amended as follows:

■ A. Adding the definitions "low enrollment contract" and "new MA plan."

■ B. Revising the definition of "unadjusted MA area-specific non-drug monthly benchmark amount."

The additions and revision read as follows:

§ 422.252 Terminology.

* * * * *

Low enrollment contract means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

* * * * *

New MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years.

* * * * *

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually that reflects the nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c) of this part, (that is, a standardized benchmark). For local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county. The rules for determining county capitation rates are specific to a time period, as set forth at § 422.258(a). Effective 2012, the MA area-specific non-drug monthly benchmark amount is called the blended benchmark amount, and is determined according to the rules set forth under § 422.258(d) of this part.

* * * * *

■ 23. Section 422.254 is amended by adding paragraph (a)(5) to read as follows:

§ 422.254 Submission of bids.

(a) * * *

(5) CMS may decline to accept any or every otherwise qualified bid submitted by an MA organization or potential MA organization.

* * * * *

■ 24. Section 422.256 is amended by revising paragraph (a) introductory text to read as follows:

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits and may decline to approve a bid if the plan sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

* * * * *

■ 25. Section 422.258 is amended as follows:

■ A. Revising paragraphs (a)(1) and (2).

■ B. In paragraph (c)(3)(i), removing the phrase "county capitation rate" and adding the phrase "amount determined under paragraph (a) of this section for the year" in its place.

■ C. Adding paragraph (d).

The revisions and additions read as follows:

§ 422.258 Calculation of benchmarks.

(a) * * *

(1) For MA local plans with service areas entirely within a single MA local area:

(i) For years before 2007, one-twelfth of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(ii) For years 2007 through 2010, one-twelfth of the applicable amount determined under section 1853(k)(1) of the Act for the area for the year, adjusted as appropriate for the purpose of risk adjustment.

(iii) For 2011, one-twelfth of the applicable amount determined under 1853(k)(1) for the area for 2010.

(iv) Beginning with 2012, one-twelfth of the blended benchmark amount described in paragraph (d) of this section, subject to paragraph (d)(8) of this section and adjusted as appropriate for the purpose of risk adjustment.

(2) For MA local plans with service areas including more than one MA local area, an amount equal to the weighted average of amounts described in paragraph (a)(1) of this section for the year for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted

as appropriate for the purpose of risk adjustment.

* * * * *

(d) *Determination of the blended benchmark amount*—(1) *General rules.* For the purpose of paragraphs (a) and (b) of this section, the term blended benchmark amount for an area for a year means the sum of two components: the applicable amount determined under section 1853(k)(1) of the Act and the specified amount determined under section 1853(n)(2) of Act. The weights for each component are based on the phase-in period assigned each area, as described in paragraphs (d)(8) and (d)(9) of this section. At the conclusion of an area's phase-in period, the blended benchmark for an area for a year equals the section 1853(n)(2) of the Act specified amount described in paragraph (d)(2) of this section. The blended benchmark amount for an area for a year (which takes into account paragraph (d)(8) of this section), cannot exceed the applicable amount described in paragraph (d)(2) of this section that would be in effect but for the application of this paragraph.

(2) *Applicable amount.* For the purpose of paragraphs (a) and (b) of this section, the applicable amount determined under section 1853(k)(1) of the Act for a year is—

(i) In a rebasing year (described at § 422.306(b)(2), an amount equal to the greater of the average FFS expenditure amount at § 422.306(b)(2) for an area for a year and the minimum percentage increase rate at § 422.306(a) for an area for a year.

(ii) In a year when the amounts at § 422.306(b)(2) are not rebased, the minimum percentage increase rate at § 422.306(a) for the area for the year.

(iii) In no case the blended benchmark amount for an area for a year, determined taking into account paragraph (d)(8) of this section, be greater than the applicable amount at paragraph (d)(2) of this section for an area for a year.

(iv) Paragraph (d) of this section does not apply to the PACE program under section 1894 of Act.

(3) *Specified amount.* For the purpose of paragraphs (a) and (b) of this section, the specified amount under section 1853(n)(2) of the Act is the product of the base payment amount for an area for a year (adjusted as required under § 422.306(c)) multiplied by the applicable percentage described in paragraph (d)(5) of this section for an area for a year.

(4) *Base payment amount.* The base payment amount is as follows:

(i) For 2012, the average FFS expenditure amount specified in § 422.306(b)(2), determined for 2012.

(ii) For subsequent years, the average FFS expenditure amount specified in § 422.306(b)(2).

(5) *Applicable percentage.* Subject to paragraph (d)(7) of this section, the applicable percentage is one of four values assigned to an area based on Secretary's determination of the quartile ranking of the area's average FFS expenditure amount (described at § 422.306(b)(2) and adjusted as required at § 422.306(c)), relative to this amount for all areas.

(i) For the 50 States or the District of Columbia, a county with an average FFS expenditure amount adjusted under § 422.306(c) that falls in the—

(A) Highest quartile of such rates for all areas for the previous year receives an applicable percentage of 95 percent;

(B) Second highest quartile of such rates for all areas for the previous year receives an applicable percentage of 100 percent;

(C) Third highest quartile of such rates for all areas for the previous year receives an applicable percentage of 107.5 percent; or

(D) Lowest quartile of such rates for all areas for the previous year receives an applicable percentage of 115 percent.

(ii) To determine the applicable percentages for a territory, the Secretary ranks such areas for a year based on the level of the area's § 422.306(b)(2) amount adjusted under § 422.306(c), relative to the quartile rankings computed under paragraph (d)(5)(i) of this section.

(6) *Additional rules for determining the applicable percentage.* (i) In a contract year when the average FFS expenditure amounts from the previous year were rebased (according to the periodic rebasing requirement at § 422.306(b)(2)), the Secretary must determine an area's applicable percentage based on a quartile ranking of the previous year's rebased FFS amounts adjusted under § 422.306(c).

(ii) If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year's ranking, the applicable percentage for the area in the year must be the average of the applicable percentage for the previous year and the applicable percentage that would otherwise apply for the area for the year in the absence of this transitional provision.

(7) *Increases to the applicable percentage for quality.* Beginning with 2012, the blended benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to a 5-star rating system (based on the data collected under section 1852(e) of the Act). Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.

(i) *Qualifying plan.* Beginning with 2012, a qualifying plan means a plan that had a quality rating of 4 stars or higher based on the most recent data available for such year. For a qualifying plan, the applicable percentage at paragraph (d)(5) of this section must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 3.0 percentage points.

(C) For 2014 and subsequent years, by 5.0 percentage points.

(ii) *Qualifying county.* (A) A *qualifying county* means a county that meets the following three criteria:

(*1*) Has an MA capitation rate that, in 2004, was based on the amount specified in section 1853(c)(1)(B) of the Act for a Metropolitan Statistical Area with a population of more than 250,000.

(*2*) Of the MA-eligible individuals residing in the county, at least 25 percent of such individuals were enrolled in MA plans as of December 2009.

(*3*) Has per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the Original Medicare fee-for-service program for the year.

(B) Beginning with 2012, for a qualifying plan serving a qualifying county, the increase to the applicable percentage described at paragraph (d)(7)(i) of this section must be doubled for the qualifying county.

(iii) MA organizations that fail to report data as required by the Secretary must be counted as having a rating of fewer than 3.5 stars at the plan or contract level, as determined by the Secretary.

(iv) *Application of applicable percentage increases to low enrollment contracts.* (A) For 2012, for an MA plan that the Secretary determines is unable to have a quality rating because of low enrollment, the Secretary treats this plan as a qualifying plan under paragraph (d)(7)(i) of this section.

(B) For 2013 and subsequent years, the Secretary develops a methodology to apply to MA plans with low enrollment

(as defined by the Secretary) to determine whether a low enrollment contract is a qualifying plan.

(v) *Application of increases in applicable percentage to new MA plans.* A new MA plan (as defined at § 422.252) that meets criteria specified by the Secretary must be treated as a qualifying plan under paragraph (d)(7)(i) of this section, except that the applicable percentage must be increased as follows:

(A) For 2012, by 1.5 percentage points.

(B) For 2013, by 2.5 percentage points.

(C) For 2014 and subsequent years, by 3.5 percentage points.

(8) *Determination of phase-in period for the blended benchmark amount.* For 2012 through 2016, the blended benchmark amount for an area for a year depends on the phase-in period assigned to that area. The Secretary assigns one of three phase-in periods to each area: 2-year, 4 year, or 6 year. The phase-in period assigned to an area is based on the size of the difference between the 2010 applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount defined at paragraph (d)(8)(i) of this section.

(i) The projected 2010 benchmark amount is calculated once for the purpose of determining the phase-in period for an area. It is equal to one-half of the 2010 applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) modified to apply to 2010 (as described in (d)(8)(ii) of this section).

(ii) To assign a phase-in period to an area, the specified amount is modified as if it applies to 2010, and is the product of—

(A) The 2010 base payment amount adjusted as required under § 422.306(c) of this part; and

(B) The applicable percentage determined as if the reference to the "previous year" at paragraph (d)(5) of this section were deemed a reference to 2010 and increased as follows:

(*1*) The increase at paragraph (d)(7)(i) of this section for a qualifying plan in the area is applied as if the reference to a qualifying plan for 2012 were deemed a reference for 2010; and

(*2*) The increase at paragraph (d)(7)(ii) of this section is applied as if the determination of a qualifying county were made for 2010.

(iii) *Two-year phase-in.* An area is assigned the 2-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is less than $30.

(iv) *Four-year phase-in.* An area is assigned the 4-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $30 but less than $50.

(v) *Six-year phase-in.* An area is assigned the 6-year phase-in period if the difference between the applicable amount at paragraph (d)(2) of this section and the projected 2010 benchmark amount at paragraph (d)(8)(i) of this section is at least $50.

(9) *Impact of phase-in period on calculation of the blended benchmark amount.* (i) *Weighting for the 2-year phase-in.* (A) For 2012, the blended benchmark is the sum of one-half of the applicable amount at paragraph (d)(2) of this section and one-half of the specified amount at paragraph (d)(3) of this section.

(B) For 2013 and subsequent years, the blended benchmark equals the specified amount.

(ii) *Weighting for the 4-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) of this section and the specified amount at paragraph (d)(2) of this section in the following proportions:

(A) For 2012, three-fourths of the applicable amount for the area for the year and one-fourth of the specified amount for the area and year.

(B) For 2013, one-half of the applicable amount for the area for the year and one-half of the specified amount for the area and year.

(C) For 2014, one-fourth of the applicable amount for the area for the year and three-fourths of the specified amount for the area and year.

(D) For 2015 and subsequent years, the blended benchmark equals the specified amount for the area and year.

(iii) *Weighting for the 6-year phase-in.* The blended benchmark is the sum of the applicable amount at paragraph (d)(2) and the specified amount at paragraph (d)(3) of this section in the following proportions:

(A) For 2012, five-sixths of the applicable amount for the area and year and one-sixth of the specified amount for the area and year.

(B) For 2013, two-thirds of the applicable amount for the area and year and one-third of the specified amount for the area and year.

(C) For 2014, one-half of the applicable amount for the area and year and one-half of the specified amount for the area and for year.

(D) For 2015, one-third of the applicable amount for the area and year and two-thirds of the specified amount for the area and for year.

(E) For 2016, one-sixth of the applicable amount for the area and year and five-sixths of the specified amount for the area and for year.

(F) For 2017 and subsequent years, the blended benchmark equals the specified amount for the area and year.

■ 26. Section 422.260 is added to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

(a) *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act.

(b) *Definitions.* The following definitions apply to this section:

Quality bonus payment (QBP) means—

(i) Enhanced CMS payments to MA organizations based on the organization's demonstrated quality of its Medicare contract operations; or

(ii) Increased beneficiary rebate retention allowances based on the organization's demonstrated quality of its Medicare contract operations.

Quality bonus payment (QBP) determination methodology means the formula CMS adopts for evaluating whether MA organizations qualify for a QBP.

Quality bonus payment (QBP) status means a MA organization's standing with respect to its qualification to—

(i) Receive a quality bonus payment, as determined by CMS; or

(ii) Retain a portion of its beneficiary rebates based on its quality rating, as determined by CMS.

(c) *Administrative review process for QBP status appeals.* (1) Reconsideration request. An MA organization may request reconsideration of its QBP status.

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. The error could impact an individual measure's value or the overall star rating.

(ii) The reconsideration official's decision is final and binding unless a request for an informal hearing is filed in accordance with paragraph (2) of this section.

(2) *Informal hearing request.* An MA organization may request an informal hearing on the record following the reconsideration official's decision regarding its QBP status.

(i) The MA organization seeking an appeal of the reconsideration official's decision regarding its QBP status must do so by providing written notice to CMS within 10 business days of the issuance of the reconsideration decision. The notice must specify the errors the MA organization asserts that CMS made in making the QBP determination and how correction of those errors could result in the organization's qualification for a QBP or a higher QBP.

(ii) The MA organization may not request an informal hearing of its QBP status unless it has already requested and received a reconsideration decision in accordance with paragraph (c)(1) of this section.

(iii) The informal hearing request must pertain only to the measure(s) and value(s) in question that precipitated the request for reconsideration.

(iv) The informal hearing is conducted by a CMS hearing officer on the record. The hearing officer receives no testimony, but may accept written statements with exhibits from each party in support of their position in the matter.

(v) The MA organization must provide clear and convincing evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect.

(vi) The hearing officer issues the decision by electronic mail to the MA organization.

(vii) The hearing officer's decision is final and binding.

(3) *Limits to requesting an administrative review.* (i) CMS may limit the measures or bases for which a contract may request an administrative review of its QBP status.

(ii) An administrative review cannot be requested for the following: the methodology for calculating the star ratings (including the calculation of the overall star ratings); cut-off points for determining measure thresholds; the set of measures included in the star rating system; and the methodology for determining QBP determinations for low enrollment contracts and new MA plans.

(4) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the appeal of the QBP status. The officer must be an individual who did not directly participate in the initial QBP determination.

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process that demonstrates that the initial QBP determination was incorrect.

■ 27. Amend § 422.266 by revising paragraph (a) to read as follows:

§ 422.266 Beneficiary rebates.

(a) *Calculation of rebate.* (1) For 2006 through 2011, an MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans.

(2) For 2012 and subsequent years, an MA organization must provide to the enrollee a monthly rebate equal to a specified percentage of the average per capita savings (if any) at § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans. For 2012 and 2013, this percentage is based on a combination of the (a)(1) rule of 75 percent and the (a)(2)(ii) rules that set the percentage based on the plan's quality rating under a 5 star rating system, as determined by the Secretary under § 422.258(d)(7). For 2014 and subsequent years, this percentage is determined based only on the paragraph (a)(2)(ii) of this section.

(i) *Applicable rebate percentage for 2012 and 2013.* Subject to paragraphs (a)(2)(iii) and (iv) of this section, the transitional applicable rebate percentage is, for a year, the sum of two amounts as follows:

(A) *For 2012.* Two-thirds of the old proportion of 75 percent of the average per capita savings; and one-third of the new proportion assigned the plan under paragraph (a)(2)(ii) of this section, based on the quality rating specified in § 422.258(d)(7).

(B) *For 2013.* One-third of the old proportion of 75 percent of the average per capita savings; and two-thirds of the new proportion assigned the plan under paragraph (d)(2)(ii) of this section, based on the quality rating at § 422.258(d)(7).

(ii) *Final applicable rebate percentage.* For 2014 and subsequent years, and subject to paragraphs (a)(2)(iii) and (iv) of this section, the final applicable rebate percentage is as follows:

(A) In the case of a plan with a quality rating under such system of at least 4.5 stars, 70 percent of the average per capita savings;

(B) In the case of a plan with a quality rating under such system of at least 3.5 stars and less than 4.5 stars, 65 percent of the average per capita savings.

(C) In the case of a plan with a quality rating under such system of less than 3.5 stars, 50 percent of the average per capita savings.

(iii) *Treatment of low enrollment contracts.* For 2012, in the case of a plan described at § 422.258(d)(7)(iv), the plan must be treated as having a rating of 4.5 stars for the purpose of determining the beneficiary rebate amount.

(iv) *Treatment of new MA plans.* For 2012 or a subsequent year, a new MA plan defined at § 422.252 that meets the criteria specified by the Secretary for purposes of § 422.258(d)(7)(v) must be treated as a qualifying plan under § 422.258(d)(7)(i), except that plan must be treated as having a rating of 3.5 stars for purposes of determining the beneficiary rebate amount.

* * * * *

Subpart G—Payments to Medicare Advantage Organizations

■ 28. Amend § 422.308 by adding paragraphs (c)(4) through (6) to read as follows:

* * * * *

(c) * * *

(4) *Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals.* (i) *Application of payment rules.* For plan year 2011 and subsequent plan years, in the case of a plan described in paragraph (c)(4)(ii) of this section, the Secretary may apply the payment rules under section 1894(d) of the Act (other than paragraph (3) of that section) rather than the payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

(ii) *Plan described.* A plan described in this paragraph is a fully integrated dual-eligible special needs plan, as defined at § 422.2, and has a similar average level of frailty (as determined by the Secretary) as the PACE program.

(5) *Application of coding adjustment.* (i) In applying the adjustment under paragraph (c)(1) of this section for health status to payment amounts, the Secretary ensures that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between MA plans and providers under Part A and B to the extent that the Secretary has identified such differences.

(ii) In order to ensure payment accuracy, the Secretary annually conducts an analysis of the differences described in paragraph (c)(5)(i) of this section.

(A) The Secretary completes such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years.

(B) In conducting such analysis, the Secretary uses data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(iii) In calculating each year's adjustment, the adjustment factor is as follows:

(A) For 2014, not less than the adjustment factor applied for 2010, plus 1.3 percentage points.

(B) For each of the years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage points.

(C) For 2019 and each subsequent year, not less than 5.7 percent.

(iv) Such adjustment is applied to risk scores until the Secretary implements risk adjustment using MA diagnostic, cost, and use data.

(6) *Improvements to risk adjustment for special needs individuals with chronic health conditions*—(i) *General rule.* For 2011 and subsequent years, for purposes of the adjustment under paragraph (c)(1) of this section with respect to individuals described in paragraph (c)(6)(ii) of the section, the Secretary uses a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. Such risk score is used instead of the default risk score for new enrollees in MA plans that are not specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of the Act).

(ii) *Individuals described.* An individual described in this clause is a special needs individual described in section 1859(b)(6)(B)(iii) of the Act who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

(iii) *Evaluation.* For 2011 and periodically thereafter, the Secretary evaluates and revises the risk adjustment system under this paragraph in order to, as accurately as possible, account for—

(A) Higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness; and

(B) Costs that may be associated with higher concentrations of beneficiaries with the conditions specified in paragraph (c)(6)(iii)(A) of this section.

(iv) *Publication of evaluation and revisions.* The Secretary publishes, as part of an announcement under section 1853(b) of the Act, a description of any evaluation conducted under paragraph (c)(6)(iii) of this section during the preceding year and any revisions made under paragraph (c)(6)(iii) of this section as a result of such evaluation.

* * * * *

Subpart J—Special Rules for MA Regional Plans

§ 422.458 [Amended]

■ 29. In § 422.458, paragraph (f) is removed.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

■ 30. Amend § 422.502 as follows:

■ A. Redesignating paragraph (b) as paragraph (b)(1).

■ B. Adding paragraph (b)(2).

■ C. Revising paragraph (c)(2)(i).

The revisions read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.

(c) * * *

(2) * * *

(i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization, CMS gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

* * * * *

■ 32. Amend § 422.504 as follows:

■ A. Redesignating paragraph (a)(14) as paragraph (a)(16).

■ B. Adding new paragraphs (a)(14) and (a)(15).

■ C. Revising newly redesignated paragraph (a)(16).

■ D. Adding paragraph (n).

The additions and revision read as follows.

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(14) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(15) Address complaints received by CMS against the MAO by—

(i) Addressing and resolving complaints in the CMS complaint tracking system.

(ii) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the MA plan's main Web page.

(16) An MA organization's compliance with paragraphs (a)(1) through (15) and (c) of this section is material to performance of the contract.

* * * * *

(n) *Release of summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

(1) For Part C, the following data—

(i) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.

(ii) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).

(iii) Average Part C risk score for each MA plan offered.

(iv) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(2) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

■ 33. Amend § 422.506 by adding paragraph (a)(5) to read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(5) During the same 2-year period as specified in paragraph (a)(4) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

■ 34. Amend § 422.508 by adding paragraph (d) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

* * * * *

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(1) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors of the entity, if the organization is organized as a corporation.

■ 35. Amend § 422.512 as follows:

A. Redesignating paragraph (e) as (e)(1).

B. Adding a new paragraph (e)(2).

§ 422.512 Termination of contract by the MA organization.

* * * * *

(e) * * *

(2) During the same 2-year period specified in paragraph (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors of the entity, if the organization is organized as a corporation.

Subpart M—Grievances, Organization Determinations, and Appeals

■ 36. Amend § 422.562 by adding paragraph (a)(4) to read as follows:

§ 422.562 General provisions.

* * * * *

(a) * * *

(4) An MA organization must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

* * * * *

■ 37. Amend § 422.566 by adding paragraph (d) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(d) *Who must review organization determinations.* If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

■ 38. Amend § 422.622 by revising paragraph (g)(1) to read as follows:

§ 422.622 Requesting immediate QIO review of the decision to discharge from the inpatient hospital.

* * * * *

(g) * * *

(1) *Right to request a reconsideration.* If the enrollee is still an inpatient in the hospital and is dissatisfied with the determination, he or she may request a reconsideration according to the procedures described in § 422.626(g).

* * * * *

■ 39. Amend § 422.626 by revising paragraph (g)(3) to read as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(g) * * *

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ, the MAC, or a Federal court, as provided for under this subpart.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

■ 40. Amend § 422.2264 by revising paragraph (e) to read as follows:

§ 422.2264 Guidelines for CMS review.

* * * * *

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, MA organizations must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

■ 41. Amend § 422.2272 by adding paragraph (e) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Terminate upon discovery any unlicensed agent or broker employed as a marketing representative and notify any beneficiaries enrolled by an unqualified agent or broker of the agent's or broker's status and, if requested, of their options to confirm enrollment or make a plan change (including a special election period, as described in § 422.62(b)(3)(ii)).

■ 42. Amend § 422.2274 by revising the introductory text and paragraphs (b) and (c) to read as follows:

§ 422.2274 Broker and agent requirements.

For purposes of this section "compensation" includes pecuniary or nonpecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees. "Compensation" does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a MA organization markets through

independent (that is, non-employee) brokers or agents, the requirements in paragraph (a) of this section must be met. The requirements in paragraphs (b) through (e) of this section must be met if a MA organization markets through any broker or agent, whether independent (that is, non-employee) or employed.

* * * * *

(b) It must ensure that all agents selling Medicare products are trained annually through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

* * * * *

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 43. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart A—General Provisions

■ 44. Amend § 423.4 by adding the definitions of "fiscally sound operation" and "pharmacist" to read as follows:

§ 423.4 Definitions.

* * * * *

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

* * * * *

Pharmacist means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

* * * * *

Subpart B—Eligibility and Enrollment

■ 45. Amend § 423.34 as follows:
■ A. Revising paragraphs (c) and (d)(1).
■ B. Adding paragraph (d)(4).

The revisions and addition read as follows:

§ 423.34 Enrollment of low-income subsidy eligible individuals.

* * * * *

(c) *Reassigning low income subsidy eligible individuals*—(1) *General rule.* Notwithstanding § 423.32(e) of this subpart, during the annual coordinated election period, CMS may reassign certain low income subsidy eligible individuals in another PDP if CMS determines that the further enrollment is warranted, except as specified in paragraph (c)(2) of this section.

(2) *Part D prescription drug plans that waive a de minimis premium amount.* If a Part D plan offering basic prescription drug coverage in the area where the beneficiary resides has a monthly beneficiary premium amount that exceeds the low-income subsidy amount by a de minimis amount, and the Part D plan volunteers to waive that de minimis amount in accordance with § 423.780, then CMS does not reassign low income subsidy individuals who would otherwise be enrolled under paragraph (d)(1) of this section on the basis that the monthly beneficiary premium exceeds the low-income subsidy by a de minimis amount. A Part D plan that volunteers to waive such a de minimis amount agrees to do so for each month during the contract year for which a beneficiary qualifies for 100 percent low-income premium subsidy as provided in § 423.780(f).

(d) *Automatic enrollment rules*—(1) *General rule.* Except for low income subsidy eligible individuals who are qualifying covered retirees with a group health plan sponsor, as specified in paragraph (d)(3) of this section, CMS enrolls those individuals who fail to enroll in a Part D plan into a PDP offering basic prescription drug coverage in the area where the beneficiary resides that has a monthly beneficiary premium amount that does not exceed the low income subsidy amount (as defined in § 423.780(b) of this part). In the event that there is more than one PDP in an area with a monthly beneficiary premium at or below the low income premium subsidy amount, individuals are enrolled in such PDPs on a random basis.

* * * * *

(4) *Enrollment in PDP plans that voluntarily waive a de minimis premium amount.* CMS may include in the process specified in paragraph (d)(1) of this section that PDPs that voluntarily waive a de minimis amount as specified in § 423.780, if CMS determines that such inclusion is warranted.

* * * * *

■ 46. Amend § 423.38 as by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(b) *Annual coordinated election period*—(1) *For 2006.* This period begins on November 15, 2005 and ends on May 15, 2006.

(2) *For 2007 through 2010.* The annual coordinated election period for the following calendar year is November 15 through December 31.

(3) *For 2011 and subsequent years.* Beginning with 2011, the annual coordinated election period for the following calendar year is October 15 through December 7.

* * * * *

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment period.* Beginning in 2011, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in § 422.62(a)(7), may also elect a PDP during this time.

■ 47. Amend § 423.40 by adding paragraph (d) to read as follows:

§ 423.40 Effective dates.

* * * * *

(d) *PDP enrollment period to coordinate with the MA annual disenrollment period.* Beginning in 2011, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in § 422.62(a)(7) will be effective the first day of the month following the month in which the enrollment in the PDP is made.

■ 48. Amend § 423.44 by revising the section heading and adding paragraphs (d)(1)(vi), (d)(1)(vii), and (e) as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(d) * * *

(1) * * *

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS may reinstate enrollment in the PDP, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

(vii) *No extension of grace period.* A beneficiary's enrollment in the PDP may not be reinstated if the only basis for such reinstatement is a change in the individual's circumstances subsequent to the involuntary disenrollment for non-payment of premiums.

* * * * *

(e) *Involuntary disenrollment by CMS*—(1) *General rule.* CMS will disenroll individuals who fail to pay the Part D income related monthly adjustment amount (Part D—IRMAA) specified in § 423.286(d)(4) and § 423.293(d) of this part.

(2) *Initial grace period.* For all Part D—IRMAA amounts directly billed to an enrollee in accordance with § 423.293(d)(2), the grace period ends with the last day of the third month after the billing month.

(3) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failing to pay the Part D—IRMAA within the initial grace period specified in paragraph (e)(2) of this section, CMS (or an entity acting on behalf of CMS) may reinstate enrollment, without interruption of coverage, if the individual shows good cause as specified in § 423.44(d)(1)(vi), pays all Part D—IRMAA arrearages, and any overdue premiums due the Part D plan sponsor within 3 calendar months after the disenrollment date.

(4) *Notice of termination.* Where CMS has disenrolled an individual in accordance with paragraph (e)(1) of this section, the Part D plan sponsor must provide notice of termination in a form and manner determined by CMS.

(5) *Effective date of disenrollment.* After a grace period and notice of termination has been provided in accordance with paragraphs (e)(2) and (4) of this section, the effective date of disenrollment is the first day following the last day of the initial grace period.

Subpart C—Benefits and Beneficiary Protections

■ 49. Amend § 423.100 as follows:

■ A. Adding the definitions of "Applicable beneficiary," "Applicable drug under the Medicare coverage gap discount program," and "Coverage gap."

■ B. Revising paragraph (2) of the definition of "Dispensing fees" and paragraph (2)(ii) of the definition of "Incurred costs."

The additions and revisions read as follows:

§ 423.100 Definitions.

* * * * *

Applicable beneficiary means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA–PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3) Is not entitled to an income-related subsidy under section 1860D–14(a) of the Act;

(4) Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year;

(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) of the Act; and

(6) Has a claim that—

(i) Is within the coverage gap;

(ii) Straddles the initial coverage period and the coverage gap;

(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

* * * * *

Coverage gap means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

* * * * *

Dispensing fees * * *

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.

* * * * *

Incurred costs * * *

(2) * * *

(ii) Under a State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or

* * * * *

■ 50. Amend § 423.104 as follows:

■ A. Revising paragraphs (d)(2)(i) introductory text, (d)(2)(ii), (d)(3) introductory text, and (d)(4).

■ B. Redesignating paragraph (d)(5)(iii)(B) as (d)(5)(iii)(F).

■ C. Adding new paragraphs (d)(5)(iii)(B) through (E).

■ D. Revising newly redesignated paragraph (d)(5)(iii)(F).

■ E. Adding paragraph (d)(5)(v).

The revisions and additions read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible

specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

* * * * *

(ii) *Tiered copayments.* A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraphs (d)(2)(i)(B) and (d)(4) of this section and are approved as described in § 423.272(b)(2).

(3) *Initial coverage limit.* Except as provided in paragraphs (d)(4) and (d)(5) of this section, the initial coverage limit is equal to—

* * * * *

(4) *Cost-sharing in the coverage gap for applicable beneficiaries.* (i) Coinsurance in the coverage gap (as defined in § 423.100) for costs for covered Part D drugs that are not applicable drugs (as defined in § 423.100) under the Medicare coverage gap discount program that is—

(A) Equal to the generic gap coinsurance percentage described in paragraph (d)(4)(iii) of this section; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(ii) Coinsurance in the coverage gap for the actual cost minus the dispensing fee and any vaccine administration fee for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program that is—

(A) Equal to the difference between the applicable gap coinsurance percentage described in paragraph (d)(4)(iv) of this section and the discount percentage determined under the Medicare coverage gap discount program; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(iii) *Generic gap coinsurance percentage.* The generic gap coinsurance percentage is equal to—

(A) For 2011, 93 percent.

(B) For years 2012 through 2019, the amount specified in this paragraph for the previous year, decreased by 7 percentage points.

(C) For 2020 and each subsequent year, 25 percent.

(iv) *Applicable gap coinsurance percentage.* The applicable gap coinsurance percentage is equal to—

(A) For 2013 and 2014, 97.5 percent.

(B) For 2015 and 2016, 95 percent.

(C) For 2017, 90 percent.

(D) For 2018, 85 percent.

(E) For 2019, 80 percent.

(F) For 2020 and subsequent years, 75 percent.

(5) * * *

(iii) * * *

(B) *For each year 2007 through 2013.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of $50.

(C) *For years 2014 and 2015.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, minus 0.25 percentage point.

(D) *For each year 2016 through 2019.* The amount specified in this paragraph for the previous year, increased by the lesser of—

(*1*) The annual percentage increase specified in (d)(5)(v) of this section plus 2 percentage points; or

(*2*) The annual percentage increase specified in (d)(5)(iv) of this section.

(E) *For 2020.* The amount specified in this paragraph for 2013 increased by the annual percentage increases specified in paragraph (d)(5)(iv) of this section for 2014 through 2020, and rounded to the nearest $50.

(F) *For 2021 and subsequent years.* The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest $50.

* * * * *

(v) *Additional annual percentage increase.* The annual percentage increase for each year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

* * * * *

■ 51. Section 423.120 is amended as follows:

■ A. Revising paragraphs (b)(3)(iii)(B) and (b)(3)(iv).

■ B. Adding paragraph (d).

The revisions and addition read as follows.

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(iii) * * *

(B) In the long-term care setting, the temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) must be for up to at least 91 days and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed, unless a lesser amount is actually prescribed by the prescriber.

(iv) Ensure written notice is provided to each affected enrollee within 3 business days after adjudication of the temporary fill. For long-term care residents dispensed multiple supplies of a Part D drug, in increments of 14-days-or-less, consistent with the requirements under § 423.154, the written notice must be provided within 3 business days after adjudication of the first temporary fill.

* * * * *

(d) *Treatment of compounded drug products.* With respect to multi-ingredient compounds, a Part D sponsor must—

(1) Make a determination as to whether the compound is covered under Part D.

(i) A compound that contains at least one ingredient covered under Part B as prescribed and dispensed or administered is considered a Part B compound, regardless of whether other ingredients in the compound are covered under Part B as prescribed and dispensed or administered.

(ii) Only compounds that contain at least one ingredient that independently meets the definition of a Part D drug, and that do not meet the criteria under paragraph (d)(1)(i) of this section, may be covered under Part D. For purposes of this paragraph (d) these compounds are referred to as Part D compounds.

(iii) For a Part D compound to be considered on-formulary, all ingredients that independently meet the definition of a Part D drug must be considered on-formulary (even if the particular Part D drug would be considered off-formulary if it were provided separately—that is, not as part of the Part D compound).

(iv) For a Part D compound that is considered off-formulary—

(A) Transition rules apply such that all ingredients in the Part D compound that independently meet the definition of a Part D drug must become payable in the event of a transition fill under § 423.120(b)(3); and

(B) All ingredients that independently meet the definition of a Part D drug must be covered if an exception under § 423.578(b) is approved for coverage of the compound.

(2) Establish consistent rules for beneficiary payment liabilities for both ingredients of the Part D compound that

independently meet the definition of a Part D drug and non-Part D ingredients.

(i) For low income subsidy beneficiaries the copayment amount is based on whether the most expensive ingredient that independently meets the definition of a Part D drug in the Part D compound is a generic or brand name drug (as described under § 423.782).

(ii) For any non-Part D ingredient of the Part D compound (including drugs described under § 423.104(f)(1)(ii)(A)), the Part D sponsor's contract with the pharmacy must prohibit balance billing the beneficiary for the cost of any such ingredients.

■ 52. Amend § 423.128 as follows:
■ A. Revising paragraph (b)(7).
■ B. Adding paragraphs (d)(1)(iii) and (d)(1)(iv).

The revision and additions read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(b) * * *

(7*) Grievance, coverage determination, and appeal procedures.* All grievance, coverage determination, and appeal rights and procedures required under § 423.562 et. seq., including—

(i) Access to a uniform model form used to request a coverage determination under § 423.568 or § 423.570, and a uniform model form used to request a redetermination under § 423.582 or § 423.584, to the extent such uniform model forms have been approved for use by CMS;

(ii) Immediate access to the coverage determination and redetermination processes via an Internet Web site; and

(iii) A system that transmits codes to network pharmacies so that the network pharmacy is notified to populate and/or provide a printed notice at the point-of-sale to an enrollee explaining how the enrollee can request a coverage determination by contacting the plan sponsor's toll free customer service line or by accessing the plan sponsor's internet Web site.

* * * * *

(d) * * *

(1) * * *

(iii) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(iv) Provides immediate access to the coverage determination and redetermination processes.

* * * * *

Subpart D—Cost Control and Quality Improvement Requirements

■ 53. Amend § 423.150 as follows:
■ A. Redesignating paragraphs (b) through (g) as paragraphs (c) through (h).
■ B. Adding a new paragraph (b) to read as follows:

§ 423.150 Scope.

* * * * *

(b) Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

* * * * *

■ 54. Amending § 423.153 as follows:
■ A. Revising paragraph (d)(1)(vii)(B).
■ B. Adding paragraph (d)(1)(vii)(D).

The revision and addition read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(B) Annual comprehensive medication review with written summaries. The comprehensive medication review must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting and may result in a recommended medication action plan.

* * * * *

(D) Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format.

* * * * *

■ 55. Section 423.154 is added to read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(a) *In general.* Except as provided in paragraph (b) of this section, when dispensing covered Part D drugs to enrollees who reside in long-term care facilities, a Part D sponsor must—

(1) Require all pharmacies servicing long-term care facilities, as defined in § 423.100 to—

(i) Dispense solid oral doses of brand-name drugs, as defined in § 423.4, to enrollees in such facilities in no greater than 14-day increments at a time;

(ii) Permit the use of uniform dispensing techniques for Part D drugs dispensed to enrollees in long-term care facilities under paragraph (a)(1)(i) of this section as defined by each of the long-term care facilities in which such enrollees reside; and

(2) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section, and on the nature and quantity of unused brand and generic drugs, as defined in § 423.4, dispensed by the pharmacy to enrollees residing in a LTC facility. Reporting on unused drugs is waived for Part D sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs, as defined in § 423.4, in no greater than 7-day increments.

(b) *Exclusions.* CMS excludes from the requirements under paragraph (a) of this section—

(1) Solid oral doses of antibiotics; or

(2) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance (for example, oral contraceptives).

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section for pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/MR) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

(d) *Applicability date.* The applicability date for this section is January 1, 2013. Nothing precludes a Part D sponsor and pharmacy from mutually agreeing to an earlier implementation date.

(e) *Copayments.* Regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply.

(f) *Unused drugs returned to the pharmacy.* The terms and conditions that must be offered by a Part D sponsor under § 423.120(a)(5) must include provisions that address the disposal of drugs that have been dispensed to an enrollee in a long-term care facility but not used and which have been returned to the pharmacy, in accordance with Federal and State regulations, as well as whether return for credit and reuse is authorized where permitted under State law.

Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

■ 56. Amend § 423.265 by adding paragraph (b)(3) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(3) CMS may decline to accept any or every bid submitted by a Part D sponsor or potential Part D sponsor.

* * * * *

■ 57. Amend § 423.272 by adding paragraph (b)(4) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(4) CMS may decline to approve a bid if the Part D sponsor proposes significant increases in cost sharing or decreases in benefits offered under the plan.

* * * * *

■ 58. Amend § 423.286 as follows:

■ A. Revising paragraph (a).

■ B. Adding paragraph (d)(4).

The revision and addition read as follows:

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3), (d)(4), and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

* * * * *

(d) * * *

(4) *Increase for income-related monthly adjustment amount (Part D—IRMAA).* Beginning January 1, 2011, Medicare beneficiaries enrolled in a Medicare Part D plan must pay an income-related monthly adjustment amount in addition to the Part D premium as determined under paragraph (c) of this section and adjusted under paragraph (d) of this section, if the enrollee's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.2115.

(i) *Social Security Administration determination.* (A) SSA determines which Part D enrollees are subject to the Part D—IRMAA and the amount each enrollee will have to pay.

(B) If an individual disagrees with SSA's determination that such individual is subject to the Part D—IRMAA, or about the amount the individual must pay, an individual may file an appeal or request a new initial determination consistent with 20 CFR part 418.

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent; and the base beneficiary premium as determined under paragraph (c) of this section.

* * * * *

■ 59. Amend § 423.293 as follows:

■ A. Redesignating paragraphs (d) and (e) as (e) and (f), respectively.

■ B. Add new paragraph (d).

§ 423.293 Collection of monthly beneficiary premium.

* * * * *

(d) *Collection of the income-related monthly adjustment amount (Part D—IRMAA).* (1) *Collection through withholding.* Where the Social Security Administration has determined the income-related monthly adjustment amount for an individual whose income exceeds the income threshold amounts specified at 20 CFR 418.2115, the Part D—IRMAA must be paid through withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board (RRB) or the Office of Personnel Management (OPM) in the manner that the Part B premium is withheld.

(2) *Collection through direct billing.* In cases where an enrollee's benefit payment check is not sufficient to have the Part D—IRMAA withheld, or if an enrollee is not receiving such benefits, the beneficiary must be billed directly for the Part D—IRMAA. The beneficiary will have the option of paying the amount through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or according to other means that CMS may specify.

(3) *Failure to pay the income-related monthly adjustment amount: General rule.* CMS will terminate Part D coverage for any individual who fails to pay the Part D—IRMAA as determined by the Social Security Administration. CMS will terminate an enrollee's Part D coverage as specified in § 423.44(e).

* * * * *

Subpart J—Coordination Under Part D Plan With Other Prescription Drug Coverage

■ 60. Amend § 423.464 by revising paragraph (f)(2) to read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(f) * * *

(2) *Treatment under out-of-pocket rule.* (i) For purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under § 423.104(d)(5)(iii), a Part D plan must—

(A) Include the enrollee's incurred costs (as defined in § 423.100); and

(B) Exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage.

(ii) A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

* * * * *

Subpart K—Application Procedures and Contracts With PDP Sponsors

■ 61. Amend § 423.503 as follows:

■ A. Redesignating paragraph (b) as paragraph (b)(1).

■ B. Adding paragraph (b)(2).

■ C. Revising paragraph (c)(2)(i).

The revisions and addition read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

* * * * *

(b) * * *

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part D program.

* * * * *

(c) * * *

(2) * * *

(i) If CMS finds that the applicant does not appear qualified to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

* * * * *

■ 62. Amend § 423.505 as follows:

■ A. Adding paragraphs (b)(22) and (b)(23).

■ B. Adding paragraph (o).

The additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Address complaints received by CMS against the Part D sponsor by—

(i) Addressing and resolving complaints in the CMS complaint tracking system.

(ii) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the Part D plan's main Web page.

(23) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

* * * * *

(o) *Release of summary CMS payment data.* The contract must provide that the Part D sponsor acknowledges that CMS releases to the public summary reconciled Part D payment data after the reconciliation of Part D payments for the contract year as follows:

(1) The average per member per month Part D direct subsidy standardized to the 1.0 (average risk score) beneficiary for each Part D plan offered.

(2) The average Part D risk score for each Part D plan offered.

(3) The average per member per month Part D plan low-income cost sharing subsidy for each Part D plan offered.

(4) The average per member per month Part D Federal reinsurance subsidy for each Part D plan offered.

(5) The actual Part D reconciliation payment data summarized at the Parent Organization level including breakouts of risk sharing, reinsurance, and low income cost sharing reconciliation amounts.

■ 63. Amend § 423.507 as follows:

■ A. Redesignating paragraph (a)(4) as paragraph (a)(5).

■ B. Adding a new paragraph (a)(4) to read as follows:

§ 423.507 Nonrenewal of contract.

(a) * * *

(4) During the same 2-year period specified under paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or by any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

■ 64. Amend § 423.508 by adding paragraph (f) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *

(f) *Prohibition against Part D program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the 2-year period specified in paragraph (e) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(1) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

■ 65. Amend § 423.509 by adding paragraph (e) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *

(e) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.

■ 66. Amend § 423.510 as follows:

■ A. Redesignating paragraph (e) as (e)(1).

■ B. Adding a new paragraph (e)(2).

The addition reads as follows:

§ 423.510 Termination of contract by Part D sponsor.

* * * * *

(e) * * *

(2) During the same 2-year period specified in (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

* * * * *

Subpart M—Grievances, Coverage Determinations, and Appeals

■ 67. Amend § 423.562 as follows:

■ A. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (a)(1)(iii) and (iv), respectively.

■ B. Adding new paragraph (a)(1)(ii).

■ C. Revising paragraph (a)(3).

■ D. Adding paragraph (a)(5).

The revision and additions read as follows:

§ 423.562 General provisions.

(a) * * *

(1) * * *

(ii) Use a single, uniform exceptions and appeals process which includes, procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128 (b)(7) and (d)(1)(iii).

* * * * *

(3) A Part D plan sponsor must arrange with its network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist. These notices must comply with the standards established in § 423.128(b)(7)(iii).

* * * * *

(5) A Part D plan sponsor must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory,

Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

* * * * *

■ 68. Amend § 423.566 by adding paragraph (d) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(d) *Who must review coverage determinations.* If the Part D plan sponsor expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

■ 69. Amend § 423.568 by revising paragraph (f) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(f) *Written notice for denials by a Part D plan sponsor.* If a Part D plan sponsor decides to deny a drug benefit, in whole or in part, it must give the enrollee written notice of the determination. The initial notice may be provided orally, so long as a written follow-up notice is mailed to the enrollee within 3 calendar days of the oral notification.

* * * * *

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

■ 70. Section 423.772 is amended by adding the definition of "Individual receiving home and community-based services" to read as follows:

§ 423.772 Definitions.

* * * * *

Individual receiving home and community-based services means a full-benefit dual-eligible individual who is receiving services under a home and community-based program authorized for a State in accordance with one of the following:

(1) Section 1115 of the Act.

(2) Section 1915(c) or (d) of the Act.

(3) State plan amendment under section 1915(i) of the Act.

(4) Services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) of the Act or section 1932 of the Act.

* * * * *

■ 71. Amend § 423.780 as follows:

■ A. Revising paragraph (b)(2)(ii)(C).

■ B. Adding paragraph (f).

The revision and addition read as follows:

§ 423.780 Premium subsidy.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(C) The MA monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Act) for a MA–PD plan and determined before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) of the Act for that plan and year involved.

* * * * *

(f) *Waiver of de minimis premium amounts.* CMS will permit a Part D plan to waive a de minimis amount that is above the monthly beneficiary premium defined in § 423.780(b)(2)(ii)(A) or (B) for full subsidy individuals as defined in § 423.780(a) or § 423.780(d)(1), provided waiving the de minimis amount results in a monthly beneficiary premium that is equal to the established low income benchmark as defined in § 423.780(b)(2).

■ 72. In § 423.782, revise paragraph (a)(2)(ii) to read as follows:

§ 423.782 Cost-sharing subsidy.

* * * * *

(a) * * *

(2) * * *

(ii) Full-benefit dual-eligible individuals who are institutionalized or who are receiving home and community-based services have no cost-sharing for Part D drugs covered under their PDP or MA–PD plans.

* * * * *

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

■ 73. Amend § 423.884 as follows:

■ A. Redesignating paragraph (c)(3)(ii) and (c)(3)(iii) as paragraphs (c)(3)(iii) and (c)(3)(iv), respectively.

■ B. Adding a new subparagraph (c)(3)(ii).

■ C. Revising paragraphs (d) introductory text, (d)(1)(i) and (ii), and (d)(5)(iii)(C).

The addition and revisions read as follows:

§ 423.884 Requirements for qualified retiree prescription drug plans.

* * * * *

(c) * * *

(3) * * *

(ii) Acknowledge that at the same time CMS releases Part C and Part D summary payment data in accordance with § 422.504(n) and § 423.505(o) CMS will also release Part D retiree drug subsidy payment data for the most recently reconciled year including the name of the eligible sponsor, the total gross aggregate dollar amount of the CMS subsidy, and the number of eligible retirees;

* * * * *

(d) *Actuarial attestation—general.* The sponsor of the plan must provide to CMS an attestation in a form and manner specified by CMS that the actuarial value of the retiree prescription drug coverage under the plan is at least equal to the actuarial value of the defined standard prescription coverage (as defined at § 423.100), not taking into account the value of any discount or coverage provided during the coverage gap (as defined at § 423.100). The attestation must meet all of the following standards:

(1) * * *

(i) The actuarial gross value of the retiree prescription drug coverage under the plan for the plan year is at least equal to the actuarial gross value of the defined standard prescription drug coverage under Part D for the plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

(ii) The actuarial net value of the retiree prescription drug coverage under the plan for that plan year is at least equal to the actuarial net value of the defined standard prescription drug coverage under Part D for that plan year in question, not taking into account the value of any discount or coverage provided during the coverage gap.

* * * * *

(5) * * *

(iii) * * *

(C) The valuation of defined standard prescription drug coverage for a given plan year is based on the initial coverage limit cost-sharing and out-of-pocket threshold for defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount or coverage provided during the coverage gap.

Subpart V—Part D Marketing Requirements

■ 74. In § 423.2264, revise paragraph (e) to read as follows:

§ 423.2264 Guidelines for CMS review.

* * * * *

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals. Specifically, Part D plan sponsors must translate marketing materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

■ 75. Amend § 423.2272 by adding paragraph (e) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(e) Terminate upon discovery any unlicensed agent or broker employed as a marketing representative and notify any beneficiaries enrolled by an unqualified agent or broker of the agent's or broker's status and, if requested, of their options to confirm enrollment or make a plan change (including a special election period, as described in § 423.38(c)(8)(i)(C)).

■ 76. Amend § 423.2274 by revising the introductory text and paragraphs (b) and (c) to read as follows:

§ 423.2274 Broker and agent requirements.

For purposes of this section "compensation" includes pecuniary or nonpecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees. "Compensation" does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; reimbursement for mileage to, and from, appointments with beneficiaries; or reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials. If a Part D sponsor markets through independent (that is, non-employee) brokers or agents, the requirements in paragraph (a) of this section must be met. The requirements in paragraphs (b) through (e) of this section must be met if a Part D sponsor markets through any broker or agent, whether independent (that is, non-employee) or employed.

* * * * *

(b) It must ensure that all agents selling Medicare products are trained annually, through a CMS endorsed or approved training program or as specified by CMS, on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually by CMS endorsed or approved training program or as specified by CMS.

* * * * *

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: March 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: March 31, 2011.

Kathleen Sebelius,

Secretary.

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Part III

Department of Energy

10 CFR Part 431

Energy Conservation Program: Test Procedures for Walk-In Coolers and Walk-In Freezers; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2008–BT–TP–0014]

RIN 1904–AB85

Energy Conservation Program: Test Procedures for Walk-In Coolers and Walk-In Freezers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: On January 4, 2010, the U.S. Department of Energy (DOE) issued a notice of proposed rulemaking (January 2010 NOPR) to establish new test procedures for walk-in coolers and walk-in freezers (WICF or walk-ins). On September 9, 2010, DOE issued a supplemental notice of proposed rulemaking (September 2010 SNOPR) to propose changes to the test procedures that it proposed in the NOPR. Those proposed rulemakings serve as the basis for today's action. DOE is issuing a final rule that establishes new test procedures for measuring the energy efficiency of certain walk-in cooler and walk-in freezer components including panels, doors, and refrigeration systems. These test procedures will be mandatory for product testing to demonstrate compliance with energy standards that DOE is establishing in a separate, but concurrent rulemaking, and for representations starting 180 days after publication. This final rule incorporates by reference industry test procedures that, along with calculations established in the rule, can be used to measure the energy consumption or performance characteristics of certain components of walk-in coolers and walk-in freezers. Additionally, the final rule clarifies the definitions of "Display door," "Display panel," "Door," "Envelope," "K-factor," "Panel," "Refrigerated," "Refrigeration system," "U-factor," "Automatic door opener/closer," "Core region," "Edge region," "Surface area," "Rating condition," and "Percent time off" as applicable to walk-in coolers and walk-in freezers.

DATES: The effective date of this rule is May 16, 2011. The final rule changes will be mandatory for product testing starting October 12, 2011.

The incorporation by reference of certain publications listed in this rule was approved by the Director of the Federal Register on May 16, 2011.

ADDRESSES: The public may review copies of all materials related to this rulemaking at the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., Suite 600, Washington, DC (202) 586–2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Please contact Ms. Brenda Edwards at the above telephone number, or by e-mail at *Brenda_Edwards@ee.doe.gov,* for additional information regarding visiting the Resource Room.

Docket: The docket is available for review at regulations.gov, including Federal Register notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials. All documents in the docket are listed in the regulations.gov index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/commercial/wicf.html.* This web page will contain a link to the docket for this notice on the regulations.gov site. The regulations.gov web page will contain simple instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Mr. Charles Llenza, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Telephone:* (202) 586–2192. E-mail: *Charles.Llenza@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Telephone:* (202) 586–8145. E-mail: *Michael.Kido@hq.doe.gov* or Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Telephone:* (202) 586–7796. *E-mail: Elizabeth.Kohl@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This final rule incorporates by reference into subpart R of Title 10, Code of Federal Regulations, part 431 (10 CFR part 431), the following industry standards:

(1) AHRI 1250 (I–P)–2009, "2009 Standard for Performance Rating of Walk-In Coolers and Freezers," approved 2009.

(2) ASTM C1363–05, "Standard Test Method for Thermal Performance of Building Materials and Envelope Assemblies by Means of a Hot Box Apparatus," approved May 1, 2005.

(3) DIN EN 13164:2009–02, "Thermal insulation products for buildings—Factory made products of extruded polystyrene foam (XPS)—Specification," approved February 2009.

(4) DIN EN 13165:2009–02, "Thermal insulation products for buildings—Factory made rigid polyurethane foam (PUR) products—Specification," approved February 2009.

(5) NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors," approved 2010.

Copies of ASTM standards can be obtained from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959, (610) 832–9585, or *http://www.astm.org.*

Copies of AHRI standards can be obtained from *AHRI.* Air-Conditioning, Heating and Refrigeration Institute, 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, (703) 600–0366, or *http://www.ahrinet.org.*

Copies of DIN EN standards can be obtained from *CEN.* European Committee for Standardization (French: Norme or German: Norm), Avenue Marnix 17, B–1000 Brussels, Belgium, *Tel:* + 32 2 550 08 11, *Fax:* + 32 2 550 08 19 or *http://www.cen.eu.*

Copies of NFRC standards can be obtained from *NFRC.* National Fenestration Rating Council, 6305 Ivy Lane, Ste. 140, Greenbelt, MD 20770, (301) 589–1776, or *http://www.nfrc.org.*

You can also view copies of these standards at the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., 6th Floor, Washington, DC 20024, (202) 586–2945, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

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I. Authority and Background

Title III of the Energy Policy and Conservation Act (42 U.S.C. 6291–6317; "EPCA" or, "the Act") sets forth a variety of provisions designed to improve energy efficiency. (All references to EPCA refer to the statute as amended through the Energy Independence and Security Act of 2007 (EISA 2007), Public Law 110–140 (Dec. 19, 2007)). Part C of Title III (42 U.S.C. 6311–6317), which was subsequently redesignated as Part A–1 for editorial reasons, establishes an energy conservation program for certain industrial equipment. This includes walk-in coolers and walk-in freezers, the subject of today's notice. (42 U.S.C. 6311(1), (20), 6313(f), and 6314(a)(9))

Under EPCA, this program consists essentially of three parts: (1) Testing, (2) labeling, and (3) Federal energy conservation standards. The testing requirements consist of test procedures that manufacturers of covered products or equipment must use (1) as the basis for certifying compliance with the applicable energy conservation standards adopted under EPCA, and (2) for making representations about the efficiency of those products. Similarly, DOE must use these test requirements to determine whether the products comply with any relevant standards promulgated under EPCA.

Section 312 of the Energy Independence and Security Act of 2007 ("EISA 2007") amended EPCA by adding certain equipment to this energy conservation program, including walk-in coolers and walk-in freezers (collectively "walk-in equipment," "walk-ins," or "WICF."). (42 U.S.C. 6311(1), (20), 6313(f), and 6314(a)(9)) As amended by EISA 2007, EPCA requires DOE to establish new test procedures to measure the energy use of walk-in coolers and walk-in freezers. (42 U.S.C. 6314(a)(9)(B)(i)) The new test procedures for WICF equipment are the subject of this rulemaking. EPCA also directs DOE to publish performance-based standards and promulgate labeling requirements (42 U.S.C. 6313(f)(4)(A) and 42 U.S.C. 6315(e), respectively). These actions will be covered in separate rulemakings.

In the notice of proposed rulemaking published January 4, 2010 (January 2010 NOPR or, in context, NOPR), DOE proposed to establish test procedures to measure the energy efficiency of walk-in coolers and freezers. 75 FR 186. DOE identified several issues in its proposal based on the public comments submitted in response to the January 2010 NOPR and further research. These issues included: (1) The proposed definition of a walk-in cooler or freezer with regards to the upper temperature limit; (2) the proposal to create test procedures for the envelope and refrigeration system of a walk-in cooler or freezer; (3) the proposal to group walk-in envelopes and refrigeration systems with essentially identical construction methods, materials, and components into a single basic model; and (4) the proposed calculation methodology for determining the energy consumption of units within the same basic model. 75 FR 186, (Jan. 4, 2010). On March 1, 2010, DOE held a public meeting to receive comments, data, and information on the January 2010 NOPR. Through their comments, interested parties raised significant issues and suggested changes to the proposed test procedures. DOE determined that some of these comments warranted further consideration and published a supplemental notice of proposed rulemaking on September 9, 2010 (September 2010 SNOPR or, in context, SNOPR). 75 FR 55068. DOE received 22 written comments on the September 2010 SNOPR. This final rule addresses comments from the January 2010 NOPR that were not addressed in the September 2010 SNOPR and comments received on the September 2010 SNOPR.

General Test Procedure Rulemaking Process

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA provides that test procedures "shall be reasonably designed to produce test results which reflect energy efficiency, energy use and estimated annual operating costs of a type of industrial equipment (or class thereof) during a representative average use cycle as determined by the Secretary [of Energy], and shall not be unduly burdensome to conduct." (42 U.S.C. 6314(a)(2))

Additionally, EPCA notes that if the procedure determines estimated annual operating costs, the procedure "shall provide that such costs shall be calculated from measurements of energy use in a representative average use cycle (as determined by the Secretary), and from representative average-unit costs of the energy needed to operate such equipment during such cycle." (42 U.S.C. 63114(a)(3)) Further, the statute provides that DOE "shall provide information to manufacturers of covered equipment respecting representative average unit costs of energy." *Id.*

With respect to today's rulemaking, the test procedure DOE is prescribing today is a new test procedure. Today's rule establishes a comprehensive testing regime to ensure minimum levels of performance by applying the component-based approach detailed in EISA 2007. The separate but concurrent energy conservation standards rulemaking for walk-in coolers and walk-in freezers will be based on the performance of walk-in coolers and walk-in freezers as measured by the test procedure set forth in this final rule.

II. Summary of the Final Rule

Today's final rule establishes a new test procedure for measuring the energy efficiency of walk-in cooler and walk-in freezer equipment. The test procedure is essentially composed of tests for the principal components that make up a walk-in: Panels, doors, and refrigeration. Testing individual components of walk-in coolers and walk-in freezers is simpler and less burdensome to manufacturers than testing an entire walk-in. In this test procedure, DOE also provides a method for calculating the energy use of an entire envelope, or the efficiency of a refrigeration system, based on the results of the component tests.

The test procedure incorporates by reference the industry test procedures ASTM C1363–05, "Standard Test

Method for Thermal Performance of Building Materials and Envelope Assemblies by Means of a Hot Box Apparatus,"DIN EN 13164:2009–02, "Thermal insulation products for buildings—Factory made products of extruded polystyrene foam (XPS)—Specification," DIN EN 13165:2009–02, "Thermal insulation products for buildings—Factory made rigid polyurethane foam (PUR) products—Specification," NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors," and AHRI 1250 (I–P)–2009, "2009 Standard for Performance Rating of Walk-In Coolers and Freezers."

Concurrently, DOE is undertaking an energy conservation standards rulemaking to address the statutory requirement to establish performance standards for walk-in equipment by 2012. (42 U.S.C. 6313(f)(4)(A)) DOE will use this test procedure in the concurrent process of evaluating potential performance standards for the equipment. After the compliance date of the performance standards, this walk-in cooler and walk-in freezer test procedure, along with any future statistical sampling plans that may be adopted, must be used by manufacturers to determine compliance with the standards, and by DOE to ascertain compliance with the standards in any enforcement action. Moreover, once any final test procedure is effective, any representation of the energy use of walk-in equipment or components must reflect the results of testing that equipment using the test procedure.

III. Discussion

In this section, DOE describes the overall approach it followed in developing today's test procedure for walk-in cooler and freezer equipment, including envelope components and refrigeration systems. The following section also addresses issues raised by interested parties, which consisted of the following entities:

- *Manufacturers:* American Panel, Craig Industries, CrownTonka, Heatcraft Refrigeration Products (Heatcraft), Hill Phoenix, International Cold Storage (ICS), Kysor Panel Systems (Kysor Panel), Manitowoc, Master-Bilt, Owens Corning, Nor-Lake, ThermalRite, Thermo-Kool, and Zero Zone;
- *Material suppliers:* Carpenter Company (Carpenter);
- *Trade associations:* AHRI, Center for the Polyurethanes Industry (CPI);
- *Utility companies:* Pacific Gas & Electric Company (PG&E), Southern California Edison (SCE), Sacramento Municipal Utility District (SMUD), and San Diego Gas and Electric (SDG&E);
- *Advocacy groups:* Appliance Standards Awareness Project (ASAP), Alliance to Save Energy (ASE), American Council for an Energy-Efficient Economy (ACEEE), Natural Resources Defense Council (NRDC), Northeast Energy Efficiency Partnerships (NEEP), and Northwest Energy Efficiency Alliance (NEEA);
- *Other parties:* Oak Ridge National Laboratory (ORNL), and the Small Business Administration (SBA).

A. Overall Approach: Component-Based Testing

In the framework document, DOE contemplated developing a single test for an entire walk-in cooler or freezer. *See http://www1.eere.energy.gov/buildings/appliance_standards/commercial/pdfs/wicf_framework_doc.pdf.* However, feedback from interested parties indicated that a single test procedure for the entire WICF would not be practical because many walk-ins are assembled on site with components from different manufacturers, which would make on-site testing infeasible. DOE then proposed in the January 2010 NOPR and September 2010 SNOPR to develop separate tests for the envelope and refrigeration system of a walk-in, which in aggregate would represent the performance of the entire walk-in (75 FR 186, 191 (Jan. 4, 2010) and 75 FR 55068, 55070 (Sept. 9, 2010)). DOE proposed to have one metric for the refrigeration system, which would be an efficiency metric, and one metric for the envelope, which would be an energy use metric. The envelope metric would account for electrical use of envelope components, as well as any energy used by the refrigeration system to reject the heat contributed by conduction, infiltration, and other heat sources. In this way, DOE intended to capture the energy impact of components, such as panels, that do not themselves consume electricity.

DOE received comments on the September 2010 SNOPR from interested parties stating that the walk-in cooler and walk-in freezer main components could be further broken down into their own constituent components: panels and doors of envelopes and unit coolers and condensing units of refrigeration systems. Commenters explained that all of these components could be produced by separate manufacturers and then assembled into a complete walk-in. Because of this situation, it would be difficult to determine who should test the walk-in envelope, the refrigeration system, or both. It would also be difficult to determine who would be best positioned to ensure the walk-in cooler or freezer complied with an energy conservation standard. DOE acknowledges these and similar concerns from the stakeholders.

Based on the information provided by commenters and DOE's own research, DOE has determined that a component-based approach would address the unique challenges posed in regulating the energy efficiency performance of walk-in envelopes. As noted above, these challenges include the fact that walk-in units are frequently assembled using components made by multiple manufacturers, and walk-in installers may not be equipped to test all the components that comprise a walk-in. These factors indicate that a component-based approach would not only help ensure compliance with whatever energy conservation standards that DOE sets, but also reduce the overall testing burden on the manufacturers, including small businesses who are involved in producing walk-in units, either in full or in part.

Moreover, DOE notes that the adoption of such an approach is consistent with the component-based approach that Congress took when it enacted EISA 2007. Thus, DOE is adopting a component-level approach for this rule and discusses the specific component metrics in greater detail in section III.A.1.

1. Test Metrics

As stated previously, DOE initially proposed separate test procedures for envelopes and refrigeration systems of walk-ins along with different test metrics for each. The metric for the refrigeration system would be an efficiency metric, and the metric for the envelope would be an energy use metric that would account for the electrical use of envelope components and the energy used by the refrigeration system to reject the heat contributed by conduction, infiltration, and other heat sources. To account for different sizes of envelopes, DOE further proposed that the result of the envelope test procedure should be a normalized energy use metric—the total energy use divided by the external surface area of the envelope (energy use per square foot).

Several interested parties disagreed with the proposed metrics. NEEA stated that regulating walk-in coolers and walk-in freezers on the basis of annual energy use would not accurately estimate actual energy use, and therefore such estimates would be misleading for almost all installed systems. NEEA suggested using an overall U-value for the entire envelope and a spreadsheet that calculates the overall U-factor of a walk-in by weighted area. (NEEA, No. 0061.1 at

p. 1 and 9; NEEA, No. 0061.2 at p. 1) (In this and subsequent citations, the document number refers to the number of the comment in the Docket for the DOE rulemaking on test procedures for walk-in coolers and freezers, Docket No. EERE–2008–BT–TP–0014; and the page references refer to the place in the document where the statement preceding appears.) NRDC also disagreed with the annual energy use metric because of the number of assumptions that would be required and the potential to confuse customers. (NRDC, No. 0064.1 at p. 7) NRDC further stated that normalizing energy use to the surface area would be unusual and may not be useful. (NRDC, No. 0064.1 at p. 2) NEEA suggested that the envelope metric should be a U-factor (which is a characterization of the heat loss performance). (NEEA, No. 0061.1 at p. 7) A comment submitted jointly by SCE, SDG&E, PG&E, and SMUD, hereafter referred to as the Joint Utilities, suggested an area-based conductance metric for the envelope that would consider both opaque and transparent surfaces. (The Joint Utilities, No. 0059.1 at p. 2) NRDC also suggested a metric for refrigeration systems that would encompass the total equivalent warming impact and measure the heat loads from refrigeration systems impacting a building's heating, ventilation, and air conditioning (HVAC) system. (NRDC, No. 0064.1 at p. 8) A comment submitted jointly by ACEEE, ASAP, ASE, NRDC, NEEP, and NEEA on the September 2010 SNOPR (hereafter referred to as The Joint SNOPR comment) stated that the energy conservation standard for envelopes should be the overall heat gain (U-overall) with separate standards for walk-in coolers and walk-in freezers. (Joint SNOPR Comment, No. 0074.1 at p. 2)

While other interested parties suggested specific metrics for walk-in components, manufacturers also offered suggestions for overall walk-in metrics. Craig Industries recommended combining the envelope and refrigeration calculations to calculate the overall efficiency of the complete walk-in system and labeling each walk-in with that efficiency metric. (Craig, No. 0068.1 at p. 6) Zero Zone stated that the test procedure should include performance testing to verify adequate temperatures inside the walk-in. (Zero Zone, No. 0077.1 at p. 1)

In view of the component-level approach being adopted today, DOE is not establishing an overall energy use metric for the envelope in this test procedure. Instead, DOE is establishing separate metrics for the individual components of the walk-in: the wall and ceiling panels (hereafter referred to as non-floor panels); floor panels; the display and non-display doors; and the refrigeration system. Regarding Zero Zone's suggestion that the procedure verify that adequate internal temperatures are used in evaluating a walk-in unit's efficiency, DOE does not believe that such a requirement is necessary in light of the component-based approach being adopted today.

The panel metric determined by the test procedure accounts for the conductance and is in terms of U-factor (that is, the thermal transmittance) measured in Btu/h-ft^2-°F, as NEEA, the Joint SNOPR Comment, and the Joint Utilities recommended. The metric for display and non-display doors accounts for the thermal transmittance through the door and the electricity use of any electrical components associated with the door, and is in terms of energy use, measured in kWh/day. DOE believes that requiring separate metrics for specific individual walk-in components does not constitute a substantive change from what was proposed in the September 2010 SNOPR because this Final Rule only requires tests that were proposed for components in the September 2010 SNOPR. Also, the September 2010 SNOPR and this final rule contain similar calculation methodologies.

2. Responsibility for Testing and Compliance

DOE proposed to adopt separate tests for the envelope and refrigeration system of a walk-in and require the manufacturers of each to test and certify the part they manufacture. 75 FR 186, 191 (Jan. 4, 2010) and 75 FR 55068, 55070 (Sept. 9, 2010). In response to this proposed approach, DOE received multiple comments regarding who should assume testing, certification, and compliance responsibilities. The Joint SNOPR Comment recommended that DOE focus on factory-produced products (*i.e.* kits) instead of walk-ins that are assembled on-site from components from different manufacturers. (Joint SNOPR Comment, No. 0074.1 at p. 1) The Joint SNOPR Comment further suggested that panel, refrigeration system, and door manufacturers each be responsible for compliance and certification responsibilities for their own products. (Joint SNOPR Comment, No. 0074.1 at pp. 2–3) Thermo-Kool agreed with this approach and submitted a copy of a regulatory framework proposed by NEEA, in which envelope, door, and refrigeration manufacturers would be responsible for testing and complying with the standards for the components they manufacture. (Thermo-Kool, No. 0072.1 at p. 1)

DOE received several other comments which it summarized in the certification, compliance, and enforcement (CCE) final rule, published on March 7, 2011. 76 FR 12422, 12444. In brief, some of those comments agreed with the approach suggested by the Joint SNOPR Comment and Thermo-Kool that individual component manufacturers should test, certify, and ensure compliance of their respective components. Other commenters recommended that the manufacturer, the assembler, or the system designer of the overall walk-in should be responsible for the compliance of the walk-in with the standards. 76 FR 12442–12446.

In the CCE final rule, DOE addressed these comments by defining the manufacturer of a walk-in at 10 CFR 431.302. 76 FR 12504.

The definition extends the compliance responsibility to both the component manufacturer and the assembler. In the CCE final rule, DOE clarified that component manufacturers would be the entity responsible for certifying compliance of the components they manufacture for walk-in applications and ensuring compliance with the applicable Federal standards of those components. Assemblers of the complete walk-in system are required to use only components that are certified to meet the applicable Federal standards. DOE also adopted a flexible enforcement framework in which it will determine who is responsible for noncompliance on a case-by-case basis. 76 FR 12444.

DOE notes that the provisions and clarifications in the CCE final rule were made in the context of component manufacturers certifying their components to the existing standards in EPCA, which prescribe requirements on a component-level basis. DOE has decided to continue this approach in developing test procedures and performance-based standards for walk-in coolers and freezers. DOE believes that, within the very limited context of walk in equipment, EPCA created a means for DOE to set performance-based standards for certain walk-in component manufacturers. In particular, because Congress set requirements for specific components used in walk-in applications, it provided DOE with the implicit authority to set performance-based standards at the component level for these specific components. This unique ability stems from the manner in which Congress set standards for walk-in equipment by prescribing, among

other things, specific performance-based requirements for wall, ceiling, door, and floor insulation panels used in walk-ins. *See* 42 U.S.C. 6313(f).

Because interested parties, including entities who produce these components and are subject to today's requirements, have indicated to DOE that the energy efficiency performance of WICF components would be most readily and easily tested and certified by component manufacturers, DOE intends to take this approach for WICF test procedures and performance standards. DOE acknowledges the numerous difficulties that commenters have noted with alternative proposed approaches. By requiring individual component manufacturers to certify that their components satisfy specified performance-based standards, DOE can ease the overall burden on walk-in manufacturers relative to the alternatives that were under consideration as part of the January 2010 NOPR and September 2010 SNOPR. Therefore, in this test procedure, DOE is establishing tests for the components of a walk-in (*i.e.* panels, doors, and refrigeration systems) and anticipates that component manufacturers will test their equipment using the applicable procedure and, in the future, will certify that they comply with the appropriate standard. DOE emphasizes that until performance standards are established, manufacturers are not required to use this test procedure to certify equipment to DOE (although they must use this test procedure in making representations as to the performance of their components). However, because the prescriptive standards established by the 2007 amendments to EPCA are already in effect, manufacturers must demonstrate compliance with them using the method specified in the CCE final rule. 76 FR 12422.

3. Basic Model

DOE proposed a definition of basic model for both envelopes and refrigeration systems. 75 FR 186, 188–189 (Jan. 4, 2010) and 75 FR 55068, 55071–55073 (Sept. 9, 2010). DOE received comments from interested parties on the definition and summarized them in the CCE final rule. 76 FR 12422. Consistent with its component-level approach to certification, discussed in section III.A.2, and taking the comments from interested parties into consideration, DOE decided to define a basic model for each of the key components of a walk-in, rather than defining a basic model for the entire walk-in. DOE emphasized that although the term "basic model" is defined on the component level, it is still implemented in the same manner as it is in the rest of DOE's appliance standards program; that is, a basic model consists of equipment that is essentially the same with respect to energy consumption, efficiency, or other measure of performance. 76 FR 12444–12446.

DOE provided, in relevant part, the definition of basic model in the CCE final rule at 76 FR 12504 (providing definition of "basic model" for walk-ins) (to be codified at 10 CFR 431.302).

DOE believes applying the basic model concept at the component level will reduce the testing burden on manufacturers while ensuring that their products meet any applicable standard, because it removes the difficulty of testing and/or certifying different sized walk-ins that would have different energy consumption levels. 76 FR 12445. The CCE final rule provides that manufacturers may elect to group individual models into basic models at their discretion to the extent the models have essentially identical characteristics that affect energy efficiency or energy consumption. Manufacturers may also rate models conservatively—i.e. the tested performance of the model(s) must be at least as good as the certified rating—after applying the appropriate sampling plan. 76 FR 12429. The basic model concept is applied slightly differently to panels, doors, and refrigeration systems because of their different characteristics. These differences are explained below.

a. Basic Model of Panels

Panels are construction components that are not doors and that are used to construct the envelope of the walk-in. These components comprise the elements separating the interior refrigerated environment of the walk-in from the exterior environment. In this test procedure, panels are classified as either floor panels, non-floor panels, or display panels. A display panel is a panel that is entirely or partially comprised of glass, a transparent material, or both and is used for display purposes. Floor and non-floor panels are mostly comprised of insulating material and are not primarily used for display purposes. For all types of panels, the energy efficiency metric is the U-factor, which is a measure of conductive, convective, and radiative heat transfer and which takes into account composite panel characteristics, which may include the insulation type, structural members, any type of transparent material (*e.g.* glass), and panel thickness. See section III.B.2 for details on how the U-factor is determined. DOE considers a panel basic model to include panels which do not have any differing features or characteristics that affect the U-factor. 76 FR 12504.

DOE notes that manufacturers who make customized panels may experience a higher certification burden than manufacturers of standardized panels. For example, under today's procedure, a panel's U-factor is a surface area-independent metric, which implies that variation in panel width and height alone would not be expected to affect the U-factor rating if all other characteristics were equal. In those instances where no changes in energy efficiency would occur, these panels could be grouped as a basic model. In contrast, smaller floor and non-floor panels may have a higher proportion of framing material to non-framing material, or other structural members, which could affect the overall panel U-factor rating if the framing material or framing geometry has different thermal conductivity performance than the neighboring insulation. Therefore, for two or more floor or non-floor panels that are equivalent in materials and other characteristics but differ in their frame to insulation proportions such that they have different U-factor ratings, the panels would be considered different basic models and would need to be certified independently to DOE, if the manufacturer chooses to claim different U-factor ratings. However, DOE emphasizes that as explained in section III.3, manufacturers may group models into basic models at their discretion as long as the tested performance of the models is at least as good as the certified rating.

DOE has also introduced additional provisions to reduce the testing and certification burden on floor and non-floor panel manufacturers. See section III.B.2.a for details.

As explained above, the energy efficiency metric for display panels is the U-factor, as for floor and non-floor panels. However, unlike a floor, ceiling, or wall panel, a display panel is essentially a window. Therefore, in this test procedure, DOE is requiring the U-factor of display panels to be tested using NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors," which DOE proposed in the SNOPR for measuring the U-factor of doors and windows, including their framing materials. 75 FR 55083. (Sept. 9, 2010) As with floor and non-floor panels, the basic model concept allows manufacturers to group display panels that are essentially identical in U-factor into one basic model, which DOE anticipates will reduce the testing burden on display

panel manufacturers. Also, NFRC 100–2010[E0A1] allows verified computer models to simulate a display panel's energy consumption, another factor that reduces the manufacturer's testing burden.

b. Basic Model of Doors

A door is an assembly installed in an opening on an interior or exterior wall that is used to allow access or close off the opening and that is movable in a sliding, pivoting, hinged, or revolving manner of movement. For walk-in coolers and walk-in freezers, a door includes the door panel, glass, framing materials, door plug, mullion, and any other elements that form the door or part of its connection to the wall. This test procedure defines two types of doors, display and non-display doors. Display doors are doors designed for product movement, display, or both, rather than the passage of persons, and non-display doors are considered to be all other types of doors. For all doors, the energy consumption metric that DOE is adopting in today's rule incorporates the U-factor and any electrical components built into the door. (See section I.A.1.a for details.) Calculating this metric requires the use of NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors," which DOE proposed in the SNOPR for measuring the U-factor of doors and windows, including their framing materials. 75 FR 55083. (Sept. 9, 2010) Applying the NFRC test yields an overall U-factor for the tested door. Then, through calculations outlined in Appendix A, the U-factor and the electrical energy consumption are combined to create a rating for the door.

As with panels, doors with essentially identical energy consumption levels may be grouped into a basic model and rated conservatively. 76 FR 12429 and 12504. The basic model concept can be used to reduce the testing and certification burdens by allowing manufacturers to group doors that are essentially identical in energy consumption but cosmetically different. The NFRC procedure also permits either a physical test or a verified computer model to be used when determining the U-factor of the door. The latter of these options would be expected to reduce testing burden because only a series of calculations would need to be run by an NFRC-approved computer modeling program. DOE also notes that the calculations for energy consumption of door components are not based on testing, which reduces the general testing burden for doors. Any results from physical tests, computer simulations, and calculations must be retained as required by the CCE final rule. 76 FR 12494.

c. Basic Model of Refrigeration Systems

The refrigeration system consists primarily of a compressor, condenser, unit cooler, valves, and piping. It is considered a component under the component level approach (*see* section III.A) that DOE is adopting in today's final rule. As with the panels and doors, and consistent with the approach promulgated in the CCE final rule, manufacturers may elect to group individual models into basic models at their discretion to the extent the models have essentially identical electrical, physical, and functional characteristics that affect energy efficiency or energy consumption. Furthermore, manufacturers may rate models conservatively, meaning the tested performance of the model(s) must be at least as good as the certified rating, after applying the appropriate sampling plan. 76 FR 12429. DOE believes these provisions will reduce the burden of testing for refrigeration manufacturers, including those who make customized equipment. DOE may also consider methods which allow manufacturers to use an alternate method of determining the energy use of the refrigeration system in a future rulemaking. This concept is further discussed in section III.C.3.

B. Test Procedures for Envelope Components

The envelope consists of the insulated box in which items are stored and refrigerated. In the NOPR and SNOPR, DOE proposed methods for evaluating the performance characteristics of insulation, testing thermal energy gains related to air infiltration, and determining direct electricity use and heat gain due to internal electrical components. The proposed procedure used these methods to determine the energy use associated with the envelope by calculating the effect of the envelope's characteristics and components on the energy consumption of the walk-in as a whole. Those characteristics and components included the energy consumption of electrical components present in the envelope (such as lights) and variation in the energy consumption of the refrigeration system due to heat loads introduced as a function of envelope performance (such as conduction of heat through the walls of the envelope). The impact on the refrigeration system energy consumption was determined by calculating the energy consumption of a theoretical or "nominal" refrigeration system when paired with the tested envelope. 75 FR 186, 191 (Jan. 4, 2010) and 75 FR 55068, 55074 (Sept. 9, 2010).

As described in section III.A, DOE is no longer requiring manufacturers to determine the energy consumption of the entire envelope in this final rule. Rather, DOE is establishing metrics for the principal components of the envelope (*i.e.* the panels and doors) as described in section III.A.1. In doing so, DOE is requiring manufacturers to use the same physical tests for the components that it proposed in the NOPR and SNOPR, but is introducing revisions to the calculations in Appendix A of the new procedure. These revisions will enable manufacturers to calculate the required component metrics from the results of those tests.

For panels, DOE is adopting separate approaches depending on whether a given panel is a display or non-display panel. Display panels are panels that are primarily made of transparent material and used for display purposes. Display panels are considered equivalent to windows because of their transparent characteristics and associated thermal heat transfer properties, and therefore the U-factor will be measured by NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors," which DOE proposed in the SNOPR for measuring the U-factor of doors and windows, including their framing materials. 75 FR 55083. (Sept. 9, 2010) Non-display panels are floor and non-floor panels. Since both floor and non-floor panels are typically made out of a composite of insulation, framing, and facer material, both types of panels will be tested using the same methodology. In today's rule, the physical tests pertaining to the performance of non-display panels are from ASTM C1363–05, "Standard Test Method for Thermal Performance of Building Materials and Envelope Assemblies by Means of a Hot Box Apparatus" and, for foams that experience aging, DIN EN 13164:2009–02, "Thermal insulation products for buildings—Factory made products of extruded polystyrene foam (XPS)—Specification" or DIN EN 13165:2009–02, "Thermal insulation products for buildings—Factory made rigid polyurethane foam (PUR) products—Specification," as applicable. These tests were proposed in the SNOPR. 75 FR 55068, 55075–55076 and 55081 (Sept. 9, 2010). In this final rule, panel performance is denoted by its overall U-factor, or thermal transmittance, which is determined by the test procedures and calculation methodologies described in section III.B.2.

DOE is requiring one test for door performance, NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors," which was proposed in the SNOPR. 75 FR 55083 (Sept. 9, 2010). This test measures conduction through a door, whether it is a display door or a non-display door. The total energy consumption of a door is calculated as the effect of a door's thermal load on the refrigeration system combined with the door's electrical energy use, as described in section 4.5 and section 4.4 of Appendix A of this final rule. The effect on the refrigeration system is determined by calculating the energy consumption that a theoretical or "nominal" refrigeration system would use to reject the heat that was transmitted through the door. The energy that would be used by the theoretical refrigeration system to reject a given amount of heat is represented by the energy efficiency ratio (EER) of the refrigeration system. The test procedure uses the same nominal refrigeration system EER for all tested doors to enable direct comparisons of the performance of walk-in doors across a range of sizes, product classes, and features. The nominal EER values for cooler and freezer refrigeration (i.e. 12.4 Btu/W-h and 6.3 Btu/W-h for coolers and freezers, respectively) are the same as those proposed in the SNOPR for calculating the energy use of the envelope. See 75 FR 55013 (Sept. 9, 2010).

1. Definition of Envelope

In the January 2010 NOPR, DOE proposed the following definition of "envelope:"

> Envelope means (1) a piece of equipment that is the portion of a walk-in cooler or walk-in freezer that isolates the interior, refrigerated environment from the ambient, external environment; and (2) all energy-consuming components of the walk-in cooler or walk-in freezer that are not part of its refrigeration system.

75 FR 186, 192 (Jan. 4, 2010).

The walk-in envelope was proposed to include, but not be limited to, walls, floors, ceilings, seals, windows, doors, or any combination thereof, composed of single or composite materials. DOE did not propose any changes to this definition in the September 2010 SNOPR.

Master-Bilt, BASF, ThermalRite, ACEEE, and ICS submitted written comments supporting the proposed definition for the walk-in envelope. (Master-Bilt, No. 0027.1 at p. 1; BASF, No. 0021.1 at p. 3; ThermalRite, No. 0049.1 at p. 1; ACEEE, No. 0052.1 at p. 2; ICS, No. 0045.1 at p. 1) However, Nor-Lake asked that the definition of envelope exclude components of the envelope purchased separately by the end user to enable the manufacturer of the envelope to avoid compliance responsibility for the performance of those components. (Nor-Lake, No. 0023.1 at p. 2) ICS requested clarification on the preemption of energy codes by building, electrical, and mechanical codes and stated that the definition must allow for structural and electrical safety code compliance over energy compliance when in conflict. (ICS, No. 0045.1 at p. 1) A representative from Gonzaga Law argued that the definition proposed by the DOE was too inclusive but did not propose an alternative definition. (Gonzaga Law, No. 0018 at p. 1) At the public meeting for the January 2010 NOPR, ICS suggested that DOE's standards and definitions should align with NSF's (formerly known as the National Sanitation Foundation) definition of envelope and requirements. (ICS, Public Meeting Transcript, 0016 at p. 30) (In this and subsequent citations, "Public Meeting Transcript" refers to the transcript of the March 1, 2010, public meeting on the proposed test procedures for walk-in coolers and freezers. "No. 0016" refers to the document number of the transcript in the Docket for the DOE rulemaking on test procedures for walk-in coolers and freezers, Docket No. EERE–2008–BT–TP–0014; and the page number refers to the place in the transcript where the statement preceding appears.)

DOE notes the comments and suggestions from Master-Bilt, BASF, ThermalRite, ACEEE, ICS, and Gonzaga Law. However, because DOE is taking a component-based approach, the proposed envelope definition is no longer applicable for the purpose of this test procedure. As suggested by ICS, when evaluating potential standards applicable to walk-ins, DOE will also consider their related requirements that manufacturers need to satisfy. In response to Nor-Lake's comment regarding components not supplied by the envelope manufacturer, DOE clarifies that each component manufacturer is responsible for testing its component with the appropriate test procedure as discussed in section III.A.2. The envelope component manufacturer is not responsible for the end user's implementation of the component; rather, the manufacturer would be responsible only for the component's compliance as designed. Also, the envelope assembler is responsible for using WICF-compliant components to assemble the total envelope.

2. Heat Transfer through Panels

a. U-Factor of Composite Panels Including Structural Members of Panels

EPCA specifies that ASTM C518–04, "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus," must be used to determine the K-factor of walk-in insulation. The statute defines the R-value as equal to the value of 1/K-factor multiplied by the thickness of the panel. (42 U.S.C. 6314 (a)(9)(A)(i) – (ii)) In response to the January 2010 NOPR, interested parties commented that the heat conduction through structural members must be considered because this factor could affect the conductance through the composite walk-in insulation panel. Accordingly, DOE proposed in the September 2010 SNOPR to use ASTM C1363–05, "Standard Test Method for Thermal Performance of Building Materials and Envelope Assemblies by Means of a Hot Box Apparatus," to measure the overall U-factor of fully assembled panels to help account for the impact that structural members have on the overall U-factor. 75 FR 55074.

Several interested parties—NEEA, AHRI, Master-Bilt, Thermo-Kool, Carpenter, and Bally—supported the use of ASTM C1363–05 to measure the overall panel U-factor. (NEEA, No. 0061.1 at p. 2; AHRI, No. 0070.1 at p. 2; Master-Bilt, No. 0069.1 at p. 1; Thermo-Kool, No. 0072.1 at p. 1; Carpenter, No. 0070.1 at p.2; Bally, No. 0078.1 at p. 2))

Other interested parties, however, disagreed with DOE's proposal to use ASTM C1363–05 to measure panel performance. At least some of these concerns were premised on a mistaken belief that DOE's proposal would result in the elimination of structural members embedded into panels. For example, a comment submitted jointly by the manufacturers CrownTonka, ThermalRite, and ICS (collectively referred to as the Joint Manufacturers) recommended that structural members be excluded from the stated R-value requirements for overall envelope thermal resistance. The Joint Manufacturers explained that many walk-ins require the use of structural members to comply with building codes and to help support loads placed on the building from factors such as snow and wind. The Joint Manufacturers stated that ASTM C518–04 should be used to measure the K-factor of foam, as specified in EPCA. (42 U.S.C. 6314 (a)(9)(A)(i)–(ii)) (Joint Manufacturers, No. 0062.1 at p. 1)

While American Panel agreed with DOE's general approach that the R-value

of structural members should be considered in determining the overall U-factor and submit data to demonstrate the impact of structural members on the overall U-factor, it stated that the composite panel must meet the minimum R-value requirement. American Panel continued to state that the R-value should be calculated by using a weighted percentage of foam R-value and structural R-value based on the percentage each material represents in the panel. (American Panel, No. 0057.1 at p. 1; American Panel, No. 0057.1 at p. 2; American Panel, No. 0057.3 at p. 1) It asserted that ASTM C1363–05 is not the appropriate test method for measuring the insulating values of foam, and added, along with Craig Industries and Carpenter, that ASTM C518–04 should be used to measure heat conduction through panels. (American Panel, No. 0057.1 at p. 2; Craig, No. 0068.1 at p. 2; Carpenter, No. 0067.1 at p. 2) Craig Industries was concerned that using ASTM C1363–05 to calculate the heat conduction through structural members may not take the reduction of joints (that is, panel to panel interfacing members) into consideration. Craig Industries recommended that the structural members should be tested with a procedure to represent the real R-value, which would replace the R-value of the insulation where it is replaced with structural members. (Craig, No. 0057.13 at p. 2) Carpenter further asserted that ASTM C518–04 is simpler and less costly to perform than C1363–05. (Carpenter, No. 0067.1 at p. 2) Thermo-Kool, on the other hand, disagreed with the approach of using R-value testing of different components of the composite panel to determine heat loss. (Thermo-Kool, No. 0072.1 at p. 1) Bally, who agreed with DOE's proposed approach, requested clarification specifically regarding how the two tested areas would be used to represent the performance of a panel. (Bally, No. 0078.1 at p. 2)

None of the interested parties offered any further explanation for their views other than those already described.

In this final rule, the terms "foam" and "insulation" are used synonymously, but a panel is the fully manufactured product that contains, but is not limited to, the insulating material, metal skin, framing material, other structural members, or any combination thereof. To address the Joint Manufacturers' concerns about the potential elimination of structural members, DOE emphasizes that the overall U-factor testing required by today's final rule will not prevent manufacturers from including structural members in panels because the existing standards in EPCA only regulate the R-value of the foam and do not restrict the overall panel U-factor or the R-value of the structural components. The R-value of insulation, which is 1/K-factor as determined by ASTM C518–04, will still have to comply with the existing EPCA requirements for insulation. (42 U.S.C. 6314 (a)(9)(A)(i)–(ii)) However, the overall U-factor of the fully assembled panel, including structural members, may be used to meet an energy conservation standard for panels, which will be determined in a parallel rulemaking. Including ASTM C1363–05 will provide a more accurate means to represent the overall heat transfer performance of panels. DOE believes this procedure will be beneficial because it will capture the effects of structural members that incorporate insulation or otherwise contribute to the efficiency of the walk-in.

Additionally, while DOE acknowledges the concerns raised by American Panel, the Joint Manufacturers, Craig Industries, and Carpenter, the final rule includes ASTM C1363–05 as part of the test procedure in order to determine the overall U-factor of the panel. DOE is including this protocol as part of the test procedure because heat conduction through structural members is a significant panel characteristic that is not addressed under the statutorily-prescribed testing requirements (i.e. ASTM C518–04). While ASTM C518–04 could be used to individually measure the R-value of structural members, or any other material, as Craig Industries suggested, DOE believes that this approach would be more costly because of the many materials that could comprise a panel and the need to test each material separately under that approach. Furthermore, DOE believes that panel geometry could make calculations to combine the R-value of each material into an overall panel R-value complicated and burdensome.

DOE also acknowledges Craig Industries' concern that ASTM C1363–05 does not account for the reduction of joints (that is, panel to panel interfacing members). Since DOE is adopting an approach to ensure the energy efficiency performance of particular components, an approach suggested by numerous commenters, and is no longer considering the effects of infiltration, panel joint issues are outside of this approach.

DOE notes that American Panel supported the inclusion of structural members in calculating the overall U-factor. Furthermore, DOE would like to clarify the calculation methodology to address the comment from Bally. Today's final rule adopts a weighted percentage of the panel edge (which may contain structural members) and panel core region (which may also include structural members) in order to calculate the panel's total U-factor. DOE believes that using the weighted percentage of edge U-factor and core U-factor to calculate the total U-factor will help reduce the manufacturer's testing burden.

In applying this weighted percentage approach, today's final rule provides that for floor or non-floor panels of the same thickness, construction methods, and materials, manufacturers must test a pair of 4 ft. by 8 ft. "test panels" to obtain a core U-factor and an edge U-factor. The manufacturer must then calculate the overall U-factor of other floor or non-floor panels with the same panel thickness, construction methods, and materials using the U-factor results for the core and edge region "test panels." For example, a manufacturer tests a 4 ft. by 8 ft. test panel and finds the edge region and core region U-factors. The same manufacturer also produces 6 ft. by 8 ft. panels that have identical core and edge region thickness, construction methods and materials. Therefore, the manufacturer may apply the core and edge region factors to the 6 ft. by 8 ft. panel to calculate the overall U-factor of the 6 ft. by 8 ft. panel instead of performing an additional test. DOE notes that any calculations that support the certified ratings must be retained along with the test data for the "test panels" for all basic models pursuant to the requirements for the maintenance of records promulgated in the CCE final rule. 76 FR 12494. DOE expects that, based on the information it has collected, including information made available by manufacturers on their Web sites and submitted comments, most manufacturers use the same panel thickness, materials, and construction methods for many of their panels, which results in a minimal testing burden.

In regard to American Panel's comment that the composite panel must meet the minimum R-value requirement, DOE clarifies that EPCA states that only the insulation material (that is, the foam) must meet the prescribed R-value. (42 U.S.C. 6313(f)(1)(C)) The test procedure is prescribing ASTM C1363–05 as a method of measuring the overall U-factor of the entire panel. For EPCA compliance, the R-value of the insulation must be separately determined in accordance with ASTM C518–04 as specified in EPCA. (42 U.S.C. 6313(f)(1)(C))

Finally, interested parties suggested changes to the test methodology DOE proposed. NRDC stated that irregular or non-homogeneous foam products should be tested for actual R-value where there is no quality control to maintain the orientation of the foam in the finished product. To clarify, DOE believes that when NRDC noted the concern about the orientation of the foam, they were referring to bun-stock foam products. Bun-stock products are manufactured in "buns" that may have foam cell structure similar to the grains in wood. Like wood, depending on how the buns are cut into boards, the orientation of the cell "grains" may vary by finished board. NRDC continued to suggest that if a foam product cannot be tested, then the stated R-value should be a conservative number representing the lowest R-value for a tested material. (NRDC, No. 0064.1 at p. 4) NRDC also suggested that DOE review the impact of testing the final fabricated panel rather than requiring manufacturers to specially construct units for testing, because specially constructed units may not represent the typical product. (NRDC, No. 0064.1 at p. 4) Master-Bilt suggested changing the width and length of the panel to 8 x 4 ft. +/- 1 ft. to have more tolerance and allow for the testing of standard width panels. (Master-Bilt, No. 0069.1 at p. 2)

In response to NRDC's comment about irregular or non-homogeneous foam products, DOE anticipates that the prescribed sampling procedures for certification will accurately capture the foam's R-value. A sampling plan is intended to ensure accurate and statistically repeatable results are achieved when using the test procedure. DOE notes NRDC's concern that specifically constructed units may not represent an actual product. However, in order to reduce the testing burden presented by ASTM C1365–05, DOE is maintaining the approach of specifying two test regions of a pair of representative panels. At one test region, the tester measures the U-factor of the perimeter that may contain structural members and panel-to-panel interface area (the "Panel Edge"), while at the other region the tester measures the U-factor of the core area of the panel (the "Panel Core") which may also contain structural members. The U-factor for each region is then applied to panels of the same type (that is, same foam type, framing material, and panel thickness) to obtain an overall U-factor that is representative of actual products sold by the panel manufacturer. DOE applies a calculation methodology to extrapolate the core and edge U-factor to determine the U-factor of any panel produced by a manufacturer.

In response to Master-Bilt's comment, DOE agrees that increasing the tolerance of the 8 ft x 4 ft test panel to +/− 1 ft will provide manufacturers with a greater range of standard sized panels. DOE conducted a mathematical analysis to determine how changing the tolerance would affect the U-factor as determined by ASTM C1363–05. DOE found that increasing the size tolerance of the test panel results in less than a 0.5 percent change to the U-factor as determined by ASTM C1363–05. Therefore, DOE has amended the standard size of a test panel for ASTM C1363–05 to be 8 ft x 4 ft +/− 1 ft.

b. Long-Term Thermal Resistance

In the January 2010 NOPR and September 2010 SNOPR, DOE cited several studies that conclude that lateral gas diffusion, which causes a reduction in R-value, occurs in impermeably faced foams. See 75 FR 192–194 and 75 FR 55075–55079. These types of foams are common to walk-ins. The lateral gas diffusion occurs over time and affects the energy efficiency performance of the foam as diffusion continues. To account for this aging effect on a foam's insulation performance—and, by extension, the energy consumption of a walk-in due to thermal losses attributable to this reduced performance—DOE, consistent with its proposed approach, is adopting a method to account for this phenomenon in walk-in applications. Hill Phoenix added that different methods of manufacturing panels should be taken into account when determining the test procedure. (Hill Phoenix, No. 0063.1 at p. 2)

The most significant factor affecting the efficiency of a walk-in panel is the insulating foam in a panel, and accurately capturing the foam's R-value is critical to measuring the overall performance of the panel. Panels can be in use for 10 to 20 or more years before they are replaced. Performance metrics for a panel based on initial foam R-value will tend to overestimate the amount of energy saved over this equipment's lifetime. Research on panel aging has shown that a 5-year aged R-value found by LTTR testing is representative of the panel's insulation performance over its lifetime, and there are industry tests for walk-in foam that estimate the aged R-value over time. Using these industry-developed protocols will enable manufacturers to more accurately capture the lifetime performance of a walk-in panel.

Incorporating a long term thermal resistance degradation factor improves the reliability of test results for walk-in panels. While EPCA contains standards for the R-value or insulating performance of the foam, these standards do not specify when the insulating foam must be tested. (42 U.S.C. 6313(f)(1)(C)) Variables that impact the time at which panels are tested include shipping time, production time, shipment of completed panels to test lab, and test facility availability. Changing any one of these variables could result in significantly different test results and measured R-values. This is in contrast to most other types of equipment within the appliance standards program, which would not exhibit significant differences in performance based on the length of time between manufacture and testing. Because of the unique aging profile of certain foam types, the timing of a walk-in panel test would affect both manufacturers' certification of the panel U-factors and any enforcement testing undertaken by DOE. Therefore, using LTTR values to measure foam performance eliminates the "time" variable that could affect whether a panel is shown to comply with an overall performance standard that DOE may set. The purpose of the LTTR testing is to accelerate foam aging to the point where the R-value changes relatively slowly over time and to then measure its performance, thus improving the repeatability of the test because the timing of the test is no longer critical.

In the January 2010 NOPR, DOE proposed to use ASTM C1303–08, "Standard Test Method for Predicting Long-Term Thermal Resistance of Closed-Cell Foam Insulation," to calculate the long-term thermal resistance (LTTR) of walk-in foam insulation. 75 FR 186, 193–94 (Jan. 4, 2010). In the September 2010 SNOPR, DOE proposed to use the updated version of ASTM C1303–08, which was ASTM C1303–10. 75 FR 55068, 55075 (Sept. 9, 2010). In that notice, DOE also offered an alternative method, Annex C of either DIN EN 13164:2009–02, "Thermal insulation products for buildings— Factory made products of extruded polystyrene foam (XPS)—Specification" or DIN EN 13165:2009–02, "Thermal insulation products for buildings—Factory made rigid polyurethane foam (PUR) products—Specification," as applicable, to test for the LTTR. This alternative was offered in response to concerns raised in response to the NOPR. The SNOPR requested comments on both of these alternative methods. 75 FR 55079 (Sept. 9, 2010).

In light of the comments that DOE received on all of these various testing methods, which are addressed below, DOE has decided to adopt DIN EN 13165:2009–02 or DIN EN 13164:2009–02, as applicable, as the test procedure for determining LTTR. The LTTR value determined by DIN EN 13165:2009–02 or DIN EN 13164:2009–02 will be used to determine a degradation factor, which will be the LTTR R-value divided by the initial R-value of the foam. The initial R-value will be determined in accordance with ASTM C518–04 as specified in the EISA 2007 amendments to EPCA and used to establish compliance with those statutorily-prescribed requirements. (42 U.S.C. 6313(f)(1)(C)) The degradation factor is applied to the U-factor of the panel found by ASTM C1365–05; see section 4.2 and 4.3 in Appendix A.These protocols are preferable to ASTM C1303–10 because they account for the effect of impermeable facers, which ASTM C1303–10 does not.

In response to this approach, DOE received a number of comments. Thermo-Kool noted the general need to consider LTTR. It also suggested that the potential for thermal degradation is more likely to occur at the panel joints than from actual polyurethane (*i.e.* foam) issues. (Thermo-Kool, 0072.1 at p. 1) The Joint Manufacturers recommended that structural members be considered in the long-term thermal resistance performance of any panels with structural edges because they may lessen or slow off-gassing over time. (The Joint Manufacturers, No. 0062.1 at p. 1).

American Panel and Bally opposed DOE's inclusion of a test procedure that measured LTTR. (American Panel, No. 0057.2 at p. 1; Bally, No. 0078.1 at p. 2) American Panel explained that impermeable or metal skins protect the polyurethane foam from aging and that little change will occur in the long term R-value. In support of its claim that impermeably faced metal skins protect foam from aging, American Panel submitted the results of a study conducted by Carpenter. That study found a 3.6 percent loss in insulating value of a panel after 9 years in a walk-in application. (American Panel, No. 0057.2 at p. 1) American Panel also asserted that none of its customers complained about R-value loss in the panels that American Panel sold to them. (American Panel, No. 0057.1 at p. 2)

One interested party recommended that DOE collect test data before prescribing a particular test method. Bally stated that more data from actual walk-in panels with intact metal skins and sealed edges should be collected before DOE includes a test procedure for long-term thermal resistance. (Bally, No. 0078.1 at p. 2)

DOE acknowledges Thermo-Kool's assertion that most aging occurs at the panel joints and Bally's suggestion that DOE collect more data to support long term thermal aging. DOE notes, however, that polyurethane itself has the potential to age significantly. DOE cited multiple studies, in both the January 2010 NOPR and September 2010 SNOPR, that conclude that aging occurs in most types of foams commonly used in walk-in applications, including polyurethane. 75 FR 192–194 (Jan. 4, 2010) and 75 FR 55075–55079 (Sept. 9, 2010). In response to the Joint Manufacturers' comment about accounting for the effect structural members have on LTTR, DOE also notes that no known test procedures are available that address edge sealing at this time but that this factor could be considered in a future rulemaking.

DOE also considered the merits of the submissions in support of American Panel's contention that impermeably faced foams do not undergo significant aging. After evaluating this information, however, DOE continues to believe that the inclusion of LTTR testing in the test procedure is necessary to accurately measure the R-value of foam. DOE notes that the samples in the Carpenter study cited by American Panel were taken from the center of the panel. As DOE noted in the SNOPR, another study (the Ottens study, "Industrial Experiences with CO_2 Blown Polyurethane Foams in the Manufacture of Metal Faced Sandwich Panels") found that core samples do not represent the overall aging of foam in panels because most aging occurs at the panel's perimeter. 75 FR 55068, 55077 (Sept. 9, 2010) (citing Ottens *et al.,* "Industrial Experiences with CO_2 Blown Polyurethane Foams in the Manufacture of Metal Faced Sandwich Panels," Polyurethane World, 1997.) As a result, the data from this study indicate that the Carpenter study's results do not necessarily provide an accurate portrayal of the likely effects of panel aging.

Additionally, while American Panel asserted that the lack of customer complaints about R-value loss in panels indicates that the deterioration of LTTR values is insignificant, the lack of customer complaints may be influenced by a variety of factors. For example, a panel is normally only replaced when visibly damaged. However, a panel may have reduced thermal performance without any accompanying visual cues suggesting problems with the panel. Accordingly, DOE does not believe that the statements and materials cited by American Panel support the premise that LTTR of foam is negligible for walk-in panels.

Interested parties also made comments on the specific test methods that DOE proposed. DOE received some comments from interested parties in favor of using ASTM C1303–10 to determine the LTTR of foam insulation. Owens Corning agreed that DOE should use the most current version of whichever ASTM standards it planned to use. (Owens Corning, No. 0058.1 at p. 1) Craig Industries agreed with the use of ATSM C1303–10, but stated that DOE should evaluate if ASTM C1303–10 is appropriate for all present and future foam insulation products. (Craig, No. 0068.1 at p. 4) NRDC supported testing insulated products to determine whether the R-value degraded over time, and stated that the proposed ASTM standard is acceptable and known in the industry. (NRDC, No. 0064.1 at p. 4) NEEA stated that although some interested parties have concerns about LTTR values derived from ASTM C1303–10, NEEA believed that carefully specifying the physical characteristics of the tested panel samples will address their concerns. (NEEA, No. 0061.1 at p. 2)

Some interested parties disapproved of ASTM C1303–10. American Panel, Hill Phoenix, Thermo-Kool, and the Joint Manufacturers opposed using ASTM C1303–10 as the test procedure to measure LTTR. (American Panel, No. 0057.1 at p. 2; Hill Phoenix, No. 0063.1 at p. 2; Thermo-Kool, 0072.1 at p. 1; the Joint Manufacturers, No. 0062.1 at p. 1) American Panel asserted that any testing to determine R-value must allow the foamed-in-place polyurethane to remain encapsulated by the metal facers to resemble the real-world application. (American Panel, No. 0057.1 at p. 2) Hill Phoenix and Thermo-Kool did not recommend the use of ASTM C1303–10 because, as noted in section 1.3 of ASTM C1303–10, the standard does not apply to impermeably faced foams; therefore, applying the results from ASTM C1303–10 to impermeably faced foams would be misleading. Hill Phoenix also suggested that ASTM C1303–10 would significantly overestimate foam aging of foamed-in-place polyurethane panels. (Hill Phoenix, No. 0063.1 at p. 2) The Joint Manufacturers opposed the use of ASTM C1303–10 for measuring long-term R-value decline because it is not intended for use with faced panels and unfairly penalizes foamed-in-place polyurethane that has minimal or zero exposure of permeable surfaces (the Joint Manufacturers, No. 0062.1 at p. 1)

Owens Corning stated that the prescriptive and research methods of ASTM C1303–10 are not comparable and will not generate comparable results. It added that the Canadian test procedure CAN/ULC S770, which is based on various versions of ASTM C1303, has a positive bias and may over-predict foam aging, and submitted foam aging data and an article about the CAN/ULC S770 test to support this comment. (Owens Corning, No. 0058.1 at p. 2; Owens Corning, No. 0058.1 at p. 1; Owens Corning, No. 0058.5 at p. 19; Owens Corning, No. 0058.2 at p. 2)

Carpenter and Master-Bilt also opposed the use of ASTM C1303–10 for LTTR testing and suggested possible alternatives. Carpenter suggested testing initial and aged K-factors per ASTM C518 at 20 °F and 55 °F for freezers and coolers, respectively. (Carpenter, No. 0067.1 at p. 3) Carpenter stated that ASTM C1303–10 would underestimate the LTTR of impermeably faced panels and that LTTR tests should be performed on samples with intact facers. (Carpenter, No. 0067.1 at p. 2) Similarly, Master-Bilt explained that panel edges are not 100 percent exposed, but are tight against one another and sealed with caulk and vinyl gaskets. Collectively, the caulk and gaskets significantly reduce gas migration, thus reducing the effects of aging. Therefore, in its view, the testing of skinned panels with exposed edges still considerably overstates the insulation degradation. Master-Bilt suggested that a formula based on test data from actual walk-in panels that have been installed could be used instead of ASTM C1303–10. (Master-Bilt, No. 0068.1 at p. 2)

DOE agrees with the assessment that ASTM C1303–10 is not adequate for testing impermeably faced foams. DOE believes that the concerns about ASTM C1303–10 expressed by American Panel, Hill Phoenix, Thermo-Kool, Master-Bilt, the Joint Manufacturers, Carpenter, and Owens Corning are addressed by DIN EN 13165:2009–02 and DIN EN 13164:2009–02, which account for impermeably faced foams, reduce the testing burden, and are appropriate for different types of foam. DIN EN 13165:2009–02 and DIN EN 13164:2009–02 partially rely on a formula based on test data, as suggested by Master-Bilt. DOE agrees with Owens Corning that the prescriptive and research methods of ASTM C1303–10 are not comparable, and notes that DIN EN 13165:2009–02 and DIN EN 13164:2009–02 do not have this problem.

One interested party expressed concerns about two of the studies DOE referenced in the September 2010 SNOPR. One study was the Ottens study, in which an experiment was completed on polyurethane foamed-in-place panels to assess their long-term insulating behavior. 75 FR 55068, 55077 (Sept. 9, 2010). (Ottens *et al.*, "Industrial Experiences with CO_2 Blown Polyurethane Foams in the Manufacture of Metal Faced Sandwich Panels," Polyurethane World, 1997.) In the SNOPR, DOE estimated that the test was likely representative of panels aged for at least 5 years. 75 FR at 55077 (Sept. 9, 2010). ORNL challenged this estimate and stated that the results from the Ottens study cannot be correlated to a particular aging period. (ORNL, No. 0060.1 at p. 2)

The second study DOE referenced was a round robin test using CAN/ULC–S770–03, a standard with the same test methodology as a previous version of ASTM C1303. DOE referenced the test to address concerns raised by various interested parties that the thin slicing method, CAN/ULC–S770–03. Results from the round-robin study predicted that polyurethane would perform at a lower level than extruded polystyrene or even at a level as low as expanded polystyrene. 75 FR 55079 (Sept. 9, 2010). ORNL stated the testing used in the referenced study relied on the original version of S770, which has been shown to over-predict thermal resistance. ORNL added that the test was performed on foams created with blowing agents that are no longer used, and the results are not representative of current products. (ORNL, 0060.1 at p. 2)

Regarding ORNL's comment about the Ottens study, DOE agrees that the method in the study cannot be accurately correlated to a particular aging period. However, in DOE's view, the conclusions reached in those studies illustrate that impermeably faced foams are subject to aging. DOE agrees with ORNL's evaluation of the flaws in the round robin test data but notes that the same test was used on each type of foam evaluated, which permits a comparison of the results from each type of tested foam. DOE used the results of the round robin test to demonstrate that there were no performance differences between polyurethane and polystyrene foams—not to predict the level of thermal resistance over time.

Interested parties also commented on the specific testing conditions for ASTM C1303–10. ORNL proposed that, if adopted, ASTM C1303–10 should be modified to allow the user to take multiple 12 inch x 12 inch specimens from the 48 inch x 96 inch panel, at least 12 inches away from the edge of the 48 inch x 96 inch source. (ORNL, No. 0060.1 at p. 2) ORNL suggested specifying the aging conditioning temperatures for foam insulation. ORNL explained that while most insulation foams must follow aging condition requirements, the conditions used to age bun stock foam, which is used in producing foam insulation, may be freely modified. This situation could lead to skewed comparisons between products. (ORNL, No. 0060.1 at p. 2)

Manufacturers also offered views regarding these proposed testing conditions. Craig Industries, Carpenter, and Owens Corning stated that the procedures detailed in ASTM C1303–10 should be conducted at the specified EPCA mean temperatures 55 °F and 20 °F for a cooler and freezer, respectively. (Craig Industries, 0068.1 at p. 4; Carpenter, No. 0067.1 at p. 3; Owens Corning, No. 0058.1 at p. 2) Carpenter also suggested modifying DOE's proposal by adding a provision for molding test panels using unprimed aluminum facers. (Carpenter, No. 0067.1 at p. 3) NRDC asserted that the proposed temperatures for testing insulation needed to be substantiated. (NRDC, 0064.1 at p. 4) Craig Industries asserted that the modifications to ASTM C1303–10 proposed by DOE in the September 2010 SNOPR test were acceptable, but wanted DOE to ensure that the changes would also apply to expanded polystyrene insulation. (Craig Industries, No. 0068.1 at p. 4) Bally suggested that the initial panel size should be changed to 48 inches ± 3 inches and 96 inches ± 2 inches so that a standard panel configuration could be used for the test panel. Bally stated that manufacturers could incur significant costs from manufacturing test panels. (Bally, No. 0078.1 at p. 2)

While DOE appreciates ORNL's and Bally's suggested improvements to ASTM C1303–10, these recommendations are no longer relevant since DOE has decided to adopt DIN EN 13165:2009–02 and DIN EN 13164:2009–02, which collectively address some of the shortcomings of ASTM C1303–10. For example, DIN EN 13165:2009–02 and DIN EN 13164:2009–02 provide for inclusion of metal facers, while ASTM C1303–10 does not. In regard to Bally's concern about the size of the test panel, a test panel is no longer required to be a certain size as long as the panel is large enough for the test sample to be cut from its geometric center, as prescribed in Appendix A. Additionally, given the comments from Craig Industries, Carpenter, Owens Corning, and NRDC about the temperature conditions for testing, DOE has decided to adopt the EPCA mean temperatures of 55 °F and

20 °F for a cooler and freezer, respectively for the DIN EN 13165:2009–09 and DIN EN 13164:2009–02 testing conditions. This means that when a manufacturer tests a panel for LTTR, the manufacturer will determine the initial and aged R-value as specified by DIN EN 13165:2009–09 and DIN EN 13164:2009–02 except the panel will be rated at 55 °F and 20 °F for a cooler and freezer, respectively. By deviating from the temperature condition specified in DIN EN 13165:2009–09 and DIN EN 13164:2009–02, the fixed increment values and safety increment values will be slightly more conservative than the values that would be expected if the LTTR test were performed at the temperature condition specified in DIN EN 13165:2009–09 and DIN EN 13164:2009–02, when applied to freezer panels.

In response to Craig Industries' comment that whatever method is adopted should be applicable to expanded polystyrene foam, DOE notes that the foam aging procedures it proposed are only applicable to foams that rely on low conductivity blowing agents that are intended to stay within the foam for the life of the product. Because it is DOE's understanding that expanded polystyrene foam is not blown with low conductivity blowing agents that are intended to remain in the product for its usable life and does not exhibit long term changes in thermal resistance, these tests would not apply, nor would they be needed to assess the long term thermal resistance of this type of foam.

One commenter did not agree with the proposed use of any of the protocols. Thermo-Kool disagreed with both ASTM C1303–10 and DIN EN 13165:2009–02 and DIN EN 13164:2009–02 because none of these protocols, in its view, is designated for testing composite panels faced with metal skins. (Thermo-Kool, 0072.1 at p. 1) DOE agrees with Thermo-Kool that ASTM C1303–10 was not designed to test panels with metal facers. However, DIN EN 13165:2009–02 and DIN EN 13164:2009–02 were designed to account for metal facers on foam. DIN EN 13165:2009–02 and DIN EN 13164:2009–02 allow all metal skins or facers to remain on the foam during aging and testing. See, e.g., DIN EN 13165:2009–02, Annex C (instructing in relevant part to "select a product sample including any product facing.").

DOE notes that many of the interested parties that opposed using ASTM C1303–10 to measure LTTR supported using DIN EN 13165:2009–02 and DIN EN 13164:2009–02 instead. Carpenter agreed with using DIN EN 13165:2009–02 and DIN EN 13164:2009–02 as an alternative to ASTM C1303–10. (Carpenter, No. 0067.1 at p. 2) Hill Phoenix and AHRI requested more time to review the European test procedure, but Hill Phoenix's initial assessment was that DIN EN 13165:2009–02 was a better option than ASTM C1303–10. (Hill Phoenix, No. 0063.1 at p. 2; AHRI, No. 0070.1 at p. 2) Hill Phoenix added that DOE should adopt test procedures that are appropriate for the insulation materials that could be found in walk-in panels, which DOE interprets to mean that Hill Phoenix is suggesting that DOE adopt both DIN EN 13165:2009–02 and DIN EN 13164:2009–02 if DOE uses these standards instead of ASTM C1303–10. (Hill Phoenix, No. 0063.1 at p. 2) Master-Bilt also stated DIN EN 13165:2009–02 and DIN EN 13164:2009–02 seemed to better account for long-term degradation of foam performance, though they acknowledged they did not fully understand DIN EN 13165:2009–02 and DIN EN 13164:2009–02. (Master-Bilt, No. 0069.1 at p. 2)

Other stakeholders had reservations about DIN EN 13165:2009–02 and DIN EN 13164:2009–02. Craig Industries stated that the alternatives to ASTM C1303–10 may ignore the fact that different plastic foam product insulations in the marketplace respond differently to heat. (Craig Industries, No. 0068.1 at p. 4) It added that DOE should prevent foamed-in-place walk-in manufacturers from picking the most efficient part of the panel for testing. (Craig, No. 0068.1 at p. 4) Owens Corning noted that DIN EN 13165:2009–02 and DIN EN 13164:2009–02 appeared to be material standards and not test methods, and Owens Corning asked for clarification on what the test method would be. (Owens Corning, 0058.1 at p. 1) NRDC suggested that DOE review the proposed standards, ASTM C1303–10, DIN EN 13165:2009–02, and DIN EN 13164:2009–02, to determine which standard yields better results, and what the related testing burden would be to adopt a foreign standard. (NRDC, No. 0064.1 at p. 4)

DOE notes Carpenter's, Hill Phoenix's, AHRI's, and Master-Bilt's approval of DIN EN 13165:2009–02 and DIN EN 13164:2009–02, and in light of the criticisms that DOE has received about ASTM C1303–10 and the support for DIN EN 13165:2009–02 and DIN EN 13164:2009–02, DOE has decided to adopt DIN EN 13165:2009–02 and DIN EN 13164:2009–02 as the test procedure for determining LTTR of polyurethane products and extruded polystyrene products, respectively (polyisocyanurate products are covered by the test for polyurethane products). Today's final rule provides that the LTTR value determined by Annex C of DIN EN 13165:2009–02 or DIN EN 13164:2009–02 shall be used to determine a degradation factor. The degradation factor will be the LTTR R-value divided by the original R-value of the foam. The original R-value of the foam will be tested with ASTM C518–04, as specified by the EISA 2007 amendments to EPCA, and can be used for compliance with the relevant R-value requirement established by those amendments. (42 U.S.C. 6313(f)(1)(C)) The degradation factor is applied to the U-factor of the panel found by ASTM C1365–05; see section 4.2 and 4.3 in Appendix A.

In response to Owens Corning's comment that DIN EN 13165:2009–02 and DIN EN 13164:2009–02 appeared to be material standards and not test methods, DOE notes that Annex C of both DIN EN 13165:2009–02 and DIN EN 13164:2009–02 provide the methodology for testing. DOE also notes Craig Industries' concern about using heat to test for LTTR and NRDC's recommendation that DOE compare the different standards that were proposed; however, DOE believes DIN EN 13165:2009–02 and DIN EN 13164:2009–02 are more accurate and appropriate for assessing the long-term performance of impermeably faced foams used in walk-in coolers and freezers because they permit panels to be tested with their facers, and accounts for impermeably faced foam. Also, to address Craig Industries' concern about manufacturers not all choosing the same part of the panel, DOE is requiring that this test sample should be taken from the geometric center of the test specimen.

DOE is largely incorporating DIN EN 13165:2009–02 and DIN EN 13164:2009–02 except for the requirement that the thermal resistance measurement is conducted at a mean temperature of 10 °C. DOE has decided to adopt the EPCA mean temperatures of 55 °F and 20 °F for a cooler and freezer, respectively for the DIN EN 13165:2009–09 and DIN EN 13164:2009–02 testing conditions. However, the manufacturer will still have to follow any applicable aging conditions prescribed by DIN EN 13165:2009–09 and DIN EN 13164:2009–02. By deviating from the temperature condition specified in DIN EN 13165:2009–09 and DIN EN 13164:2009–02, the fixed increment values and safety increment values will be slightly more conservative than the values that would be expected if the

LTTR test were performed at the temperature condition specified in DIN EN 13165:2009–09 and DIN EN 13164:2009–02, when applied to freezer panels.

c. Moisture Absorption

In the January 2010 NOPR, DOE discussed the possibility of testing the impact of moisture absorption on the R-value of different insulation materials, evaluated various tests developed by ASTM, and reviewed a research paper completed by the U.S. Army Corps of Engineers' Cold Regions Research and Engineering Laboratory (CRREL), which Owens Corning submitted to the docket. (Owens Corning, No. 0054.3 at p. 1) DOE initially concluded that testing the effect of moisture absorption on the R-value of insulation foam would be complex, costly, and time-consuming, and that there was no well-accepted testing method. As a result, DOE proposed that the impact of water absorption on R-value not be included in the test procedure. 75 FR 186, 194 (Jan. 4, 2010).

DOE received many comments from interested parties that supported the inclusion of some means to account for the effect of water infiltration. At the NOPR public meeting, and in several written comments, Craig Industries urged DOE to test for and include the impact of moisture absorption in foam. (Craig Industries, Public Meeting Transcript, No. 0016 at p. 248; Craig Industries, No. 0035.1 at p. 3; Craig Industries, No. 0068.1 at p. 5; Craig Industries, No. 0057.13 at p. 5) ACEEE also stated that it was imperative to include the effect of moisture absorption. (ACEE, No. 0052.1 at p. 2) Kysor maintained that moisture did not affect the R-value of poured-in-place polyurethane, but laminated panels would be severely affected by water because of the water-based glue used to bond the insulation to the metal skins. (Kysor, No. 0053.1 at p. 3)

Some interested parties suggested possible tests and studies that could be used to measure the effect of water absorption. For example, Craig Industries and Owens Corning referred to the CRREL study for information about the performance of various materials with water. (Craig Industries, No. 0054.1 at p. 2; Owens Corning, Public Meeting Transcript, No. 0016 at p. 250) Nor-Lake suggested that an adequate test for water absorption would be ASTM D2842–06, "Standard Test Method for Water Absorption of Rigid Cellular Plastics." (Nor-Lake, No. 0047.1 at p. 3) Owens Corning suggested that ASTM E96, "Standard Test Methods for Water Vapor Transmission of Materials," could be used to test water vapor permeability rates and determine the effect of moisture absorption on foam. (Owens Corning, Public Meeting Transcript, No. 0016 at p. 253; Owens Corning, No. 0048.1 at p. 1; Owens Corning, No. 0032.1 at p. 3) Owens Corning also suggested that ASTM E96 could be used to identify suitable materials for walk-in cooler and walk-in freezer applications. (Owens Corning, No. 0048.1 at p. 1 and No. 0032.1 at p. 3)

Additionally, joint comments filed by SCE, SMUD, SDG&E, and SCG on the January 2010 NOPR, hereafter referred to as the Joint Comment, added that although ASTM E96 produces a conservatively low estimate of moisture permeance at high vapor pressures, DOE should evaluate whether using ASTM E96 is better than not accounting for the effect of moisture on insulating foam. (Joint Comment, No. 0037.1 at p. 11) The Joint Comment added that there may be difficulties in testing and characterizing R-value deterioration in foams due to moisture absorption, but DOE should still consider a requirement for testing vapor permeability. (Joint Comment, No. 0037.1 at p. 1) Owens Corning also stated that, since DOE raised the proposed relative humidity assumption for the test condition from 45 percent to 75 percent in the September 2010 SNOPR, DOE implicitly acknowledged the high humidity conditions present in walk-in cooler and freezer environments, which, in its view, supported the consideration of the impact of moisture on the thermal performance of a walk-in over its lifetime. (Owens Corning, No. 0058.1 at p. 2) ACEEE suggested that because a major threat to moisture control for panels is the integrity of the exterior skin, a minimally intrusive method to determine the impact of moisture absorption would be to assess the vapor diffusion integrity of the sealed panel. (ACEEE, No. 0052.1 at p. 2)

Other interested parties did not support including water absorption in the test procedure. ThermalRite stated that moisture infiltration was unlikely to occur in properly constructed panels, water infiltration would most likely be the result of improper materials or manufacturing, and that moisture infiltration should be considered inconsequential and removed from proposed test procedures. (ThermalRite, No. 0045.1 at p.1; ThermalRite, No. 0045.1 at p. 2; ThermalRite, No. 0049.1 at p.2) ICS commented that water infiltration is related to panel installation and that there were no data to support that moisture infiltration is caused by the walk-in's manufacture or design. (ICS, Public Meeting Transcript, No. 0016 at p. 253; ICS, No. 0045.1 at p. 1) ICS went on to state that, under actual and average usage conditions, water absorption in foam is negligible and it recommended that the impact of moisture absorption should be removed from the proposed test procedure. (ICS, No. 0045.1 at p. 1; ICS, No. 0045.1 at p. 2) Hill Phoenix commented that moisture absorption was not an issue and any moisture issues were generally reported by the walk-in cooler or walk-in freezer user and were quickly repaired. (Hill Phoenix, No. 0041.1 at p. 2) Carpenter agreed with DOE that the impact of water absorption of foam would be difficult to study and quantify, and added that polyurethane foam has an inherently low permeability, which would minimize water absorption. (Carpenter, No. 0043.1 at p. 2) TAFCO concurred that moisture infiltration into polyurethane foam is not an issue, and that it would not cause the R-value to degrade significantly over time. (TAFCO, No. 0040.1 at p. 2) TAFCO also stated that they have installed panels in high-humidity environments and they did not encounter any cases of water absorption by panels. It urged that DOE not pursue this issue further. (TAFCO, No. 0040.1 at p. 2)

DOE understands that interested parties have concerns regarding the potential impact of moisture absorption on the thermal performance of insulating material over the lifetime of a walk-in cooler or freezer. Prior to the publication of the January 2010 NOPR, DOE reviewed several methods for testing vapor permeance and water absorption in foam insulation materials. However, this review of various test methods showed that there were disparities among the different methods, and that there was no general agreement upon a single approach. 75 FR 186, 194 (Jan. 4, 2010). Moreover, while these tests are designed to measure the performance of insulating foam by itself, they would not account for the many unique construction methods and combinations of materials employed by manufacturers of panels to minimize moisture infiltration.

At this time, test procedures for measuring the impact of water on foam R-value are not yet recognized by a national organization such as ASTM. DOE notes that because of the absence of any nationally recognized testing standards, it would need to develop such a protocol. To this end, one of DOE's national labs is in the process of developing procedures to evaluate the impact of moisture on insulation R-values. Accordingly, because of the potential ambiguities that are currently

present with respect to the means by which to assess the impact of moisture absorption on the thermal performance of insulating material over time, DOE is not incorporating a method to account for moisture absorption at this time. DOE may, however, consider adopting such a procedure in the future.

d. Display Panels

In the September 2010 SNOPR, DOE proposed that glass walls ("display panels") would be tested using NFRC 100–2001–E0A to measure their thermal transmittance, or U-factor. 75 FR 55068, 55098 (Sept. 9, 2010). Display panels are typically found on beer caves and share many characteristics with display doors. Notably, they are readily tested or simulated using the procedure in NFRC 100–2001–E0A. DOE received no comments regarding its proposed approach for display panels. Consequently, DOE is including this test procedure (to be codified in section 4.1 of Appendix A) to measure the thermal transmittance of display panels or walls. Additionally, to improve clarity, DOE is defining "display panels" as a panel that is entirely or partially comprised of glass, a transparent material, or both and is used for display purposes.

e. Open Areas of Walk-Ins

The test procedure DOE is establishing today contains tests for components of walk-ins that separate the interior refrigerated environment of the walk-in from the exterior. Zero Zone stated that the test procedure should include a method to determine the energy use for walk-ins that have open areas to display food. (Zero Zone, No. 0077.1 at p. 1) Because an open area does not, by definition, separate the interior refrigerated environment of the walk-in from the exterior, an open area is not a component of the walk-in that is covered under this test procedure. Accordingly, DOE is not adopting Zero Zone's suggestion.

3. Energy Use of Doors

a. U-Factor of Doors

In the September 2010 SNOPR, DOE proposed to rate the total thermal transmittance (i.e. U-factor) of doors, including their framing materials or complete door plug, using the test procedure NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors." 75 FR 55068, 55083 (Sept. 9, 2010). DOE specified internal and external rating conditions for the test procedure to closely match conditions that would be experienced by the door when it is part of a walk-in.

NEEA strongly supported DOE's use of NFRC 100–2010[E0A1] procedures for testing the performance of walk-in cooler and freezer doors. (NEEA, No. 0061.1 at p. 2) NRDC agreed with DOE's use of NFRC 100–2010[E0A1] for rating doors with the proposed changes to the temperatures used for the testing procedure. (NRDC, No. 0064.1 at p. 6)

DOE notes NEEA's and NRDC's support and has incorporated the use of NFRC 100–2001–E0A1 in this final rule. DOE also notes that none of the interested parties submitted comments that disagreed with using NFRC 100–2001–E0A1. The thermal transmittance result from NFRC 100–2001–E0A1 is then used to calculate the corresponding energy consumption of a refrigeration system whose efficiency is given in sections 4.4 and 4.5 of Appendix A for display and non-display doors, respectively. This energy metric is combined with the electricity consumption from electrical door components to calculate the door's total energy consumption.

b. Electrical Components of Doors

As described in section III.A.1, the test metric for doors includes the energy consumed by electrical components associated with a walk-in door. The electricity consumed by the door will be the sum of the rated power associated with each electricity consuming device multiplied by the assumed time the device will be operational. Percent time off (PTO) assumptions are given in sections 4.4.2 and 4.5.2 of Appendix A for display and non-display doors, respectively. PTO assumptions are specified for some electrical components, such as anti-sweat heater wire. For any electricity consuming devices for which a PTO is not specified in Appendix A, today's final rule provides that if a manufacturer can demonstrate that the device is controlled by a preinstalled timer, control system or other auto-shut-off system, the PTO is assumed to be 25 percent. For example, if a door has a thermometer mounted on it that consumes electricity, but the thermometer has a built in timer so that it shuts off at certain times, then the manufacturer of the door can use the PTO value of 25 percent when calculating the energy consumption of the thermometer.

The test procedure also provides a means for measuring the heat generation of door electrical components that are located on the inside surface of the door. This heat is added to the heat transmitted through the door and the corresponding refrigeration energy use is calculated using the method described in section III.B.3.c. The refrigeration energy use is added to the electrical energy use to calculate the total energy consumption of the door.

DOE received a comment challenging its assumptions about heat from electrical devices. Zero Zone disagreed with the assumption that all anti-condensate heat contributes to the walk-in heat load, and instead suggested that 50 to 75 percent of the anti-condensate heat going into the display case would be a more appropriate assumption. (Zero Zone, No. 0077.1 at p. 2) After further analysis, DOE agrees with Zero Zone's observation that not all anti-condensate heat necessarily contributes to the walk-in heat load because the anti-condensate heat is applied to the transparent surface of the display case. Because one side of the transparent surface is in contact with the surrounding external environment, a portion of the heat is transmitted from the display case to the surrounding environment. Therefore, DOE has revised the equations in sections 4.4.2and 4.5.2of Appendix A to capture only 75 percent of the power from anti-sweat heaters as an additional compressor load.

c. Energy Efficiency Ratio

In the January 2010 NOPR, DOE proposed to require that manufacturers measure the energy use of walk-in cooler and walk-in freezer envelopes in kWh/day. However, most metrics used to describe heat transfer losses are in units of British thermal units (Btu) per unit time. In order to convert the thermal energy transmission calculation (Btu/hr) into a measure of electrical energy consumed by the refrigeration equipment, DOE proposed to use an energy efficiency ratio based on a nominal efficiency of an assumed refrigeration system. The EER values proposed for coolers and freezers were 12.4 Btu/W-h and 6.3 Btu/W-h respectively. The values were selected to provide a means of comparison and were not intended to represent the actual efficiency of the refrigeration system with which the envelope would ultimately be paired. 75 FR 186, 197 (Jan. 4, 2010). Although the test procedure no longer requires one to calculate the overall envelope energy, the concept is still relevant for calculating door energy.

DOE received comments in response to the January 2010 NOPR regarding the use of an EER value, the assumptions used to calculate the EER value, and the proposed EER values for coolers and freezers. BASF commented that the proposed EER assumptions were reasonable. (BASF, No. 0021.1 at p. 4) Nor-Lake agreed with DOE's use of a

nominal EER value to convert the thermal energy transmission to electrical energy consumption. (Nor-Lake, No. 0047.1 at p. 5) Master-Bilt also agreed with the proposed use of a nominal EER but stated that the proposed EER values are not achievable. (Master-Bilt, No. 0027.1 at p. 2) Kason requested that the nominal EER values be reassessed to represent real world values. (Kason, No. 0055.1 at p. 4) Nor-Lake commented that the EER values on their refrigeration models did not match DOE's proposed nominal values. (Nor-Lake, 0023.1 at p. 4)

DOE considered these comments and, in conjunction with the supportive comments from Master-Bilt, Nor-Lake, and BASF, continues to use an EER value to relate the thermal energy transmission to the electrical energy consumed for doors. Despite the comments from Kason, Master-Bilt, and Nor-Lake, DOE finds 12.4 Btu/W-h and 6.3 Btu/W-h to be appropriate conversions for walk-in coolers and walk-in freezers, respectively, because these EER values correspond to nominal EER values contained in the refrigeration test procedure for unit coolers connected to multiplex condensing systems (AHRI 1250 (I–P)–2009). DOE is aware that the nominal values for this configuration may not represent all walk-ins, but notes that these EER values are intended to provide a means of comparison and not directly reflect a real walk-in installation. In particular, these EER assumptions are not intended to represent the expected efficiency of any particular refrigeration system produced by a manufacturer and are provided as a method to converting thermal energy to electrical energy consumed by a refrigeration system.

4. Heat Transfer via Air Infiltration

In the January 2010 NOPR, DOE stated that, compared with other energy consumption factors such as conduction losses through insulation, air infiltration may be the largest contributing factor to envelope thermal load. That notice identified two infiltration pathways: steady state leakage and air losses due to door-opening events. To address this issue, DOE proposed to include test procedures to measure the steady state infiltration and infiltration from door opening events and subsequently modified these test procedures in response to comments to the September 2010 SNOPR. See 75 FR 196–197 (Jan. 4, 2010) and 75 FR 55084–55086 (Sept. 9, 2010). Interested parties submitted comments pertaining to the topic of envelope infiltration, including steady state infiltration, door opening infiltration, calculations, and empirical methodologies for quantifying the effects of infiltration.

a. Steady State Infiltration

In the January 2010 NOPR, DOE proposed that steady state infiltration of fully assembled envelopes must be tested using the method described in ASTM E741–06, "Standard Test Method for Determining Air Change in a Single Zone by Means of a Tracer Gas Dilution." 75 FR 196 (Jan. 4, 2010).

Some interested parties stated that steady state infiltration should not be included in the test procedure. Hill Phoenix maintained that an insufficient amount of infiltration would occur in a properly installed walk-in, essentially suggesting that DOE abandon the inclusion of infiltration in the test. (Hill Phoenix, No. 0063.1 at p. 2) AHRI concurred, stating that a steady-state infiltration test is not necessary due to the insignificant amount of infiltration present in a walk-in * * * (AHRI, No. 0070.1 at p. 3) Master-Bilt agreed, suggesting that testing steady-state infiltration is unnecessary because this infiltration is insignificant compared with infiltration from door openings. (Master-Bilt, No. 0069.1 at p. 2) NRDC suggested that DOE confirm the assumption that the impact of infiltration and exfiltration through the envelope is minimal compared to the infiltration through the doors, and suggested that DOE should weigh each impact. (NRDC, No. 0064.1 at p. 6)

Other interested parties commented on the specific test methods DOE proposed in the January 2010 NOPR for measuring steady-state infiltration of walk-in envelopes. TAFCO stated that ASTM E741–06, Standard Test Method for Determining Air Change in a Single Zone by Means of a Tracer Gas Dilution, is an acceptable method for determining steady state air infiltration. (TAFCO, No. 0040.1 at p. 3) ACEEE also agreed with using ASTM E741–06. (ACEEE, 0052.1 at p. 3) NEEA commented that either ASTM E741–06 or a standard blower test is a reasonable method of calculating steady state infiltration, but noted that the blower test would be faster and less costly to administer. Therefore, NEEA recommended that DOE test ASTM E741–06 and the standard blower door test before prescribing which methodology must be used. (NEEA, No. 0061.1 at p. 2) Kysor, on the other hand, stated that it is neither necessary nor cost effective to assemble an entire walk-in to test for air infiltration. Kysor stated that each component should be tested separately and recommended that DOE use ASTM E1424–08, Standard Test Method for Determining the Rate of Air Leakage Through Exterior Windows, Curtain Walls, and Doors Under Specified Pressure and Temperature Differences Across the Specimen, and ASTM E2357–05, Standard Test Method for Determining Air Leakage of Air Barrier Assemblies, because either can test any assembly that will become part of a walk-in. (Kysor, No. 0053.1 at p. 3)

In the January 2010 NOPR, DOE proposed that ASTM E741–06 should be used to measure infiltration; however, in the September SNOPR, DOE determined that ASTM E741–06 could present an undue burden for manufacturers with respect to the many door combinations that are possible. Therefore, DOE proposed in its September 2010 SNOPR to also consider measuring steady state infiltration through doors using NFRC 400–2010–E0A1, "Procedure for Determining Fenestration Product Air Leakage." 75 FR 55068, 55084 (Sept. 9, 2010).

Interested parties commented on NFRC 400–2010–E0A1 and suggested alternatives. NRDC agreed with using NFRC 400–2010–E0A1 to determine infiltration of individual envelope components, but also recommended using a pressurization test to determine infiltration of fully assembled envelopes, based on ASTM D6670, "Standard Practice for Full-Scale Chamber Determination of Volatile Organic Emissions from Indoor Materials/Products." (NRDC, No. 2.3.008 at p. 6) AHRI recommended that infiltration could be estimated for a family of doors by using a scaling methodology based on a limited number of tests. AHRI cautioned DOE against requiring the manufacturer to test every single door because it would be burdensome. (AHRI, No. 2.3.015 at p.3) Some interested parties commented on the prescribed testing conditions to be implemented with NFRC 400–2010–E0A1. American Panel stated that the proposed steady state infiltration test unit is not representative of the average walk-in size and suggested a more representative size of 8 feet by 12 feet by 8 feet high. (American Panel, No. 2.3.001 at p. 3) American Panel, NEEA, and Bally concurred with DOE's assumption of 75 percent relative humidity, which DOE proposed as a condition of testing. (American Panel, No. 2.3.001 at p. 3; NEEA, No. 2.3.005 at p. 5; Bally, No. 0078.1 at p.2)

DOE notes the specific comments and suggestions from TAFCO, NEEA, ACEEE, Kysor, NRDC, AHRI, and American Panel, but has decided not to include steady state infiltration in the WICF test procedure at this time. In response to NRDC's suggestion that DOE

weigh the impact of steady-state infiltration against other sources of infiltration, DOE believes that the contribution of steady state infiltration towards the aggregate energy consumption of a well-constructed factory-built walk-in unit is most likely negligible compared to other energy consumption pathways for current WICF designs. Higher steady-state infiltration across the envelope for site-assembled walk-in coolers and freezers appears to be generally caused by poor installation and construction practices. As such, DOE is not incorporating an overall infiltration measurement, which is a factor that relies heavily on on-site assembly practices rather than the performance of individual components. Given that today's final rule includes a means to assess the performance of specific individual components, the performance of these components will be captured under the new procedure and should be sufficiently adequate prior to their installation as part of a completed walk-in unit. Should this prove not to be the case, DOE may re-examine the procedure and consider modifications to address its potential shortcomings.

b. Door Opening Infiltration

In the January 2010 NOPR, DOE proposed to calculate air infiltration associated with each door-opening event using established analytical methods based on equations and computational values published in the ASHRAE Refrigeration Handbook. DOE also made several assumptions in the test procedure that could have a significant impact on the predicted air exchange. The assumptions with the most impact were the number of doorway passages (the number of door-opening cycles for a given door), door open-close time, and the amount of time the door is held or propped open. 75 FR 186, 196 (Jan. 4, 2010). In the September 2010 SNOPR, DOE did not propose to change the basic methodology, but modified some of the assumptions in order to differentiate door types. 75 FR 55068, 55085 (Sept. 9, 2010).

Some interested parties supported the proposed method. Hired Hand agreed with the methodology used for calculating the air infiltration from door openings. (Hired Hand, Public Meeting Transcript, No. 0016 at p. 309) Hired Hand emphasized that air infiltration may be the largest contributing factor to envelope energy losses. (Hired Hand, Public Meeting Transcript, No. 0016 at p. 28; Hired Hand, Public Meeting Transcript, No. 0016 at p. 279; Hired Hand, Public Meeting Transcript, No. 0016 at p. 285) American Panel suggested the use of ASHRAE values for heat load as the best way to account for the effects of air infiltration. (American Panel, No. 0042.1 at p. 2) ThermalRite, Nor-Lake, and Master-Bilt agreed with American Panel's suggestion. (ThermalRite, No. 0049.1 at p. 2; Nor-Lake, No. 0047.1 at p.4; Master-Bilt, Public Meeting Transcript, No. 0016 at p. 311) Master-Bilt and Zero Zone also agreed with DOE's assumptions regarding infiltration attributed to door openings. (Master-Bilt, No. 0069.1 at p. 2; Zero Zone, No. 0077.1 at p. 2)

Other interested parties questioned the applicability of the method to walk-in cooler and freezer doors, or questioned DOE's assumptions in calculating door opening infiltration. Schott Gemtron contended that ASHRAE equations may be based on supermarket display cases, implying that they may not be applicable to some walk-in doors. (Schott Gemtron, Public Meeting Transcript, No. 0016 at p. 314) Hired Hand was concerned that the proposed test procedures do not account for the effect of fast-acting doors on air infiltration. (Hired Hand, Public Meeting Transcript, No. 0016 at p. 286) SCE and Hired Hand both stated that the parameters used to calculate air infiltration should clearly show the benefit of fast-acting doors. (SCE, Public Meeting Transcript, No. 0016 at p. 320; Hired Hand, Public Meeting Transcript, No. 0016 at p. 320) Hired Hand also recommended that the equations used to calculate air infiltration should be based on the operational time the doors are opened over an assumed 24-hour day. (Hired Hand, No. 0051.1 at p. 4) Zero Zone stated that any air infiltration calculations should include additional air infiltration if the evaporator is discharging air in the direction of the display doors. (Zero Zone, No. 0077.1 at p. 1) Bally stated that hybrid walk-ins, that is, walk-ins sited within another walk-in, should be given beneficial consideration. Bally explained that a walk-in freezer sited inside a walk-in cooler would experience less infiltration because of the smaller temperature differential between the interior and exterior of the freezer. (Bally, No. 0078.1 at p.2)

Interested parties also made specific comments on the effect of infiltration reduction devices (IRDs). ACEEE and ThermalRite supported the infiltration device effectiveness test methodology. (ACEEE, No. 0052.1 at p. 3; ThermalRite, No. 0049.1 at p. 2) TAFCO also stated that ASTM E741–06 is an acceptable method for determining IRD effectiveness. (TAFCO, No. 0040.1 at p. 3) NRDC stated that the proposed door opening infiltration calculation from ASHRAE Fundamentals 2009 is acceptable for conventional doors, but when doorways are protected by an air curtain or other infiltration reduction device, calculations should include the effect of such devices on energy use. (NRDC, No. 0064.1 at p. 6)

Master-Bilt commented that air infiltration from door openings cannot be modeled in a meaningful way and should be excluded from the test methodology. (Master-Bilt, No. 0027.1 at p. 2) Hill Phoenix noted that the panel manufacturer has no bearing on door opening frequency, which accounts for the majority of the infiltration. (Hill Phoenix, No. 0063.1 at p. 2) NEEA suggested that DOE should not make assumptions about the nature of the use of a particular walk-in. (NEEA, No. 0061.1 at p. 5) Instead, it recommended that DOE include a prescriptive requirement for infiltration reduction devices. (NEEA, No. 0061.1 at p. 5)

DOE has decided not to include any test procedure for door opening infiltration following its decision to have component-level test procedures and standards. Door infiltration is primarily reduced by incorporating a separate infiltration reduction device at the assembly stage of the complete walk-in. Based on DOE's understanding of the door manufacturing industry, a typical door manufacturer has very few direct means for reducing the door infiltration on its own since IRDs are generally designed and manufactured independently from doors and they require proper field installation to achieve rated performance. Consequently, at this time, DOE is not incorporating provisions that would require measuring the effectiveness of the infiltration reduction devices and door infiltration, as suggested by Master-Bilt, Hill Phoenix, and NEEA. Likewise, reduction of door infiltration due to the location of the walk-in is not captured, as suggested by Bally.

In response to NEEA's comment recommending a prescriptive standard, DOE notes that EPCA has already established a prescriptive requirement for infiltration reduction devices, and there may be limited if any benefit to DOE adding additional prescriptive standards for infiltration reduction devices. (42 U.S.C. 6313(f)(1)(B)) Nevertheless, DOE will consider the need for these types of standards within the context of its ongoing energy standards rulemaking.

5. Electrical Components

In the January 2010 NOPR, DOE proposed to calculate the energy consumption of electrical devices using their nameplate rating and duty cycle

assumptions about their daily operation. In addition, the heat loads from electrical devices were factored into the envelope refrigeration load calculations. DOE proposed to incorporate 100 percent of the electrical energy consumed to operate the devices that are internally located and to convert the electrical energy consumed to a thermal load. The associated thermal load was then used to calculate the additional refrigeration load using the nominal refrigeration EER values described in section III.B.3.c. DOE also proposed a variety of PTO values in the NOPR to account for reductions in energy use due to component control and hours of usage. 75 FR 186, 198 (Jan. 4, 2010).

BASF supported including electricity consumption as part of the energy calculation, and concurred with the duty cycle assumptions. (BASF, No. 0021.1 at p. 5) Master-Bilt and Nor-Lake also agreed with the electrical duty cycle equation proposed by DOE. (Master-Bilt, No. 0027.1 at p. 2; Nor-Lake, No. 0023.1 at p. 4) ACEEE supported the methods and assumptions for PTO values and electrical loads and agreed with the use of nameplate power ratings because it encouraged load reduction. (ACEEE, No. 0052.1 at p. 3) ThermalRite noted that while it did not fully understand how the proposed PTO values listed in the January 2010 NOPR were developed, it believed that the proposed values represented a fair method of comparison among manufacturers because the same assumptions are made for all users. ThermalRite asked that DOE ensure that the values include all device types. (ThermalRite, No. 0049.1 at p. 2) ORNL requested that DOE include the ground heater below the floor insulation as part of the energy use calculation. (ORNL, No. 0028.1 at p. 2) Craig Industries requested that DOE accommodate high-efficiency heater wires that apply heat on demand. (Craig Industries, Public Meeting Transcript, No. 0016 at p. 325 and No. 0054.1 at p. 3) Finally, Nor-Lake expressed the opinion that the proposed PTO values for lights are low because in most applications the lights would be shut off each night for 8 hours. (Nor-Lake, No. 0047.1 at p. 5)

DOE notes support from BASF, Master-Bilt, Nor-Lake, ACEEE, and ThermalRite for its methodology and assumptions. DOE is also aware of the concerns presented by ORNL, Craig Industries, and Nor-Lake. However, since DOE will implement a component-based standard, electrical components not part of a door are not included in the component test or component metric. DOE notes that assemblers or manufacturers of complete walk-ins must still use lighting that complies with the efficacy standard prescribed in EPCA. (42 U.S.C. 6313(f)(1)(G)) DOE will continue to use the method proposed in the January 2010 NOPR to calculate the energy consumption of lights, sensors, and other miscellaneous electrical devices associated with walk-in doors. Regarding Craig Industries' specific comment about door heater wire, DOE's PTO assumptions take into account demand-based control of components, which includes the loads from door heater wires. PTO assumptions are given in sections 4.4.2 and 4.5.2 of Appendix A for display and non-display doors, respectively. See section III.B.3.b for further discussion of electrical components of doors.

C. Test Procedures for Refrigeration Systems

The refrigeration system is the equipment that performs the mechanical work necessary to cool the interior space of a walk-in cooler or freezer. As previously discussed, DOE considers the refrigeration system an individual component of the walk-in cooler or walk-in freezer. Therefore, in this test procedure, DOE establishes a test of the performance of a refrigeration system itself, assuming nominal envelope characteristics. In the concurrent standards rulemaking, DOE intends to establish energy conservation standards for the refrigeration system. See generally 75 FR 17080 (April 5, 2010). The following sections address issues raised by interested parties on the January 2010 NOPR and September 2010 SNOPR.

1. Definition of Refrigeration System

In the January 2010 NOPR, DOE proposed a definition of refrigeration system that described three types of systems that would be covered: (1) Single-package systems containing the condensing and evaporator units; (2) split systems with the condensing unit and unit cooler physically separated and connected via refrigerant piping; or (3) unit coolers that receive refrigerant from a compressor rack system shared with other refrigeration equipment. 75 FR at 200 (Jan. 4, 2010). In the September 2010 SNOPR, DOE proposed minor revisions to that definition to clarify some of these terms. That notice proposed the following definitions:

> Refrigeration system means the mechanism (including all controls and other components integral to the system's operation) used to create the refrigerated environment in the interior of a walk-in cooler or freezer, consisting of (1) a packaged system where the unit cooler and condensing unit are integrated into a single piece of equipment, (2) a split system with separate unit cooler and condensing unit sections, or (3) a unit cooler that is connected to a multiplex condensing system.

75 FR 55068, 55093 (Sept. 9, 2010).

NRDC, Craig Industries, and Master-Bilt agreed with the revisions proposed in the September 2010 SNOPR. (NRDC, No. 0064.1 at p. 7; Craig Industries, No. 0068.1 at p. 5; Master-Bilt, No. 0069.1 at p. 3) Other interested parties did not agree with the classification contained in the definition or the types of systems covered. NEEA stated that the three refrigeration types do not accurately represent the market, and recommended that the equipment classification should instead match the classifications contained in DOE's regulations for commercial refrigeration equipment. (NEEA, No. 0061.1 at pp. 2 and 4) The Joint Utilities also disagreed with the concept of defining systems as "matched" ("packaged" or "split" systems as termed in the proposed definition) or "remote" (a unit cooler connected to a multiplex condensing system as in the proposed definition). (Joint Utilities, No. 0059.1 at p. 2) Like NEEA, the Joint Utilities suggested that DOE change its proposed definition by adopting the approach taken with the commercial refrigeration equipment efficiency regulations: "packaged" systems should be termed "self-contained condensing units" and all other condensing units should be considered "remote condensing units." The Joint SNOPR comment also agreed with this approach, suggesting that DOE classify refrigeration systems as self-contained (packaged systems) or unit coolers connected to remote condensing units (both dedicated and multiplex). It also suggested that for remote condensing systems, any applicable energy conservation standards should only apply to the unit cooler. (Joint SNOPR Comment, No. 0074.1 at p. 3)

DOE believes the three types of refrigeration systems described in the definition accurately represent the range of refrigeration equipment that is used in walk-in coolers and freezers. Although the definition differs from the definition for commercial refrigeration equipment, there are key differences between commercial refrigeration equipment refrigeration systems and walk-in refrigeration systems that make a new definition necessary. NEEA and the Joint Utilities refer to two common types of commercial refrigeration equipment refrigeration units. Some are "self-contained" (meaning the entire refrigeration system is built into the case). Others are "remote condensing" (meaning the unit cooler is built into the

case, but the whole case is connected to a central system of compressors and condensers (called a "rack" or "multiplex condensing system") that is connected to most or all of the refrigeration units in a building). The latter configuration is common in supermarkets. For all remote condensing systems, the commercial refrigeration equipment test procedure rulemaking assumed a certain efficiency of the multiplex condensing system and the standards rulemaking did not regulate this part of the equipment. 71 FR 71340 and 74 FR 1092.

However, "remote condensing" can also refer to a configuration in which the unit cooler is connected to a dedicated (that is, only serving that one unit) compressor and condenser that are located somewhere away from the walk-in. This configuration is very rare for commercial refrigeration equipment but comprises a large proportion of walk-in refrigeration system applications. For this reason, DOE does not agree with the suggestion of NEEA and the Joint Utilities that this configuration should be classified as "remote condensing" and does not agree that the compressor and condenser parts should not be covered under the walk-in coolers and freezers rulemaking. Rather, DOE believes that a dedicated condensing unit should be included in the rule, even if it is remotely located, because it could be viewed as part of the walk-in cooler as long as it is connected only to that cooler and not to other refrigeration equipment. For systems where the walk-in is connected to a multiplex condensing system that runs multiple pieces of equipment, the compressor and condenser would not be covered because they are not exclusively part of the walk-in.

In consideration of the above, DOE believes the commercial refrigeration equipment definition cannot be applied to walk-ins, because there is a certain type of walk-in refrigeration—namely, a split system with a dedicated but remotely located condensing unit—that is highly represented in walk-ins but rarely, if ever, represented in commercial refrigeration equipment. Thus, while the Joint Comment compares walk-in refrigeration systems to commercial refrigeration equipment, DOE believes this is not a relevant comparison. A closer comparison would be to residential central air conditioners—an example of equipment that almost always has a dedicated, but remotely located, condensing unit. In that instance, DOE's definition covers this type of remote condensing unit. Furthermore, DOE notes that manufacturers can optimize the dedicated, remote condensing unit with the unit cooler to take advantage of certain conditions such as low ambient outdoor temperatures. Therefore, DOE has retained the proposed definition's coverage of dedicated remote condensing systems. To further clarify this coverage, DOE has added the term "dedicated" to describe packaged systems and split systems in the definition it is adopting today.

2. Refrigeration Test Procedure: AHRI 1250 (I–P)–2009

DOE proposed to incorporate the industry standard AHRI 1250–2009, "2009 Standard for Performance Rating of Walk-In Coolers and Freezers," into the test procedure. (The January 2010 NOPR referred to the preliminary version of this standard, AHRI 1250P–2009. The SNOPR updated this reference to the final version.) 75 FR 186, 200–201 (Jan. 4, 2010) and 75 FR 55068, 55086 (Sept. 9, 2010). DOE proposed that manufacturers use this standard to rate the refrigeration systems of walk-in coolers and freezers.

AHRI 1250–2009 covers the testing of refrigeration systems for walk-in coolers and freezers, which includes unit coolers and condensing units that are sold together as a matched system, unit coolers and condensing units that are sold separately, and unit coolers connected to compressor racks. The procedure describes the method for measuring the refrigeration capacity and the electrical energy consumption for the condensing unit and the unit cooler, as well as the off-cycle fan energy and the defrost subsystem under specified test conditions. The standard test conditions specify the dry-bulb and wet-bulb temperatures of the air surrounding the unit cooler and the condensing unit. The standard test conditions are different for indoor and outdoor locations for the condensing unit and for coolers and freezers.

The AHRI procedure also specifies the calculations used to ascertain the nominal box loads under typical low-load and high-load conditions, expressed as a function of the ambient air temperature. (The "nominal box load" refers to the refrigeration load imposed on the system by the walk-in envelope.) During the test, the system must operate under steady-state conditions. For systems in which the condensing unit is located outdoors, the test procedure uses bin temperature data and bin hour data to represent the impact of the seasonal variation in outside ambient air temperature on energy use. The test procedure provides a calculation methodology to compute an annual walk-in efficiency factor (AWEF) for the refrigeration system under a specified load profile. For unit coolers and condensing units sold separately, the test procedure allows for testing the components individually and then calculating the system AWEF from the component test results.

Several interested parties agreed with DOE's proposed methodology. AHRI urged DOE to allow a rating of walk-in refrigeration systems using the calculation methodologies in the proposed protocols contained in AHRI 1250. (AHRI, No. 0070.1 at p. 2) American Panel, Thermo-Kool, Bally, and NRDC also supported DOE's proposal to allow the evaporator and condensing unit to be tested separately according to the proposed methodology. (American Panel, No. 0057.1 at p. 1; Thermo-Kool, No. 0072.1 at p. 1; Bally, No. 0078.1 at p. 3; NRDC, No. 0064.1 at p. 3) Craig Industries supported a formula that would allow the efficiency of the refrigeration system to be calculated from testing data provided by each component supplier. (Craig, No. 0068.1 at p. 3) Heatcraft advised that the refrigeration system procedure should allow for testing new components. (Heatcraft, No. 0065.1 at p. 1) However, the Joint Utilities disagreed with the assumption in AHRI 1250–2009 that unit coolers and remote condensing units that are sold separately will be matched and installed together, and stated that AHRI 1250–2009 does not allow unit coolers to be compared with each other unless they have been tested on the same condensing unit. (Joint Utilities, No. 0059.1 at p. 2) No parties opposed DOE's proposal to allow evaporator and condensing unit to be tested separately.

DOE notes the support of AHRI, American Panel, and NRDC for the proposed method and incorporates it into this final rule. In response to Heatcraft's suggestion that the procedure should allow for testing new components, DOE anticipates that the method will lead to manufacturers testing unit coolers and condensing units when they are manufactured separately, so that they can be used in new systems. Regarding the issues raised by Craig Industries and the Joint Utilities, DOE emphasizes that the proposed procedure contains a calculation method by which the overall refrigeration performance can be calculated using testing data from a condensing unit and unit cooler, even if the two components are provided by different suppliers. The test results for a unit cooler or condensing unit are independent from whichever condensing unit or unit cooler is matched with the tested component. In

contrast, the test results for each component are in the form of a performance curve to facilitate calculation of matched performance, which, as suggested by the Joint Utilities, does not lend itself to meaningful comparisons between unit coolers without matching the particular unit coolers with the same condensing unit. DOE acknowledges this limitation but believes it is important to maintain the results in terms of the performance curve to facilitate calculation of the performance of the system as a whole, because the entire refrigeration system is treated as a component under the approach adopted in today's final rule. Given that the refrigeration system is treated as a single component under the procedure, the procedure offers a simple method for determining the energy efficiency profile of the walk-in refrigeration system because it allows the unit cooler and condensing unit to be tested separately.

Additionally, DOE notes that if unit coolers are tested and rated as if they were to be combined with a multiplex condensing system, they could be compared against each other. The test data for unit coolers in a mix-match system include the data necessary for calculating the unit cooler's performance when paired with a multiplex condensing system. Thus, it would be relatively simple for manufacturers of unit coolers to provide both the performance data for matching purposes and the performance as connected to a multiplex condensing system. DOE may consider requiring this information as part of any related labeling requirements for WICF equipment.

While interested parties generally agreed with the adoption of AHRI 1250–2009, others disagreed with how that method would be applied to different system configurations. The Joint Utilities and NEEA both recommended that all remote condensing systems be tested using the "walk-in unit cooler match to parallel rack system" test method and noted that the matched system approach only be used for self-contained condensing units. (Joint Utilities, No. 0059.1 at p. 3; NEEA, No. 0061.1 at p. 4) The Joint Utilities further stated that the proposed AHRI 1250–2009 test method for rating dedicated remote condensing systems would create confusion and additional testing burden because there are many different test methods and categories for different locations and types of condensing units. (Joint Utilities, No. 0059.1 at pp. 2 and 5) Other interested parties questioned the methodology for rating unit coolers connected to multiplex condensing systems. American Panel stated that the exemption of multiplex equipment would give that equipment an unfair advantage over single piece equipment. (American Panel, No. 0057.1 at p. 3) Master-Bilt stated that the multiplex exemption seemed to suggest that any condensing unit connected to more than one unit cooler would not be covered. (Master-Bilt, No. 0069.1 at p. 3) NRDC stated that the proposed equations for evaluating the energy use of units with indoor condensing units and those connected to multiplex condensing systems should account for differences in the systems' ability to reject heat. (NRDC, No. 0064.1 at p. 7)

Addressing the comments from the Joint Utilities and NEEA, as discussed in section III.C.1, DOE considers dedicated remote condensing units as distinct from multiplex condensing systems in that dedicated remote condensers are part of only one walk-in, while multiplex condensing systems are connected to more than one walk-in or other unit of refrigeration equipment. DOE believes that dedicated remote condensing units represent a substantial opportunity for energy savings in a regulation for walk-in components because the configuration of a dedicated remote condensing unit is widespread in several market segments such as restaurants. Manufacturers can optimize the dedicated remote condensing unit with the unit cooler to take advantage of certain conditions such as low ambient outdoor temperatures. The approach suggested by the Joint Utilities and NEEA would exclude dedicated remote condensing units from this regulation, but DOE views these units as part of the walk-in cooler or freezer if the unit is connected only to the walk-in and not to any other refrigeration equipment. Therefore, the test procedure for walk-in refrigeration equipment accounts for these units.

To address Master-Bilt's request for clarification, for systems where the walk-in is connected to a central multiplex condensing system that runs multiple pieces of equipment, the compressor and condenser would not be covered because they are not exclusively part of the walk-in. DOE realizes there are certain condensing units that are connected to more than one unit cooler inside a single walk-in. These systems would not be considered "multiplex condensing systems" because they are connected to a single walk-in. However, if the condensing unit were connected to more than one unit cooler inside more than one walk-in or other piece of equipment, DOE would consider that a multiplex condensing system because the system's performance could not be attributed to one walk-in alone. While DOE understands American Panel's concern that multiplex condensing systems could have an advantage because those condensing units would not need to be tested, the condensing unit and compressor part of a multiplex condensing system is not exclusively part of a walk-in unit. Therefore, DOE is not covering them in this test procedure. DOE notes that unit coolers connected to the multiplex condensing systems would still be considered part of the walk-in and would need to be tested. The procedure considers the different performance of multiplex condensing systems and indoor condensing systems as recommended by NRDC. For multiplex condensing systems, the calculation of energy use includes a nominal efficiency that accounts for that type of system's ability to reject heat. The rating conditions for indoor condensing units provide an opportunity for crediting energy savings that result from an increased ability to reject heat.

Finally, one interested party proposed to expand the test procedure to provide more information than DOE previously proposed. NRDC suggested that testing data should be input into standardized calculations that would determine the overall system performance for each application and recommended that performance data should be able to be interpolated or extrapolated for hot climates. (NRDC, No. 0064.1 at p. 3) DOE notes that standardized rating conditions are not typically application-specific and may not be useful for determining the performance of the system in conditions outside the rating conditions. To provide this flexibility, as suggested by NRDC, the AHRI 1250 test procedure contains provisions for conducting testing with application ratings to obtain the performance for a particular application. However, DOE emphasizes that the standardized rating conditions are useful for comparing systems with each other and must be used for evaluating a product's compliance with a particular standard.

3. Alternative Efficiency Determination Method

For some covered equipment, DOE has allowed manufacturers to use their own methods, whether a calculation or computer simulation, to rate their equipment after they substantiate those calculation or simulation methods with test data. The purpose of this provision is to reduce the burden of testing customized, low-volume equipment. DOE has allowed rating methods in the form of alternate rating methods (ARMs)

or alternative efficiency determination methods (AEDMs). An ARM, which is allowed for rating residential central air conditioners and heat pumps, must be a representation of the test data and calculations of a mechanical vapor-compression refrigeration cycle. Manufacturers may use an ARM after submitting documentation to DOE and receiving specific approval from DOE to use that ARM to rate their equipment. (10 CFR 430.24(m)(4)-(6)) An AEDM, which is allowed for certain products and commercial equipment—including electric motors, distribution transformers, and commercial heating, ventilating, air-conditioning, and water heating (HVAC and WH) equipment—is a rating method derived from a mathematical model that represents the mechanical and electrical characteristics of the equipment and is based on engineering or statistical analysis, computer simulation or modeling, or other analytical evaluations of performance data. An AEDM must be substantiated by test data before it can be used to rate equipment. (10 CFR 431.17(a)(2)–(3); 10 CFR 431.197(a)(2); and 10 CFR 431.197(a)(2)–(3))

For the walk-in coolers and freezers rulemaking, DOE introduced the concept of an AEDM at the Framework public meeting (February 4, 2009) and requested comment on whether it could be applied to walk-ins. At the Framework public meeting, DOE asked how an AEDM could be implemented for walk-ins, what a sufficient test sample size for validating an AEDM would be, and how accurate (to what percentage) an AEDM should be. DOE did not receive any feedback regarding these questions. Several interested parties did, however, raise concerns in written comments on the Framework and during the Framework public meeting about the potential for inconsistency among manufacturers' rating methods. For example, Owens Corning stated that a single AEDM should be accepted to keep comparisons consistent (instead of different AEDMs from different manufacturers), and Craig said that requiring manufacturers to follow the same model (that is, not allowing manufacturers to use their own AEDMs) would provide consistent information to end users. (Owens Corning, No. EERE–2008–BT–STD–0015–0034.1 at p. 2; Craig, No. EERE–2008–BT–STD–0015–0025.1 at p. 5) DOE summarized and addressed these comments in the January NOPR. 75 FR 186, 190 (Jan. 4, 2010).As a result, DOE did not propose any specific provisions regarding AEDMs or any other provisions that would allow manufacturers to develop their own rating methods for walk-ins. Instead, DOE proposed its own calculation methodology for manufacturers to use in rating similar units of walk-in equipment. 75 FR 186, 191 (Jan. 4, 2010).

While the procedure divides the envelope into its major components, the refrigeration system is considered as a single component. Consistent with this approach, DOE is incorporating a single metric to cover the performance of the refrigeration system. DOE noted in the September 2010 SNOPR that the proposed refrigeration test procedure, AHRI 1250 (I–P)-2009, "2009 Standard for Performance Rating of Walk-In Coolers and Freezers," allows manufacturers to test condensing units and unit coolers separately in certain situations, and to calculate the performance of the combined system. DOE anticipated that this approach would reduce the overall testing burden by eliminating the need to test the many possible unit cooler and condensing unit combinations that could comprise a complete refrigeration system. 75 FR 55073 (Sept. 9, 2010). In proposing this approach, DOE also recognized that there could still be some burdens due to system variations. To mitigate these burdens, DOE noted that it might consider allowing manufacturers of refrigeration to use AEDMs to rate their equipment. 75 FR 55089 (Sept. 9, 2010).

In comments on the September 2010 SNOPR, interested parties commented on the burden of testing refrigeration systems because a manufacturer's product line may have many different condensing units and unit coolers, which may be similar, but not identical, and need to be tested individually. Craig Industries stated that even if unit coolers and condensing units could be tested separately, testing each component with all the options available would substantially increase the need for testing and would discourage manufacturers from improving their equipment. (Craig Industries, No. 0068.1 at p. 3) AHRI requested that DOE allow manufacturers to rate their equipment and demonstrate compliance with the Federal standard through the use of an AEDM to minimize testing burden. (AHRI, No. 0070.1 at p. 3) Manufacturers were also concerned about how they would rate custom units. Heatcraft stated that refrigeration system manufacturers would face an undue testing burden and asserted that manufacturers would not be able to sell a particular piece of equipment if it had been tested. (Heatcraft, No. 0065.1 at p. 2) DOE acknowledges that when a refrigeration system is tested, it undergoes some modifications in order to accommodate the apparatus for taking test measurements. As a result, these units can no longer be sold as new equipment after testing and are typically destroyed. This situation, in Heatcraft's view, would prevent them from selling custom equipment if the inclusion of a custom piece requires a separate test of the refrigeration system.

DOE recognizes the potential for variability with respect to walk-in components, in terms of their physical characteristics and, consequently, their energy performance or efficiency. To address Craig's concern that testing all equipment variations would be burdensome, and AHRI's request that DOE allow manufacturers to use AEDMs, DOE will continue to consider the application of AEDMs or ARMs. DOE recognizes the value of permitting the use of AEDMs and ARMs in limited instances and may consider the adoption of such methods for walk-in equipment, including the statistical basis and the sample size required to validate them, in a future rulemaking.

D. Other Issues—Definition of Walk-In Cooler or Freezer

EPCA defines walk-in equipment at 42 U.S.C. 6311(20), codified at 10 CFR 431.302.

During the public meeting for the January 2010 NOPR, Hired Hand and several interested parties stated that DOE should clarify the definition of walk-in coolers and walk-in freezers with respect to temperature limits. Multiple interested parties commented that DOE should set an upper temperature limit for walk-ins. After reviewing the comments from interested parties, DOE proposed in the September 2010 SNOPR to modify the definition of "refrigerated" within the definition of walk-in cooler or freezer to mean at or below 55 °F. 75 FR 55068, 55069 (Sept. 9, 2010).

The Joint Utilities, AHRI, American Panel, the Joint Manufacturers, NEEA, Craig Industries, Thermo-Kool, Master-Bilt, and Bally agreed to the proposed upper temperature limit of 55 °F for walk-ins. (Joint Utilities, No. 0059.1 at p. 6; AHRI, No. 0070.1 at p. 1; American Panel, No. 0057.1 at p. 1; Joint Manufacturers, No. 0062.1 at p. 1, NEEA, No. 0061.1 at p. 2; Craig Industries, No. 0068.1 at p. 1; Thermo-Kool, No. 0072.1 at p. 1; Master-Bilt, No. 0069.1 at p. 1; Bally, No. 0078.1 at p. 1) The Joint Utilities also recommended that DOE develop definitions for walk-in coolers and freezers that are similar to California Title 24, Buildings Efficiency Standards, which contain a

definition for "refrigerated warehouse" that clarifies a temperature of 55 degrees or less. (Joint Utilities, No. 0059.1 at p. 6) NEEA suggested that walk-in coolers and freezers are essentially buildings and should be modeled as such. (NEEA, No. 0061.1 at p. 5)

DOE notes that any regulation it develops must be consistent with, and fall within the parameters of, the statutory provisions set by Congress. Working within the confines of the statutorily-prescribed definition of the walk-in definition, DOE is clarifying what the term "refrigerated" means in the context of the walk-in definition to help address the concerns raised by commenters. In particular, DOE is defining "refrigerated" for purposes of walk-ins to mean "held at a temperature at or below 55 degrees Fahrenheit using a refrigeration system" as suggested by commenters. Adopting this approach should enable DOE to sufficiently account for the range of walk-in equipment that exist.

In comments on the January 2010 NOPR, interested parties expressed concern about the potential for abuse in light of the breadth of the exclusion in the statute and requested that DOE clarify the scope of this clause. At the public meeting for the January 2010 NOPR, Craig Industries stated that the definition of "medical, scientific, and research walk-ins" should be better defined, and Hired Hand agreed that the definition is unclear. (Craig Industries, Public Meeting Transcript, No. 0016 at p. 19; Hired Hand, Public Meeting Transcript, No. 0016 at p. 26) These commenters were concerned because the current statutory language does not account for the fact that, in practice, walk-ins may be used interchangeably for either food storage or medical, scientific, or research usage. Because a given walk-in sold by a company could be used in any of these types of applications, Craig Industries and Hired Hand were both concerned that a company could market its walk-in as medical equipment and avoid having to meet any energy efficiency standards. Craig Industries and Hired Hand requested that DOE work to improve the definition of exempted uses for walk-ins because the definition could create ambiguity and loopholes. (Craig Industries, Public Meeting Transcript, No. 0016 at p. 4; Hired Hand, No. 0051.1 at p. 2)

DOE is sensitive to the potential for abuse regarding walk-ins. To ensure that such abuse does not occur and to help clarify the scope of the exclusion created by Congress, DOE notes that for any walk-in—including those components that are covered by today's test procedure and any applicable standards that DOE may promulgate—a manufacturer seeking to avail itself of the statutory exclusion would, consistent with the statute, need to affirmatively demonstrate to DOE that its equipment is "designed and marketed exclusively for medical, scientific, or research purposes." 42 U.S.C. 6311(20)(B). Further, while DOE is currently unaware of any instances where this exclusion is being abused, DOE will monitor the situation and take steps to prevent these types of activities from occurring when it receives sufficient information substantiating the existence of such activities. In examining whether a given walk-in satisfies the statutory exclusion, DOE may consider a number of factors, including, but not limited to, how a particular walk-in has been designed, how it has been marketed, to whom the equipment has been distributed, and steps taken by manufacturers. Accordingly, while DOE appreciates the concerns raised by Craig Industries and Hired Hand, DOE has decided that, at this time, the exclusion set by Congress is sufficiently clear. DOE may revisit this issue in the future if necessary.

One commenter requested clarification of the 3,000 square foot provision. Bally suggested that DOE add a corroborating cubic foot threshold, and stated that the large variability in panel heights could impact the energy conservation standards. (Bally, No. 0078.1 at p. 1) Under the component-level test procedures established today, a cubic foot threshold for a walk-in is not necessary. Rather, a panel is considered as an individual component and its dimensions, including its height, are accounted for in the calculation methodology that DOE developed.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget has determined that test procedure rulemakings do not constitute "significant regulatory actions" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *http://www.gc.doe.gov.*

DOE reviewed the test procedures considered in today's final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003.

As discussed in detail below, DOE found that because these test procedures have not previously been required of manufacturers, all manufacturers, including small manufacturers, could experience a financial burden associated with new testing requirements. While examining this issue, DOE determined that it could not certify that this rule would not have a significant effect on a substantial number of small entities. Therefore, DOE prepared an Initial Regulatory Flexibility Analysis (IRFA) for this rulemaking. 75 FR 55068, 55087. The Final Regulatory Flexibility Analysis (FRFA) set forth below, which describes potential impacts on small businesses associated with walk-in cooler and freezer testing requirements, incorporates the IRFA and changes made to the IRFA in response to the comments from interested parties, including the Small Business Administration (SBA), on the September 2010 SNOPR.

1. Statement of the Need for, and Objectives of, the Rule

A statement of the need for, and objectives of, the rule is stated elsewhere in the preamble and not repeated here.

2. Summary of the Significant Issues Raised by the Public Comments, DOE's Response to These Issues, and Any Changes Made in the Proposed Rule as a Result of Such Comments

The comments received on the IRFA and the economic impacts of the rule and responses thereto are provided in the analysis below.

3. Description and Estimated Number of Small Entities Regulated

DOE uses the SBA small business size standards published on January 31, 1996, as amended, to determine whether any small entities would be required to comply with the rule. 61 FR 3286; see also 65 FR 30836, 30850 (May 15, 2000), as amended. 65 FR 53533, 53545 (September 5, 2000). The size standards are codified at 13 CFR Part 121. The standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *http://www.sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.*

In the January 2010 NOPR and September 2010 SNOPR, DOE classified walk-in cooler and freezer equipment manufacturing under NAICS 333415, "Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing," which has a size standard of 750 employees. 75 FR 186, 204 (Jan. 4, 2010) and 75 FR 55068, 55087 (Sept. 9, 2010). After reviewing industry sources and publicly available data, DOE identified at least 37 small manufacturers of walk-in cooler and freezer envelopes and at least 5 small manufacturers of walk-in cooler and freezer refrigeration systems that met this criterion. DOE also noted that the walk-in industry can be characterized by a few manufacturers that are subsidiaries of much larger companies (that would not be considered small businesses) and a large number of small companies as categorized by NAICS code 333415. Furthermore, more than half of small walk-in manufacturers have 100 or fewer employees. 75 FR at 55088 (Sept. 9, 2010).

Interested parties commented on the market characterization DOE presented in the September 2010 SNOPR. SBA agreed with DOE's characterization of the walk-in manufacturing industry. (SBA, No. 0066.1 at p. 2) American Panel stated that most walk-in companies are small businesses and would be at a disadvantage compared to the large conglomerates. American Panel characterized the majority of small walk-in manufacturers as making between $10 and $25 million in sales while large manufacturers represent $75 million in walk-in sales and $250 million in overall sales. (American Panel, No. 0057.1 at p. 3) American Panel stated that the cost of testing would be passed down to the product selling price, which would trickle down and seriously impact small business restaurant owners. (American Panel, No. 0057.1 at p. 4) Zero Zone agreed that small manufacturers would be impacted by the regulations and stated that many will not be able to stay in business once they are burdened with the costs of certification. (Zero Zone, No. 0077.1 at p. 2)

In response to comments on the January 2010 NOPR and September 2010 SNOPR regarding DOE's proposed standards for WICF, DOE is taking a component-level approach in the WICF test procedure rulemaking. Specifically, DOE is establishing test procedures for individual components of a walk-in: Panels, doors, and refrigeration systems. Manufacturers of these components will be required to test the components they manufacture for walk-ins and certify that they meet any applicable component performance standard. This approach will mitigate the overall burdens posed by this regulation and ensure that those burdens are borne on those manufacturers who are best suited and positioned to conduct these types of tests. See section III.A for further details on this approach.

As a result of this approach, DOE re-evaluated the number of small manufacturers it identified in the September 2010 SNOPR for this final rule. Because DOE is considering refrigeration systems as a single component under the proposed approach, DOE estimates that there are 4 small manufacturers of refrigeration systems. Furthermore, DOE notes that entities it previously considered walk-in envelope manufacturers also manufacture the panels. As a result, DOE estimates that there are 37 small manufacturers of panels. For doors, DOE notes that some of the panel manufacturers make doors and others buy doors from suppliers. DOE researched manufacturers who solely manufacture the doors of WICF, and estimates that there are four small manufacturers of walk-in doors who do not also manufacture panels. DOE notes SBA's and American Panel's characterization of the walk-in industry as being composed mainly of small manufacturers. DOE believes the new approach of regulating WICFs at the component level will reduce burden on small manufacturers because the testing and compliance burden will be reduced due to an enhanced ability to apply the basic model concept. *See* section III.A.3.a for details. In response to American Panel's comment that the cost of testing would affect small restaurant owners, DOE notes that this analysis considers entities who are directly regulated by this test procedure rulemaking (*i.e.,* manufacturers). The concurrent energy conservation standards rulemaking will address effects on walk-in manufacturers' customers.

4. Description and Estimate of Compliance Requirements and Description of Steps To Minimize the Economic Impact on Small Entities

DOE recognizes the particular burden of the test procedures on small manufacturers. DOE does not expect that small manufacturers would have fewer basic models or component types than large manufacturers. Therefore, a small manufacturer could have the same total cost of testing as a large manufacturer, but this cost would be a higher percentage of a small manufacturer's annual revenues. Thus, the differential impact associated with walk-in cooler and walk-in freezer test procedures on small businesses may be significant even if the overall testing burden is reduced as described elsewhere in the preamble.

Due to the nature of walk-in coolers and freezers within the appliance standards program, DOE is considering use of a component-based approach to walk-in standards, setting individual performance standards for each component. This approach would require the component manufacturers to test the components they manufacture for walk-in applications, comply with the applicable performance standard for those components, and certify to DOE that those components meet the standard. See section III.A for details on this approach. At this time there are no performance standards in place for walk-in equipment, as those standards are being developed in a concurrent rulemaking. Details on the performance standards rulemaking can be found on the DOE Web site at *http://www1.eere.energy.gov/buildings/appliance_standards/commercial/wicf.html.* However, manufacturers will be required to use these test procedures to certify performance once any final standards are issued and must use the test procedures outlined in this final rule if they make representations as to the performance of their components.

To further address concerns about costs, DOE is anticipating developing a sampling plan in a future rulemaking to determine how many units of each walk-in component must be tested. In such a rulemaking, DOE will consider the impacts to small businesses.

a. Panel and Door Manufacturer Testing Impacts

In the September 2010 SNOPR, DOE proposed to require envelope manufacturers to test their equipment in accordance with several industry test standards: ASTM C1363–05, "Standard

Test Method for Thermal Performance of Building Materials and Envelope Assemblies by Means of a Hot Box Apparatus;" DIN EN 13164:2009–02, "Thermal insulation products for buildings—Factory made products of extruded polystyrene foam (XPS)—Specification;" DIN EN 13165:2009–02, "Thermal insulation products for buildings—Factory made rigid polyurethane foam (PUR) products—Specification;" and NFRC 100–2010[E0A1], "Procedure for Determining Fenestration Product U-factors."

DOE spoke with industry experts to determine the approximate cost of each test. Under the new component level approach to testing, entire walk-ins are not required to be tested or certified. Rather, component manufacturers are required to test and certify their own components. Therefore, DOE evaluated the cost of each test to the component manufacturer. For foam used in panels, a test using DIN EN 13164:2009–02 or DIN EN 13165:2009–02 costs approximately $5,000 for each type of foam, though DOE has found that most manufacturers use only one type. The test result would be used to calculate the LTTR for all the manufacturer's panels that use that type of foam. For the panels themselves, a test using ASTM C1363–05 costs approximately $5,000. Manufacturers would need to test the core and edge U-factor of a pair of 4 ft. by 8 ft. panels, for each foam type, frame type, and panel thickness they manufacture. DOE estimated that manufacturers use either one or two types of foam and may have up to nine different combinations of frame type and panel thickness. Using this estimate, the total cost of testing compliance with a panel standard could be up to an average of $5,000–$10,000 for the foam panels and $45,000 to test the U-factors of the different panel configurations. However, for manufacturers who have fewer unique combinations of frame type and panel thickness, the testing cost would be substantially less. DOE has incorporated other burden reducing measures to reduce cost. Specifically, it incorporated a method that allows manufacturers to test a reference panel that is 4 ft. by 8 ft. and then calculate the U-factor of other panels of different dimensions from those test results as long as certain aspects of the panels are the same. See section III.B.2 for details.

For doors, a test of door U-factor using NFRC 100 costs approximately $5,000. DOE estimates that a typical door manufacturer would have to certify up to 20 to 40 basic models of doors, which would cost $100,000 to $200,000 if each door were to be physically tested. However, NFRC 100 also permits computer modeling of a door's U-factor, which could further reduce the testing cost. See section III.B.3 for discussion of the NFRC testing requirements for doors.

The estimated costs only include the cost of one test on each basic model, and do not include additional testing on the same basic model that may be required as part of a sampling plan. As mentioned above, DOE anticipates developing sampling plans in a future rulemaking to determine how many tests need to be performed on the same type of envelope component, to ensure the test results are repeatable and statistically valid.

b. Refrigeration System Manufacturer Testing Impacts

The test procedure for refrigeration systems will require manufacturers to perform testing in accordance with a single industry test standard: AHRI 1250 (I–P)–2009, "2009 Standard for Performance Rating of Walk-In Coolers and Freezers." DOE researched the cost of performing this test and, based on discussions with experts, estimates that a test using AHRI 1250 (I–P)–2009 would likely cost approximately $8,500. DOE estimates that the total testing cost for a typical refrigeration manufacturer could be approximately $425,000, based on an estimate of 50 basic models, but that it could be higher for manufacturers of more customized equipment. For instance, a manufacturer with 200 basic models would incur a testing cost of approximately $1.7 million.

To address concerns of manufacturer impact, DOE is including burden-reducing measures for refrigeration system manufacturers. The test procedure referenced in this final rule, AHRI 1250–2009, allows for rating the condensing unit and the unit cooler separately and then calculating their combined efficiency. This reduces testing burden by not requiring testing of every combination. Allowing such a calculation to be used will significantly decrease the number of tests. See section III.C.2 for details. DOE also notes that the CCE final rule, published March 7, 2011, allows that in general, manufacturers may elect to group individual models of equipment into basic models at their discretion to the extent the models have essentially identical electrical, physical, and functional characteristics that affect energy efficiency or energy consumption. Furthermore, manufacturers may rate models conservatively, meaning the tested performance of the model(s) must be at least as good as the certified rating, after applying the appropriate sampling plan. 76 FR 12429. DOE believes these provisions will reduce the burden of testing for refrigeration manufacturers because they will reduce the number of basic models a manufacturer must test. DOE may also consider allowing manufacturers to use validated alternative methods to rate their equipment. See section III.C.3 for further discussion of these methods.

DOE also considered a number of alternatives to these test procedures, including test procedures that incorporate industry test standards other than the referenced standards, DIN EN 13164:2009–02, DIN EN 13165:2009–02, ASTM C1363–05, and AHRI 1250–2009, all previously described in section III. (DOE also notes that NFRC 100, the test method adopted for determining the U-factor of doors, was the least burdensome test DOE identified.) Instead of requiring DIN EN 13164:2009–02 or DIN EN 13165:2009–02 for testing the long-term thermal properties of insulation, DOE could require only ASTM C518–04, "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus," which tests the thermal properties of insulation at a certain point in time (that is, the point of manufacture). This test could also be used in place of ASTM 1363–05. A test conducted as per ASTM C518–04 would cost approximately $500 to $1,000, as compared to $5,000 for a test conducted as per DIN EN 13164:2009–02 or DIN EN 13165:2009–02 and $5,000 for a test conducted as per ASTM C1363–05. DOE is including ASTM C1363–05 as part of the test procedure because heat conduction through structural members is a significant panel characteristic that is not addressed under ASTM C518–04. See section III.B.2.a for details. DOE is including DIN EN 13164:2009–02 and DIN EN 13165:2009–02 as part of the test procedure because these methods account for the effect of aging on foam's insulation performance, a phenomenon that is not captured under ASTM C518–04. See section III.B.2.b for details.

C. Review Under the Paperwork Reduction Act of 1995

Manufacturers of walk-in cooler and walk-in freezer components must certify to DOE that their equipment complies with any applicable energy conservation standard. In certifying compliance, manufacturers must test their equipment according to the DOE test procedure for walk-in cooler and walk-in freezer components, including any amendments adopted for that test procedure. DOE has adopted regulations

for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including walk-in cooler and walk-in freezer components. 76 FR 12442 (March 7, 2011). The collection-of-information requirement for the certification and recordkeeping has been approved by OMB under control number 1910–1400. The public reporting burden for the certification is estimated to average 20 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to Charles Llenza (see **ADDRESSES**) and by e-mail to *Christine_J._Kymn@omb.eop.gov.*

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this final rule, DOE establishes a new test procedure for walk-in coolers and walk-in freezers. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this rule establishes a test procedure without affecting the amount, quality or distribution of energy usage, and, therefore, will not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that does not result in any environmental impacts. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE examined this final rule and determined that it will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of today's final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://www.gc.doe.gov.* DOE examined today's final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under theTreasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule

that may affect family well-being. Today's final rule will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights" 53 FR 8859 (March 18, 1988), that this regulation will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed today's final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

Today's regulatory action is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The procedures addressed by this action incorporate the following commercial standards: ASTM C1363–05, AHRI 1250 (I–P)–2009, DIN EN 13164:2009–02, DIN EN 13165:2009–02, and NFRC 100–2010[E0A1]. DOE has evaluated these standards and is unable to conclude whether they fully comply with the requirements of section 32(b) of the FEAA (i.e. whether they were developed in a manner that fully provides for public participation, comment, and review.) DOE has consulted with both the Attorney General and the Chairman of the FTC about the impact on competition of using the methods contained in these standards and has received no comments objecting to their use.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of today's rule before its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

N. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation, Incorporation by reference, Reporting and recordkeeping requirements.

Issued in Washington, DC, on March 30, 2011.

Kathleen Hogan,

Deputy Assistant Secretary for Energy Efficiency, Office of Technology Development, Energy Efficiency and Renewable Energy.

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 431.302 is amended by adding, in alphabetical order, new definitions for "Display door," "Display panel," "Door", "Envelope," "K-factor," "Panel," "Refrigerated," "Refrigeration system," and "U-factor" to read as follows:

§ 431.302 Definitions concerning walk-in coolers and walk-in freezers.

* * * * *

Display door means a door designed for product movement, display, or both, rather than the passage of persons.

Display panel means a panel that is entirely or partially comprised of glass, a transparent material, or both and is used for display purposes.

Door means an assembly installed in an opening on an interior or exterior wall that is used to allow access or close off the opening and that is movable in a sliding, pivoting, hinged, or revolving manner of movement. For walk-in coolers and walk-in freezers, a door includes the door panel, glass, framing materials, door plug, mullion, and any other elements that form the door or part of its connection to the wall.

Envelope means—

(1) The portion of a walk-in cooler or walk-in freezer that isolates the interior, refrigerated environment from the ambient, external environment; and

(2) All energy-consuming components of the walk-in cooler or walk-in freezer that are not part of its refrigeration system.

K-factor means the thermal conductivity of a material.

* * * * *

Panel means a construction component that is not a door and is used to construct the envelope of the walk-in, i.e., elements that separate the interior refrigerated environment of the walk-in from the exterior.

Refrigerated means held at a temperature at or below 55 degrees Fahrenheit using a refrigeration system.

Refrigeration system means the mechanism (including all controls and other components integral to the

system's operation) used to create the refrigerated environment in the interior of a walk-in cooler or freezer, consisting of:

(1) A packaged dedicated system where the unit cooler and condensing unit are integrated into a single piece of equipment; or

(2) A split dedicated system with separate unit cooler and condensing unit sections; or

(3) A unit cooler that is connected to a multiplex condensing system.

U-factor means the heat transmission in a unit time through a unit area of a specimen or product and its boundary air films, induced by a unit temperature difference between the environments on each side.

* * * * *

■ 3. Section 431.303 is amended by:

■ a. Redesignating paragraph (b) as paragraph (c);

■ b. Adding at the end of the sentence in redesignated paragraph (c)(1), "and Appendix A to Subpart R of Part 431".

■ c. Adding new paragraphs (b), (c)(2), (d), and (e) to read as follows.

§ 431.303 Materials incorporated by reference.

* * * * *

(b) *AHRI.* Air-Conditioning, Heating, and Refrigeration Institute, 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, (703) 600–0366, or *http://www.ahrinet.org.*

(1) AHRI 1250 (I–P)-2009, ("AHRI 1250"), 2009 Standard for Performance Rating of Walk-In Coolers and Freezers, approved 2009, IBR approved for § 431.304.

(2) [Reserved]

(c) * * *

(2) ASTM C1363–05, ("ASTM C1363"), Standard Test Method for Thermal Performance of Building Materials and Envelope Assemblies by Means of a Hot Box Apparatus, approved May 1, 2005, IBR approved for Appendix A to Subpart R of part 431.

(d) *CEN.* European Committee for Standardization (French: Norme or German: Norm), Avenue Marnix 17, B–1000 Brussels, Belgium, *Tel:* + 32 2 550 08 11, *Fax:* + 32 2 550 08 19 or *http://www.cen.eu/.*

(1) DIN EN 13164:2009–02, ("DIN EN 13164"), Thermal insulation products for buildings—Factory made products of extruded polystyrene foam (XPS)—Specification, approved February 2009, IBR approved for Appendix A to Subpart R of part 431.

(2) DIN EN 13165:2009–02, ("DIN EN 13165"), Thermal insulation products for buildings—Factory made rigid polyurethane foam (PUR) products—Specification, approved February 2009, IBR approved for Appendix A to Subpart R of part 431.

(e) *NFRC.* National Fenestration Rating Council, 6305 Ivy Lane, Ste. 140, Greenbelt, MD 20770, (301) 589–1776, or *http://www.nfrc.org/.*

(1) NFRC 100–2010[E0A1], ("NFRC 100"), Procedure for Determining Fenestration Product U-factors, approved June 2010, IBR approved for Appendix A to Subpart R of part 431.

(2) [Reserved]

■ 4. Section 431.304 is amended by redesignating paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) as (b)(1), (b)(2), (b)(3), and (b)(4), respectively, and by adding new paragraphs (b)(5), (b)(6), (b)(7), and (b)(8) to read as follows.

§ 431.304 Uniform test method for the measurement of energy consumption of walk-in coolers and walk-in freezers.

* * * * *

(b) * * *

(5) Determine the U-factor, conduction load, and energy use of walk-in cooler and walk-in freezer display panels, floor panels, and non-floor panels by conducting the test procedure set forth in Appendix A to this subpart, sections 4.1, 4.2, and 4.3, respectively.

(6) Determine the energy use of walk-in cooler and walk-in freezer display doors and non-display doors by conducting the test procedure set forth in Appendix A to this subpart, sections 4.4 and 4.5, respectively.

(7) Determine the Annual Walk-in Energy Factor of walk-in cooler and walk-in freezer refrigeration systems by conducting the test procedure set forth in AHRI 1250 (incorporated by reference; see § 431.303).

(8) Determine the annual energy consumption of walk-in cooler and walk-in freezer refrigeration systems:

(i) For systems consisting of a packaged dedicated system or a split dedicated system, where the condensing unit is located outdoors, by conducting the test procedure set forth in AHRI 1250 and recording the annual energy consumption term in the equation for annual walk-in energy factor in section 7 of AHRI 1250:

$$\text{Annual Energy Consumption} = \sum_{j=1}^{n} E(t_j)$$

where t_j and n represent the outdoor temperature at each bin j and the number of hours in each bin j, respectively, for the temperature bins listed in Table D1 of AHRI 1250.

(ii) For systems consisting of a packaged dedicated system or a split dedicated system where the condensing unit is located in a conditioned space, by performing the following calculation:

$$\text{Annual Energy Consumption} = \left(\frac{0.33 \times \mathring{BLH} + 0.67 \times \mathring{BLL}}{\text{Annual Walk-in Energy Factor}}\right) \times 8760$$

where $\mathring{BLH}$ and $\mathring{BLL}$ for refrigerator and freezer systems are defined in sections 6.2.1 and 6.2.2, respectively, of AHRI 1250 and the annual walk-in energy factor is calculated from the results of the test procedures set forth in AHRI 1250.

(iii) For systems consisting of a single unit cooler or a set of multiple unit coolers serving a single piece of equipment and connected to a multiplex condensing system, by performing the following calculation:

$$\text{Annual Energy Consumption} = \left(\frac{0.33 \times \dot{BLH} + 0.67 \times \dot{BLL}}{\text{Annual Walk-in Energy Factor}}\right) \times 8760$$

where $\dot{BLH}$ and $\dot{BLL}$ for refrigerator and freezer systems are defined in section 7.9.2.2 and 7.9.2.3, respectively, of AHRI 1250 and the annual walk-in energy factor is calculated from the results of the test procedures set forth in AHRI 1250.

■ 5. Appendix A to subpart R of part 431 is added to read as follows:

Appendix A to Subpart R of Part 431—Uniform Test Method for the Measurement of Energy Consumption of the Components of Envelopes of Walk-In Coolers and Walk-In Freezers

1.0 Scope

This appendix covers the test requirements used to measure the energy consumption of the components that make up the envelope of a walk-in cooler or walk-in freezer.

2.0 Definitions

The definitions contained in § 431.302 are applicable to this appendix.

3.0 Additional Definitions

3.1 Automatic door opener/closer means a device or control system that "automatically" opens and closes doors without direct user contact, such as a motion sensor that senses when a forklift is approaching the entrance to a door and opens it, and then closes the door after the forklift has passed.

3.2 Core region means the part of the panel that is not the edge region.

3.3 Edge region means a region of the panel that is wide enough to encompass any framing members and edge effects. If the panel contains framing members (e.g. a wood frame) then the width of the edge region must be as wide as any framing member plus 2 in. ± 0.25 in. If the panel does not contain framing members then the width of the edge region must be 4 in. ± 0.25 in. For walk-in panels that utilize vacuum insulated panels (VIP) for insulation, the width of the edge region must be the lesser of 4.5 in. ± 1 in. or the maximum width that does not cause the VIP to be pierced by the cutting device when the edge region is cut.

3.4 Surface area means the area of the surface of the walk-in component that would be external to the walk-in. For example, for panel, the surface area would be the area of the side of the panel that faces the outside of the walk-in. It would not include edges of the panel that are not exposed to the outside of the walk-in.

3.5 Rating conditions means, unless explicitly stated otherwise, all conditions shown in Table A.1. For installations where two or more walk-in envelope components share any surface(s), the "external conditions" of the shared surface(s) must reflect the internal conditions of the adjacent walk-in. For example, if a walk-in component divides a walk-in freezer from a walk-in cooler, then the internal conditions are the freezer rating conditions and the external conditions are the cooler rating conditions.

3.6 Percent time off (PTO) means the percent of time that an electrical device is assumed to be off.

TABLE A.1—TEMPERATURE CONDITIONS

	Value
Internal Temperatures (cooled space within the envelope):	
Cooler Dry Bulb Temperature ..	35 °F
Freezer Dry Bulb Temperature	−10 °F
External Temperatures (space external to the envelope):	
Freezer and Cooler Dry Bulb Temperatures.	75 °F
Subfloor Temperatures:	
Freezer and Cooler Dry Bulb Temperatures.	55 °F

4.0 Calculation Instructions

4.1 Display Panels

(a) Calculate the U-factor of the display panel in accordance with section 5.3 of this appendix, Btu/h-ft² – °F.

(b) Calculate the display panel surface area, as defined in section 3.4 of this appendix, A_{dp}, ft², with standard geometric formulas or engineering software.

(c) Calculate the temperature differential, ΔT_{dp}, °F, for the display panel, as follows:

$$\Delta T_{dp} = \left|T_{DB,ext,dp} - T_{DB,int,dp}\right| \qquad (4\text{-}1)$$

Where:

$T_{DB,ext,dp}$ = dry-bulb air external temperature, °F, as prescribed in Table A.1; and

$T_{DB,int,dp}$ = dry-bulb air temperature internal to the cooler or freezer, °F, as prescribed in Table A.1.

(d) Calculate the conduction load through the display panel, $Q_{cond\text{-}dp}$, Btu/h, as follows:

$$Q_{cond,dp} = A_{dp} \times \Delta T_{dp} \times U_{dp} \qquad (4\text{-}2)$$

Where:

A_{dp}= surface area of the walk-in display panel, ft²;

ΔT_{dp}= temperature differential between refrigerated and adjacent zones, °F; and

U_{dp} = thermal transmittance, U-factor, of the display panel in accordance with section 5.3 of this appendix, Btu/h-ft² – °F.

(e) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/W-h

(2) For freezers, use EER = 6.3 Btu/W-h

(f) Calculate the total daily energy consumption, E_{dp}, kWh/day, as follows:

$$E_{dp} = \frac{Q_{cond,dp}}{EER} \times \frac{24\ \text{h} \times 1\ \text{kW}}{1\ \text{day} \times 1000\ \text{W}} \qquad (4\text{-}3)$$

Where:

$Q_{cond,dp}$ = the conduction load through the display panel, Btu/h; and

EER = EER of walk-in (cooler or freezer), Btu/W-h.

4.2 Floor Panels

(a) Calculate the surface area, as defined in section 3.4 of this appendix, of the floor panel edge, as defined in section 3.3, $A_{fp\ edge}$, ft², with standard geometric formulas or engineering software as directed in section 5.1 of this appendix.

(b) Calculate the surface area, as defined in section 3.4 of this appendix, of the floor panel core, as defined in section 3.2, $A_{fp\ core}$, ft², with standard geometric formulas or

engineering software as directed in section 5.1 of this appendix.

(c) Calculate the total area of the floor panel, A_{fp}, ft², as follows:

$$A_{fp} = A_{fp\ core} + A_{fp\ edge} \quad (4\text{-}4)$$

Where:

$A_{fp\ core}$ = floor panel core area, ft²; and

$A_{fp\ edge}$ = floor panel edge area, ft².

(d) Calculate the temperature differential of the floor panel, ΔT_{fp}, °F, as follows:

$$\Delta T_{fp} = |T_{ext,fp} - T_{DB,int,fp}| \quad (4\text{-}5)$$

Where:

$T_{ext,\ fp}$ = subfloor temperature, °F, as prescribed in Table A.1; and

$T_{DB,int,\ fp}$ = dry-bulb air internal temperature, °F, as prescribed in Table A.1. If the panel spans both cooler and freezer temperatures, the freezer temperature must be used.

(e) Calculate the floor foam degradation factor, DF_{fp}, unitless, as follows:

$$DF_{fp} = \frac{R_{LTTR,fp}}{R_{0,fp}} \quad (4\text{-}6)$$

Where:

$R_{LTTR,fp}$ = the long term thermal resistance R-value of the floor panel foam in accordance with section 5.2 of this appendix, h-ft²-°F/Btu; and

$R_{o,fp}$ = the R-value of foam determined in accordance with ASTM C518 (incorporated by reference; see section § 431.303) for purposes of compliance with the appropriate energy conservation standard, h-ft²-°F/Btu.

(f) Calculate the U-factor for panel core region modified by the long term thermal transmittance of foam, $U_{LT,fp\ core}$, Btu/h-ft² – °F, as follows:

$$U_{LT,fp\ core} = \frac{U_{fp\ core}}{DF_{fp}} \quad (4\text{-}7)$$

Where:

$U_{fp\ core}$ = the U-factor in accordance with section 5.1 of this appendix, Btu/h-ft²-°F; and

DF_{fp} = floor foam degradation factor, unitless.

(g) Calculate the overall U-factor of the floor panel, U_{fp}, Btu/h-ft²-°F, as follows:

$$U_{fp} = \frac{A_{fp\ edge} \times U_{fp\ edge} + A_{fp\ core} \times U_{LT,fp\ core}}{A_{fp}} \quad (4\text{-}8)$$

Where:

$A_{fp\ edge}$ = area of floor panel edge, ft²;

$U_{fp\ edge}$ = U-factor for panel edge area in accordance with section 5.1 of this appendix, Btu/h-ft²-°F;

$A_{fp\ core}$ = area of floor panel core, ft²;

$U_{LT,fp\ core}$ = U-factor for panel core region modified by the long term thermal transmittance of foam, Btu/h-ft²-°F; and

A_{fp} = total area of the floor panel, ft².

(h) Calculate the conduction load through floor panels, $Q_{cond\text{-}fp}$, Btu/h,

$$Q_{cond-fp} = \Delta T_{fp} \times A_{fp} \times U_{fp} \quad (4\text{-}9)$$

Where:

ΔT_{fp} = temperature differential across the floor panels, °F;

A_{fp} = total area of the floor panel, ft²; and

U_{fp} = overall U-factor of the floor panel, Btu/h-ft²-°F.

(i) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/W-h

(2) For freezers, use EER = 6.3 Btu/W-h

(j) Calculate the total daily energy consumption, E_{fp}, kWh/day, as follows:

$$E_{fp} = \frac{Q_{cond-fp}}{EER} \times \frac{24\ h \times 1\ kW}{1\ day \times 1000\ W} \quad (4\text{-}10)$$

Where:

$Q_{cond\text{-}fp}$ = the conduction load through the floor panel, Btu/h; and

EER = EER of walk-in (cooler or freezer), Btu/W-h.

4.3 Non-Floor Panels

(a) Calculate the surface area, as defined in section 3.4, of the non-floor panel edge, as defined in section 3.3, $A_{nf\ edge}$, ft², with standard geometric formulas or engineering software as directed in section 5.1 of this appendix.

(b) Calculate the surface area, as defined in section 3.4, of the non-floor panel core, as defined in section 3.2, $A_{nf\ core}$, ft², with standard geometric formulas or engineering software as directed in section 5.1 of this appendix.

(c) Calculate total non-floor panel area, A_{nf}, ft²:

$$A_{nf} = A_{nf\ edge} + A_{nf\ core} \quad (4\text{-}11)$$

Where:

$A_{nf\ edge}$ = non-floor paneledge area,ft²; and

$A_{nf\ core}$ = non-floor panel core area, ft².

(d) Calculate temperature differential, ΔT_{nf}, °F:

$$\Delta T_{nf} = |T_{DB,ext,nf} - T_{DB,int,nf}| \quad (4\text{-}12)$$

Where:

$T_{DB,ext,\ nf}$ = dry-bulb air external temperature, °F, as prescribed in Table A.1; and

$T_{DB,int,\ nf}$ = dry-bulb air internal temperature, °F, as prescribed in Table A.1. If the non-floor panel spans both cooler and freezer temperatures, then the freezer temperature must be used.

(e) Calculate the non-floor foam degradation factor, DF_{nf}, unitless, as follows:

$$DF_{nf} = \frac{R_{LTTR,nf}}{R_{o,nf}} \quad (4\text{-}13)$$

Where:

$R_{LTTR,nf}$ = the R-value of the non-floor panel foam in accordance with section 5.2 of this appendix, h-ft²-°F/Btu; and

$R_{o,nf}$ = the R-value of foam determined in accordance with ASTM C518 (incorporated by reference; see section § 431.303) for purposes of compliance with the appropriate energy conservation standard, h-ft²-°F/Btu.

(f) Calculate the U-factor, $U_{LT,nf\ core}$, Btu/h-ft²-°F, as follows:

$$U_{LT,nf\ core} = \frac{U_{nf\ core}}{DF_{nf}} \qquad (4\text{-}14)$$

Where:

$U_{nf\ core}$ = the U-factor, in accordance with section 5.1 of this appendix, of non-floor panel, Btu/h- ft²-°F; and

DF_{nf} = the non-floor foam degradation factor, unitless.

(g) Calculate the overall U-factor of the non-floor panel, U_{nf}, Btu/h-ft²-°F, as follows:

$$U_{nf} = \frac{A_{nf\ edge} \times U_{nf\ edge} + A_{nf\ core} \times U_{LT,nf\ core}}{A_{nf}} \qquad (4\text{-}15)$$

Where:

$A_{nf\ edge}$ = area of non-floor panel edge, ft²;

$U_{nf\ edge}$ = U-factor for non-floor panel edge area in accordance with section 5.1 of this appendix, Btu/h-ft²-°F;

$A_{nf\ core}$ = area of non-floor panel core, ft²;

$U_{LT,nf\ core}$ = U-factor for non-floor panel core region modified by the long term thermal transmittance of foam, Btu/h-ft²-°F; and

A_{nf} = total area of the non- floor panel, ft².

(h) Calculate the conduction load through non-floor panels, $Q_{cond\text{-}nf}$, Btu/h,

$$Q_{cond-nf} = \Delta T_{nf} \times A_{nf} \times U_{nf} \qquad (4\text{-}16)$$

Where:

ΔT_{nf} = temperature differential across the non-floor panels, °F;

A_{nf} = total area of the non-floor panel, ft²; and

U_{nf} = overall U-factor of the non-floor panel, Btu/h-ft²-°F.

(i) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/W-h

(2) For freezers, use EER = 6.3 Btu/W-h

(j) Calculate the total daily energy consumption, E_{nf}, kWh/day, as follows:

$$E_{nf} = \frac{Q_{cond-nf}}{EER} \times \frac{24\ h \times 1\ kW}{1\ day \times 1000\ W} \qquad (4\text{-}17)$$

Where:

$Q_{cond\text{-}nf}$ = the conduction load through the non-floor panel, Btu/h; and

EER = EER of walk-in (cooler or freezer), Btu/W-h.

4.4 Display Doors

4.4.1 Conduction Through Display Doors

(a) Calculate the U-factor of the door in accordance with section 5.3 of this appendix, Btu/h-ft²-°F

(b) Calculate the surface area, as defined in section 3.4 of this appendix, of the display door, A_{dd}, ft², with standard geometric formulas or engineering software.

(c) Calculate the temperature differential, ΔT_{dd}, °F, for the display door as follows:

$$\Delta T_{dd} = \left| T_{DB,ext,dd} - T_{DB,int,dd} \right| \qquad (4\text{-}18)$$

Where:

$T_{DB,ext,\ dd}$ = dry-bulb air temperature external to the display door, °F, as prescribed in Table A.1; and

$T_{DB,int,\ dd}$ = dry-bulb air temperature internal to the display door, °F, as prescribed in Table A.1.

(d) Calculate the conduction load through the display doors, $Q_{cond\text{-}dd}$, Btu/h, as follows:

$$Q_{cond,dd} = A_{dd} \times \Delta T_{dd} \times U_{dd} \qquad (4\text{-}19)$$

Where:

ΔT_{dd} = temperature differential between refrigerated and adjacent zones, °F;

A_{dd} = surface area walk-in display doors, ft²; and

U_{dd} = thermal transmittance, U-factor of the door, in accordance with section 5.3 of this appendix, Btu/h-ft²-°F.

4.4.2 Direct Energy Consumption of Electrical Component(s) of Display Doors

Electrical components associated with display doors could include, but are not limited to: Heater wire (for anti-sweat or anti-freeze application); lights (including display door lighting systems); control system units; and sensors.

(a) Select the required value for percent time off (PTO) for each type of electricity consuming device, PTO_t (%)

(1) For lights without timers, control system or other demand-based control, PTO = 25 percent. For lighting with timers, control system or other demand-based control, PTO = 50 percent.

(2) For anti-sweat heaters on coolers (if included): Without timers, control system or other demand-based control, PTO = 0 percent. With timers, control system or other demand-based control, PTO = 75 percent. For anti-sweat heaters on freezers (if included): Without timers, control system or other auto-shut-off systems, PTO = 0 percent. With timers, control system or other demand-based control, PTO = 50 percent.

(3) For all other electricity consuming devices: Without timers, control system, or other auto-shut-off systems, PTO = 0 percent. If it can be demonstrated that the device is controlled by a preinstalled timer, control system or other auto-shut-off system, PTO = 25 percent.

(b) Calculate the power usage for each type of electricity consuming device, $P_{dd\text{-}comp,u,t}$, kWh/day, as follows:

$$P_{dd-comp,u,t} = P_{rated,u,t} \times (1 - PTO_{u,t}) \times n_{u,t} \times \frac{24h}{day} \qquad (4\text{-}20)$$

Where:

u = the index for each of type of electricity-consuming device located on either (1) the interior facing side of the display door or within the inside portion of the display door, (2) the exterior facing side of the display door, or (3) any combination of (1) and (2). For purposes of this calculation, the interior index is represented by u = int and the exterior index is represented by u = ext. If the electrical component is both on the interior and exterior side of the display door then u = int. For anti-sweat heaters sited anywhere in the display door, 75 percent of the total power is be attributed to u = int and 25 percent of the total power is attributed to u = ext;

t = index for each type of electricity consuming device with identical rated power;

$P_{rated,u,t}$ = rated power of each component, of type t, kW;

$PTO_{u,t}$ = percent time off, for device of type t, %; and

$n_{u,t}$ = number of devices at the rated power of type t, unitless.

(c) Calculate the total electrical energy consumption for interior and exterior power, $P_{dd\text{-}tot,\ int}$ (kWh/day) and $P_{dd\text{-}tot,\ ext}$ (kWh/day), respectively, as follows:

$$P_{dd-tot,int} = \sum_{1}^{t} P_{dd-comp,int,t} \qquad (4\text{-}21)$$

$$P_{dd-tot,ext} = \sum_{1}^{t} P_{dd-comp,ext,t} \qquad (4\text{-}22)$$

Where:

t = index for each type of electricity consuming device with identical rated power;

$P_{dd\text{-}comp,int,\ t}$ = the energy usage for an electricity consuming device sited on the interior facing side of or in the display door, of type t, kWh/day; and

$P_{dd\text{-}comp,ext,\ t}$ = the energy usage for an electricity consuming device sited on the external facing side of the display door, of type t, kWh/day.

(d) Calculate the total electrical energy consumption, $P_{dd\text{-}tot}$, (kWh/day), as follows:

$$P_{dd-tot} = P_{dd-tot,int} + P_{dd-tot,ext} \qquad (4\text{-}23)$$

Where:

$P_{dd\text{-}tot,int}$ = the total interior electrical energy usage for the display door, kWh/day; and

$P_{dd\text{-}tot,ext}$ = the total exterior electrical energy usage for the display door, kWh/day.

4.4.3 Total Indirect Electricity Consumption Due to Electrical Devices

(a) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/Wh

(2) For freezers, use EER = 6.3 Btu/Wh

(b) Calculate the additional refrigeration energy consumption due to thermal output from electrical components sited inside the display door, $C_{dd\text{-}load}$, kWh/day, as follows:

$$C_{dd-load} = P_{dd-tot,int} \times 3.\frac{412}{EER}\frac{Btu}{W-h} \qquad (4\text{-}24)$$

Where:

EER = EER of walk-in cooler or walk-in freezer, Btu/W-h; and

$P_{dd\text{-}tot,int}$ = The total internal electrical energy consumption due for the display door, kWh/day.

4.4.4 Total Display Door Energy Consumption

(a) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/W-h

(2) For freezers, use EER = 6.3 Btu/W-h

(b) Calculate the total daily energy consumption due to conduction thermal load, $E_{dd,\ thermal}$, kWh/day, as follows:

$$E_{dd,thermal} = \frac{Q_{cond,dd}}{EER} \times \frac{24\ h \times 1\ kW}{1\ day \times 1000\ W} \qquad (4\text{-}25)$$

Where:

$Q_{cond,\ dd}$ = the conduction load through the display door, Btu/h; and

EER = EER of walk-in (cooler or freezer), Btu/W-h.

(c) Calculate the total energy, $E_{dd,tot}$, kWh/day,

$$E_{dd,tot} = E_{dd,thermal} + P_{dd-tot} + C_{dd-load} \qquad (4\text{-}26)$$

Where:

$E_{dd,\ thermal}$ = the total daily energy consumption due to thermal load for the display door, kWh/day;

$P_{dd\text{-}tot}$ = the total electrical load, kWh/day; and

$C_{dd\text{-}load}$ = additional refrigeration load due to thermal output from electrical components contained within the display door, kWh/day.

4.5 Non-Display Doors

4.5.1 Conduction Through Non-Display Doors

(a) Calculate the surface area, as defined in section 3.4 of this appendix, of the non-display door, A_{nd}, ft², with standard geometric formulas or with engineering software.

(b) Calculate the temperature differential of the non-display door, ΔT_{nd},°F, as follows:

$$\Delta T_{nd} = \left|T_{DB,ext,nd} - T_{DB,int,nd}\right| \qquad (4\text{-}27)$$

Where:

$T_{DB,ext,\ nd}$ = dry-bulb air external temperature, °F, as prescribed by Table A.1; and

$T_{DB,int,\ nd}$ = dry-bulb air internal temperature, °F, as prescribed by Table A.1. If the component spans both cooler and freezer spaces, the freezer temperature must be used.

(c) Calculate the conduction load through the non-display door: $Q_{cond\text{-}nd}$, Btu/h,

$$Q_{cond-nd} = \Delta T_{nd} \times A_{ndploor anels\ and\ another\ foam\ type\ for\ floor\ panelsand\ one\ foam\ type\ for\ pan\ el\text{s},i=2a\ freezer\ glass\ door\ open} \qquad (4\text{-}28)$$

Where:

ΔT_{nd} = temperature differential across the non-display door, °F;

U_{nd} = thermal transmittance, U-factor of the door, in accordance with section 5.3 of this appendix, Btu/h-ft²-°F; and

A_{nd} = area of non-display door, ft².

4.5.2 Direct Energy Consumption of Electrical Components of Non-Display Doors

Electrical components associated with a walk-in non-display door comprise any components that are on the non-display door and that directly consume electrical energy. This includes, but is not limited to, heater wire (for anti-sweat or anti-freeze application), control system units, and sensors.

(a) Select the required value for percent time off for each type of electricity consuming device, PTO_t (%)

(1) For lighting without timers, control system or other demand-based control, PTO = 25 percent. For lighting with timers, control system or other demand-based control, PTO = 50 percent.

(2) For anti-sweat heaters on coolers (if included): Without timers, control system or other demand-based control, PTO = 0 percent. With timers, control system or other demand-based control, PTO = 75 percent. For anti-sweat heaters on freezers (if included): Without timers, control system or other auto-shut-off systems, PTO = 0 percent. With timers, control system or other demand-based control, PTO = 50 percent.

(3) For all other electricity consuming devices: Without timers, control system, or other auto-shut-off systems, PTO = 0 percent. If it can be demonstrated that the device is controlled by a preinstalled timer, control system or other auto-shut-off system, PTO = 25 percent.

(b) Calculate the power usage for each type of electricity consuming device, $P_{nd\text{-}comp,u,t}$, kWh/day, as follows:

$$P_{nd-comp,u,t} = P_{rated,u,t} \times \left(1 - PTO_{u,t}\right) \times n_{u,t} \times \frac{24h}{day} \qquad (4\text{-}29)$$

Where:

u = the index for each type of electricity-consuming device located on either (1) the interior facing side of the display door or within the inside portion of the display door, (2) the exterior facing side of the display door, or (3) any combination of (1) and (2). For purposes of this calculation, the interior index is represented by u = int and the exterior index is represented by u = ext. If the electrical component is both on the interior and exterior side of the display door then u = int. For anti-sweat heaters sited anywhere in the display door, 75 percent of the total power is attributed to u = int and 25 percent of the total power is attributed to u = ext;

t = index for each type of electricity consuming device with identical rated power;

$P_{rated,u,t}$ = rated power of each component, of type t, kW;

$PTO_{u,t}$ = percent time off, for device of type t, %; and

$n_{u,t}$ = number of devices at the rated power of type t, unitless.

(c) Calculate the total electrical energy consumption for interior and exterior power, $P_{nd\text{-}tot,\ int}$ (kWh/day) and $P_{nd\text{-}tot,\ ext}$ (kWh/day), respectively, as follows:

$$P_{nd-tot,int} = \sum_{1}^{t} P_{nd-comp,int,t} \qquad (4\text{-}30)$$

$$P_{nd-tot,ext} = \sum_{1}^{t} P_{nd-comp,ext,t} \qquad (4\text{-}31)$$

Where:

t = index for each type of electricity consuming device with identical rated power;

$P_{nd\text{-}comp,int,\ t}$ = the energy usage for an electricity consuming device sited on the internal facing side or internal to the

non-display door, of type t, kWh/day; and

$P_{nd\text{-}comp,ext,\ t}$ = the energy usage for an electricity consuming device sited on the external facing side of the non-display door, of type t, kWh/day. For anti-sweat heaters,

(d) Calculate the total electrical energy consumption, $P_{nd\text{-}tot}$, kWh/day, as follows:

$$P_{nd-tot} = P_{nd-tot,int} + P_{nd-tot,ext} \qquad (4\text{-}32)$$

Where:

$P_{nd\text{-}tot,int}$ = the total interior electrical energy usage for the non-display door, of type t, kWh/day; and

$P_{nd\text{-}tot,ext}$ = the total exterior electrical energy usage for the non-display door, of type t, kWh/day.

4.5.3 Total Indirect Electricity Consumption Due to Electrical Devices

(a) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/Wh

(2) For freezers, use EER = 6.3 Btu/Wh

(b) Calculate the additional refrigeration energy consumption due to thermal output from electrical components associated with the non-display door, $C_{nd\text{-}load}$, kWh/day, as follows:

$$C_{nd-load} = P_{nd-tot,int} \times 3.\frac{412}{EER}\frac{Btu}{W-h} \qquad (4\text{-}33)$$

Where:

EER = EER of walk-in cooler or freezer, Btu/W-h; and

$P_{nd\text{-}tot,int}$ = the total interior electrical energy consumption for the non-display door, kWh/day.

4.5.4 Total Non-Display Door Energy Consumption

(a) Select Energy Efficiency Ratio (EER), as follows:

(1) For coolers, use EER = 12.4 Btu/W-h

(2) For freezers, use EER = 6.3 Btu/W-h

(b) Calculate the total daily energy consumption due to thermal load, $E_{nd,\ thermal}$, kWh/day, as follows:

$$E_{nd,thermal} = \frac{Q_{cond-nd}}{EER} \times \frac{24\ h \times 1\ kW}{1\ day \times 1000\ W} \qquad (4\text{-}34)$$

Where:

$Q_{cond\text{-}nd}$ = the conduction load through the non-display door, Btu/hr; and

EER = EER of walk-in (cooler or freezer), Btu/W-h.

(c) Calculate the total energy, $E_{nd,tot}$, kWh/day, as follows:

$$E_{nd,tot} = E_{nd,thermal} + P_{nd-tot} + C_{load} \qquad (4\text{-}35)$$

Where:

$E_{nd,\ thermal}$ = the total daily energy consumption due to thermal load for the non-display door, kWh/day;

$P_{nd\text{-}tot}$ = the total electrical energy consumption, kWh/day; and

$C_{nd\text{-}load}$ = additional refrigeration load due to thermal output from electrical components contained on the inside face of the non-display door, kWh/day.

5.0 Test Methods and Measurements

5.1 Measuring Floor and Non-Floor Panel U-Factors

Follow the test procedure in ASTM C1363, (incorporated by reference; see § 431.303), exactly, with these exceptions:

(1) Test Sample Geometry Requirements

(i) Two (2) panels, 8 ft. ± 1 ft. long and 4 ft. ± 1 ft. wide must be used.

(ii) The panel edges must be joined using the manufacturer's panel interface joining system (e.g., camlocks, standard gasketing, etc.).

(iii) The Panel Edge Test Region, see figure 1, must be cut using the following dimensions:

1. If the panel contains framing members (e.g. a wood frame), then the width of edge (W) must be as wide as any framing member plus 2 in. ± 0.25 in. For example, if the face of the panel contains 1.5 in. thick framing members around the edge of the panel, then width of edge (W) = 3.5 in. ± 0.25 in and the Panel Edge Test Region would be 7 in. ± 0.5 in. wide.

2. If the panel does not contain framing members, then the width of edge (W) must be 4 in. ± 0.25 in.

3. Walk-in panels that utilize vacuum insulated panels (VIP) for insulation, width of edge (W) = the lesser of 4.5 in. ± 1 in. or the maximum width that does not cause the VIP to be pierced by the cutting device when the edge region is cut.

(iv) Panel Core Test Region of length Y and height Z, see Figure 1, must also be cut from one of the two panels such that panel length = Y + X, panel height = Z + X where X = 2W.

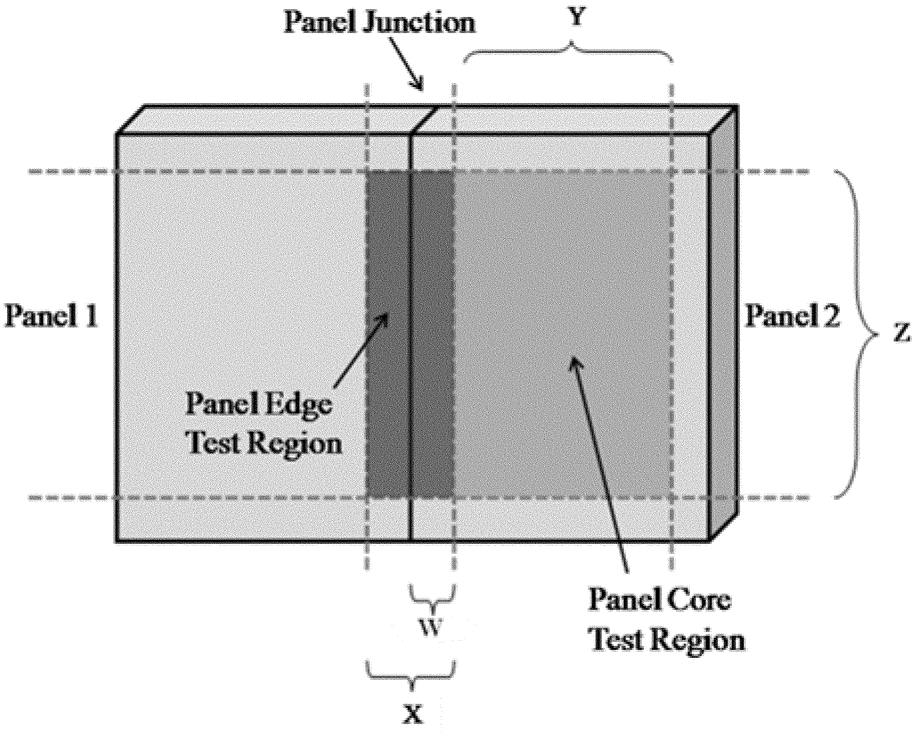

Figure 1 ASTM C1363 Test Regions (Note: diagram not drawn to scale)

(2) Testing Conditions

(i) The air temperature on the "hot side", as denoted in ASTM C1363, of the non-floor panel should be maintained at 75 °F ± 1 °F.

1. Exception: When testing floor panels, the air temperature should be maintained at 55 °F ± 1 °F.

(ii) The temperature on the "cold side", as denoted in ASTM C1363, of the panel should be maintained at 35 °F ± 1 °F for the panels used for walk-in coolers and − 10 °F ± 1 °F for panels used for walk-in freezers.

(iii) The air velocity must be maintained as natural convection conditions as described in ASTM C1363. The test must be completed using the masked method and with surround panel in place as described in ASTM C1363.

(3) Required Test Measurements

(i) Non-floor Panels

1. Panel Edge Region U-factor: $U_{nf,\ edge}$

2. Panel Core Region U-factor: $U_{nf,\ core}$

(ii) Floor Panels

1. Floor Panel Edge Region U-factor: $U_{fp,\ edge}$

2. Floor Panel Core Region U-factor: $U_{fp,\ core}$

5.2 Measuring Long Term Thermal Resistance (LTTR) of Insulating Foam

Follow the test procedure in Annex C of DIN EN 13164 or Annex C of DIN EN 13165 (as applicable), (incorporated by reference; see § 431.303), exactly, with these exceptions:

(1) Temperatures During Thermal Resistance Measurement

(i) For freezers: 35 °F ± 1 °F must be used

(ii) For coolers: 55 °F ± 1 must be used

(2) Sample Panel Preparation

(i) A 800mm × 800mm square (× thickness of the panel) section cut from the geometric center of the panel that is being tested must be used as the sample for completing DIN EN 13165.

(ii) A 500mm × 500mm square (× thickness of the panel) section cut from the geometric center of the panel that is being tested must be used as the sample for completing DIN EN 13164.

(3) Required Test Measurements

(i) Non-floor Panels

1. Long Term Thermal Resistance: $R_{LTTR,nf}$

(ii) Floor Panels

1. Long Term Thermal Resistance: $R_{LTTR,fp}$

5.3 U-factor of Doors and Display Panels

(a) Follow the procedure in NFRC 100, (incorporated by reference; see § 431.303), exactly, with these exceptions:

(1) The average convective heat transfer coefficient on both interior and exterior surfaces of the door should be based on the coefficients described in section 4.3 of NFRC 100.

(2) Internal conditions:

(i) Air temperature of 35 °F (1.7 °C) for cooler doors and − 10 °F (− 23.3 °C) for freezer doors

(ii) Mean inside radiant temperature must be the same as shown in section 5.3(a)(2)(i), above.

(3) External conditions

(i) Air temperature of 75 °F (23.9 °C)

(ii) Mean outside radiant temperature must be the same as section 5.3(a)(3)(i), above.

(4) Direct solar irradiance = 0 W/m² (Btu/h-ft²).

(b) Required Test Measurements

(i) Display Doors and Display Panels

1. Thermal Transmittance: U_{dd}

(ii) Non-Display Door

1. Thermal Transmittance: U_{nd}

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