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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 741

RIN 3133–AD66

Interest Rate Risk Policy and Program

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA is issuing a final rule requiring Federally insured credit unions to develop and adopt a written policy on interest rate risk management and a program to effectively implement that policy, as part of their asset liability management responsibilities. The interest rate risk policy and implementation program will be among the factors NCUA will consider in determining a credit union's insurability. To assist credit unions, the final rule includes an appendix setting forth guidance on developing an interest rate risk policy and an effective implementation program based on generally recognized best practices for safely and soundly managing interest rate risk.

DATES: This rule is effective on September 30, 2012.

FOR FURTHER INFORMATION CONTACT: Jeremy Taylor, Senior Capital Markets Specialist, Office of Examination and Insurance, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314, or telephone: (703) 518–6620.

SUPPLEMENTARY INFORMATION:

I. Background
II. Subject-by-Subject Discussion of Comments on Proposed Rule
III. Regulatory Procedures

I. Background [1]

A. *What Is Interest Rate Risk?* The term ''interest rate risk'' (''IRR'') refers to the vulnerability of a credit union's financial condition to adverse movements in market interest rates. Although some IRR is a normal part of financial intermediation,[2] it still may negatively affect a credit union's earnings, net worth, and its net economic value, which is the difference between the market value of assets and the market value of liabilities. Changes in interest rates influence a credit union's earnings by altering interest-sensitive income and expenses (*e.g.,* loan income and share dividends). Changes in interest rates also affect the economic value of a credit union's assets and liabilities because the present value of future cash flows and, in some cases, the cash flows themselves may change when interest rates change. IRR takes several forms: Repricing risk, yield curve risk, spread risk, basis risk, and options risk. For definitions of these risks, see section IX. of Appendix B following the final rule text below.

B. *Why is NCUA Amending the Existing Rule?* In the past, NCUA issued guidance on asset/liability management and IRR management in *Letters to Credit Unions.*[3] NCUA believes Federally-insured credit unions (''FICUs''), relying on this guidance, generally have managed their IRR adequately. However, FICUs have recently experienced increasing exposure to IRR due to changes in balance sheet composition and increased uncertainty in the financial markets. This increase has heightened the importance for FICUs to have strong policies and programs explicitly addressing the credit union's management of controls for IRR.

Therefore, it is both timely and appropriate to require certain credit unions to have a formal policy addressing IRR management and a corresponding program to effectively implement that policy. Further, it is incumbent upon NCUA, as steward of the National Credit Union Share Insurance Fund (''the Fund''), to consider a credit union's IRR management policy and implementation program as a factor in determining whether the Fund should insure its member deposits.

C. *What Were the Requirements of the Proposed Rule?* The existing regulation on insurability of accounts prescribes certain criteria NCUA must consider in ''determining the insurability of a credit union * * * and in continuing the insurability of its accounts.'' 12 CFR 741.3. Among the ''factors * * * to be considered in determining whether the credit union's financial condition and policies are both safe and sound,'' are the existence of written lending and investment policies. *Id.* § 741.3(b)(2)–(3). IRR management policies and practices are absent from the existing factors.

In response to credit unions' increasing exposure to IRR, NCUA issued a proposed rule in March 2011 amending section 741.3(b) to require, as an additional factor in determining whether a ''credit union's financial condition and policies are both safe and sound,'' the existence of a written policy on IRR management and a program to effectively implement that policy (together ''an IRR policy and program''). 76 FR 16570 (Mar. 24, 2011). The proposed rule set an effective date for compliance at three months after the publication of the final rule in the **Federal Register**.

As proposed, the rule would apply to two categories of FICUs, (a) those having more than $50 million in assets; and (b) those having assets between $10 million and $50 million whose ratio of first mortgage loans, plus investments with maturities greater than five years (the

[1] President Obama signed the Plain Writing Act of 2010 (Pub. L. 111–274) into law on October 13, 2010, to ''improve the effectiveness and accountability of Federal agencies to the public by promoting clear Government communication that the public can understand and use.'' This preamble is written to meet the plain writing objectives.

[2] The process of channeling funds from savers to investors.

[3] Letters to Credit Unions: 99–CU–12, Real Estate Lending and Balance Sheet Risk Management, Aug. 1999; 00–CU–10, Asset Liability Management Examination Procedures, Nov. 2000; 00–CU–13, Liquidity and Balance Sheet Risk Management, Dec. 2000; 01–CU–08, Liability Management—Highly Rate-Sensitive and Volatile Funding Sources, July 2001; 01–CU–19, Managing Share Inflows in Uncertain Times, Oct. 2001; 03–CU–11, Non-Maturity Shares and Balance Sheet Risk, July 2003; 03–CU–15, Real Estate Concentrations and Interest Rate Risk Management for Credit Unions with Large Positions in Fixed-Rate Mortgage Portfolios, Sept. 2003; 06–CU–16, Interagency Guidance on Nontraditional Mortgage Product Risk, Oct. 2006; 10–CU–06, Interagency Advisory on Interest Rate Risk Management, Jan. 6, 2010. NCUA plans to issue a Letter to Credit Unions addressing the ''Interagency Advisory on Interest Rate Risk Management, Frequently Asked Questions'' that was issued on January 12, 2012.

numerator), equals or exceeds 100% of its net worth (the denominator). This ratio is known as the ''Supervisory Interest Rate Risk Threshold Ratio'' (''SIRRT ratio'') and is explained in section II.D. of this preamble. Conversely, the rule would not apply to FICUs with assets of less than $10 million, or to those with assets between $10 million and $50 million whose combined first mortgage loans, plus investments with maturities greater than five years, are *less than* 100% of its net worth.

To help credit unions understand and meet NCUA's expectations for compliance with amended section 741.3(b), the proposed rule included an appendix (''Appendix B'') setting forth comprehensive guidance on developing both a written policy on IRR management and a program to effectively implement that policy.[4] Appendix B acknowledges that it is not possible to establish a ''one-size-fits-all'' template of IRR management standards and metrics that would be appropriate for all FICUs. Rather, it recognizes that IRR management requires specialized judgments based on each credit union's business objectives and ability to withstand risk.

Appendix B leaves to each affected credit union's board of directors the obligation and responsibility to make those judgments. Yet, it also provides them a framework of five fundamental elements of an effective IRR management program: A comprehensive, written IRR policy; accountable IRR oversight by board of directors and management; appropriate IRR measurement and monitoring systems; good internal controls; and informed decision-making based on IRR measurement system results. It also provides guidelines for determining the adequacy of IRR policy and effectiveness of implementation program. The appendix also includes guidance for large credit unions with complex or high-risk balance sheets.

II. Subject-by-Subject Discussion of Comments on Proposed Rule

The proposed rule was issued with a 60-day comment period that expired on May 23, 2011. 76 FR 16570. NCUA received 48 comment letters in response—29 from Federally-insured credit unions, 13 from credit union industry trade associations, one from an association of state credit union supervisory authorities, and 5 from industry consultants. Five commenters affirmatively supported the proposed rule; 29 commenters either opposed the rule or did not state a definitive position; and 14 commenters addressed particular aspects of the rule or made suggestions for improving it. The comments on the proposed rule are addressed as follows:

A. *Authority to Impose Insurability Criteria.* A trade association compared the existing insurability factors requiring a lending policy and an investment policy with the proposed requirement for an IRR management policy and implementation program. This commenter distinguished between lending and investment authorities and limitations that are ''specifically detailed in the Federal Credit Union Act'' and the authority to require IRR management, which it contends ''is a regulatory directive and is not addressed in the Act.'' The suggestion that there is authority in the Act to require the existing lending and investment policies but not to require an IRR management policy and implementation program is incorrect.[5] The basis for both the existing and proposed factors for insurability is safety and soundness. As section 741.3(b) itself confirms, the ''financial policies and conditions'' it prescribes are ''factors * * * to be considered in determining whether the credit union's financial condition and policies are *both safe and sound.''*

B. *Regulatory Burden and Duplication.* A number of commenters said that requiring an IRR management policy and implementation program as insurability criteria imposes an excessive regulatory burden on credit unions, especially in the wake of the regulatory mandates imposed as a result of the Dodd-Frank Wall Street Reform and Consumer Protection Act, 12 U.S.C. 5301 *et seq.* Emphasizing this point, some commenters protested that other financial regulators have not introduced IRR management rules.

A number of commenters also noted that mechanisms to manage credit unions' IRR already exist that are sufficient to monitor and assess shifts in IRR and to indicate when corrective action is warranted. For example, they cite interagency advisories, NCUA *Letters to Credit Unions,* and credit union examinations themselves. *See* footnote 3 above. NCUA does not dispute the utility of these existing mechanisms, but does not agree that they are sufficient in an environment of increased risk exposure and interest rate volatility. As detailed in sections C. and D. below in this preamble, IRR exposure at credit unions is on the rise to the point that it is higher than at peer commercial banks.

It is unclear that the numerous *Letters to Credit Unions* NCUA has periodically issued, providing supervisory advice and guidance on IRR management, has led to improvements in IRR management that are sufficient to meet the growing risk exposure and increasing interest rate volatility. Appendix B to the final rule is intended to complement the existing guidance by providing a framework for each credit union to develop its own definitive IRR policy and program. Accordingly, the final rule adopts as timely and prudent the proposed requirements for an IRR management policy and implementation program as additional criteria for insurability.

C. *Need for Interest Rate Risk Policy and Program.* A number of commenters asserted that NCUA has not demonstrated a need to require an IRR management policy and implementation program beyond the conclusion that IRR exposure has increased. One commenter contended that the past performance of credit unions in managing net interest margins following periods of rising rates suggests that an IRR management policy and implementation program is unnecessary. Recent relevant data demonstrates otherwise.

NCUA compared IRR exposure since 1996 of credit unions versus commercial banks based on growth in real estate loans as a percentage of total assets. At year-end 2010, residential mortgages accounted for 30.7% of credit union assets compared to only 18.4% at peer commercial banks. In 1996, residential mortgages as a percent of total assets for both credit unions and banks were in the 15–20% range.[6] While peer institutions have retreated from booking mortgage loans, credit unions have increased residential mortgage holdings and taken on more interest rate risk in the process.

Other NCUA data show the percent of credit unions with exposure to mortgages, and the median level of

[4] NCUA plans to introduce a new IRR questionnaire that corresponds to Appendix B of the final rule to replace the IRR questionnaire presently used by examiners. The present questionnaire is located on NCUA's Web site at: *http://www.ncua.gov/Resources/CUs/ALM/Pages/ALMReview.aspx.*

[5] The Act itself *does* contain authority for adding the IRR policy and implementation program as an insurability criterion. Title II of the Act requires NCUA, when granting insurance to a Federal or state credit union, to consider the applicant's ''history, financial condition and management policies,'' 12 U.S.C. 1781(c)(1)(A), and to *deny* insurance if it finds that the applicant's ''financial condition and policies are unsafe or unsound.'' *Id.* § 1781(c)(2).

[6] *See* ''Interest Rate Risk Proposal Gets Ahead of the Curve,'' *The NCUA Report* (Apr. 2011, No. 4). This article concluded that the IRR exposure of Federally insured credit unions has risen steeply since 1996 relative to peer commercial banks.

credit union IRR exposure to net worth by asset size cohort at year-end 2010, as depicted in Table 1:

by asset size cohort at year-end 2010, as depicted in Table 1:

Table 1:[7]

	% Credit Unions with Exposure		Median Exposure/Net Worth	
Asset size cohort	First mortgages	Residential mortgages repricing >5 years	First mortgages	Residential mortgages repricing >5 years
<$10 million	19.0%	26.0%	0.0%	0.0%
$10 to $50 million	72.9%	81.5%	56.4%	69.9%
$50 to $100 million	96.1%	96.7%	140.1%	128.6%

Each of these measures indicates that the risk from changing interest rates to credit unions with long-term fixed cash flows increases with asset size and the escalation occurs most significantly in the $10 million to $50 million asset cohort.

Credit unions can use sales of real estate loans originated to reduce IRR exposure on their balance sheets. In that regard, a trade association commented that credit unions' sales of first mortgage originations during the current interest rate cycle have increased from 25–30% of first mortgage loans granted to over 50%. The trade association argued that credit unions manage their net interest margin in this and other ways. The commenter noted that following a 300 basis point increase in the Fed funds rate in 1994 and a 425 basis point increase in 2004–2006, credit union net interest margins fell only by 1 basis point in 1995, by 15 basis points in 2005, and by 11 basis points in 2006.

Credit unions can manage net interest margins, for example, by means of share deposit pricing. On this point, the commenter also suggested the Federal Reserve is not expected to raise interest rates quickly. The commenter also asserted that liquidity at credit unions might allow them to offset IRR exposure due to their record levels of long-term assets by raising deposit rates more slowly. NCUA notes that in January 2012 the Federal Reserve indicated that it expected economic conditions to warrant keeping the Federal funds rate at exceptionally low levels at least through late 2014.

NCUA acknowledges the aggregate upward trend over the long term in credit unions' sales of first mortgage real estate loans that they originated. Most recently, the percentage of first mortgage real estate loans sold fell to 44.8% of loans granted year to date in the 3rd quarter of 2011, but this was from a high for the full year of 51.9% in 2010. NCUA notes that the present 44.8% level remains significantly greater than the most recent low point of 26.3% of loans sold for the year in 2007. The increase is concentrated in the largest credit unions, however. For example, the percentage of first mortgage real estate loans sold in the $10 million to $50 million asset cohort was 16.0% of first mortgage real estate loans granted at credit unions year to date in the 3rd quarter of 2011, and 14.5% of first mortgage real estate loans granted for the year in December 2007.

NCUA also acknowledges that credit unions use deposit interest rates to mitigate the impact of increases in short-term rates on their net interest margin. Understanding IRR requires taking into account the historical levels of interest rates. Short-term rates presently are 500 basis points below 2006–2007 levels, and any return even to average long-term rates is likely to stress credit unions' ability to manage such a change in the level of interest rates. Reluctance to increase deposit interest rates sufficiently in an effort to enhance earnings and mitigate interest rate risk could trigger unexpected deposit outflows and thereby increase a credit union's liquidity risk.

All these indicators of IRR exposure point to heightened risk for credit unions. While acknowledging that credit unions act in various ways to manage IRR, the consistent rise in IRR at credit unions relative to other peer institutions deserves regulatory attention and is warranted as a prerequisite for insurability.

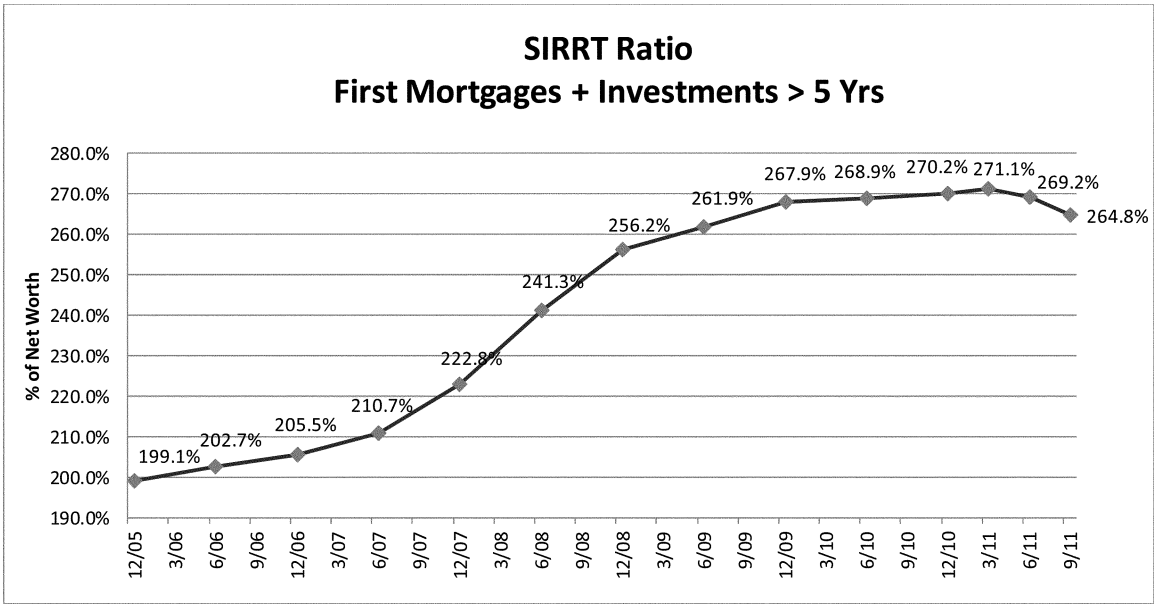
D. *Supervisory Interest Rate Risk Threshold (SIRRT).* For credit unions in the asset cohort of $10 million to $50 million, the proposed and final rules rely on the SIRRT ratio as a reliable indicator of IRR concentration:

$$\frac{\text{Total first mortgages held + Total Investments with maturities greater than 5 years}}{\text{Total Net Worth}}$$

A credit union in that asset cohort must develop and adopt an IRR policy and program only if its SIRRT ratio *equals or exceeds* 100% of its net worth, *i.e.,* a ratio of 1:1. The rule does not require a credit union with assets under $10 million to develop and adopt an IRR policy and program, regardless of its SIRRT.

NCUA has tracked the SIRRT ratio among the population of FICUs as an aggregate percentage of their net worth from 2005 (when Call Reports started to break out investment maturities at 5 years) to September 2011. Table 2 below depicts this aggregate ratio:

[7] *See* ''Size Matters: Another Perspective on IRR,'' *The NCUA Report* (June 2011, No. 6).



As previously discussed, the percentage of residential real estate loans declined from a high point of almost 35% of assets in 2008 to 30.7% of assets in 2010. See footnote 6 above. However, this does not take into account the movement of FICU assets into long-term investments since 2008, as the growth in consumer demand for mortgage loans slowed during this recessionary period. When these elements are included, as Table 2 shows, the SIRRT ratio increased from 256.2% of net worth in 2008 to a high of 271.1% in March 2011. The ratio declined to 264.8% in September 2011. Nonetheless, since 2005, the ratio has increased from 199.1%. In sum, credit union assets that present the highest IRR exposure have increased relative to credit union net worth and have reached a significantly higher level. The IRR exposure levels depicted by the data also indicate that credit unions' net interest margin performance, as previously discussed, does not eliminate the need for an IRR policy and IRR management program.

Several commenters questioned the components of the SIRRT numerator. Some advocated limiting the maturity of first mortgages to match the 5-year maturity limit of investments. Others supported excluding adjustable rate mortgages from the numerator. One commenter argued that the numerator should distinguish between fixed-rate and variable-rate loans.

NCUA does not believe the components of the numerator of the SIRRT ratio should be changed. Adjustable rate mortgages carry modeling risk because these loans are complex. Specifically, they have periodic and lifetime caps with varying reset dates and margins that must be incorporated to reflect risk. These complex mortgages should therefore be included in the SIRRT ratio.

A number of commenters addressed the asset size thresholds for subjecting credit unions to the IRR policy and program. Of these, several favored raising the asset ''floor'' to $20 million and $50 million, respectively, thus excluding credit unions below the ''floor.'' One commenter criticized use of asset thresholds altogether, asserting that IRR may be present in credit unions regardless of asset size. One commenter agreed that small credit unions should be excluded by adhering to the $10 million asset ''floor'' originally proposed.

The comments on the SIRRT ratio overlook the fundamental reasons for reliance on the ratio. Net worth is the reserve of funds available to absorb the risks of a credit union, and it is therefore the best measure against which to gauge the credit union's risk exposure. A credit union where the SIRRT ratio is at or over 1:1 is exposed to IRR at a heightened level. This requires additional attention by credit unions in the $10 million to $50 million asset cohort to their IRR policy and management program in order to manage this risk. At year-end 2010 in the $10 million to $50 million asset cohort, median first mortgages to net worth (56.4%) exceeded the median for all credit unions (35.0%). Additional NCUA data also shows at year-end 2010 that for credit unions in the $10 million to $50 million asset cohort with a SIRRT ratio at or above 1:1, median first mortgages to net worth was 179.9% of net worth, and median long-term residential mortgages repricing at or longer than five years to net worth was 148.1% of net worth. By comparison, credit unions in the $10 million to $50 million asset cohort with a SIRRT ratio below 1:1 have a 2.7% ratio of median first mortgages to net worth and a 28.5% ratio of median long-term residential mortgages to net worth. NCUA therefore concludes that the SIRRT ratio effectively partitions risk.

NCUA devised the SIRRT ratio's ''floor'' and ''ceiling'' thresholds to minimize regulatory burden and at the same time ensure adequate regulatory coverage of total credit union assets. Applying the thresholds to the $10 million to $50 million asset cohort achieves both of these objectives. Moreover, the data indicates that a credit union's IRR exposure as its assets grow is likely to occur at the $10 million to $50 million asset range At year-end 2010, among the total population of FICUs, 3,184 credit unions had a SIRRT ratio equal to or exceeding 100% of their net worth, whereas 4,155 credit unions had a SIRRT ratio less than 100% of their net worth, thus minimizing regulatory burden. At the same time, applying the SIRRT ratio to the $10 million to $50 million asset cohort would have imposed the IRR policy and program requirement on 95.5% of credit union assets, or $873.6 billion out of a total of $914.4 billion in credit union assets.

NCUA reviewed data as of September 30, 2011 for purposes of the final rule. The SIRRT ratio is depicted in Table 3 for credit unions by asset cohort and it demonstrates the segregation of risk. As shown in Table 2 previously, the

aggregate SIRRT ratio for all credit unions was 264.8%.

Table 3:

Credit Union SIRRT Ratio	*CU's Not Covered by Rule*	*CU's Covered by Rule*
<$10 million	28.10%	N/A
$10 to $50 million	30.28%	226.53%
≥$50 million	N/A	280.24%

The distribution of the number of credit unions not covered and covered by the rule is depicted in Table 4 and it shows that 1,316 credit unions in the $10 to $50 Million asset cohort would not have been covered by the rule, and 54.8% of all credit unions would not have been covered by the rule.

Table 4:

Number of Credit Unions	*# CU's Not Covered by Rule*	*# CU's Covered by Rule*	*Total*
<$10 million	2,617	0	2,617
$10 to $50 million	1,316	1,058	2,374
≥$50 million	0	2,188	2,188
Total	3,933	3,246	7,179
% of Total	54.8%	45.2%	100%

The distribution of credit union assets not covered and covered by the rule is depicted in Table 5, which shows that 95.9% of all credit union assets would have been covered by the rule based on September 30, 2011 data.

Table 5:

Credit Union Assets	*CU Assets Not Covered by Rule ($ Billion)*	*CU Assets Covered by Rule ($ Billion)*	*Total ($ Billion)*
<$10 million	10.23	0.00	10.23
$10 to $50 million	28.99	28.66	57.65
≥$50 million	0.00	883.27	883.27
Total	39.22	911.93	951.15
% of Total	4.1%	95.9%	100%

Accordingly, the proposed $10 million ''floor'' and the proposed $50 million ''ceiling'' thresholds as applied to the SIRRT ratio continue to provide effective segregation of risk while reasonably minimizing regulatory burden.

E. *Application of the Rule.* Many commenters expressed concern about how the proposed rule would be applied in practice. Several observed that it would impose a ''one-size-fits-all'' set of IRR policies, or be used as a checklist by examiners, or viewed by examiners as a mandate, or inhibit the flexibility of credit unions, thereby allowing examiners to micro-manage them. A number of commenters were concerned that examiners would apply the rule subjectively, leading to ''generic standards.'' Others predicted that examiners would rely on peer data and simplified assumptions. Finally, several noted the absence from the rule of an express definition of what constitutes an ''effective program.''

It is not the intent of the rule for examiners to subjectively impose unduly standardized supervisory oversight. Examiners will be expected to apply the standards within a consistent framework based on their knowledge of each credit union's operations and available resources. While the rule itself does not define what is an ''effective program,'' the guidance in Appendix B does. It provides that ''an effective IRR management program identifies, measures, monitors, and controls IRR

and is central to safe and sound credit union operations.'' Further, as the preamble to the proposed rule also recognized: ''it is impossible to establish specific, regulatory requirements for IRR that would be appropriate for all FICUs. IRR management involves judgment by a FICU based on its own individual mission, structure, and circumstances. Any rule must take into account the diversity of FICUs and avoid a one-size-fits-all approach. Accordingly, FICUs should devise a policy and risk management program appropriate to their own situation.'' 76 FR 16571. The NCUA Board reaffirms the notion that IRR management must be individualized, while subject to regulatory oversight and prudent insurability standards.

NCUA acknowledges that using simplifying assumptions to apply the rule involves a certain degree of subjectivity, but believes this is a necessary part of the supervision process. Any assumption used to aggregate data or categorize financial instruments can be a simplifying assumption. However, NCUA does not take issue with using such assumptions or generic standards so long as these are consistent with the best practices described in the January 2010 FFIEC Advisory on Interest Rate Risk Management and take into account the size, complexity and risk exposure of the credit union. NCUA recognizes the use of peer data may be appropriate. Simplifying assumptions are part of the practice of IRR management and are an issue only when they cause either credit union management or an examiner to underestimate complexity. For example, a credit union may use simplifying assumptions in the process of modeling IRR, and these can be acceptable so long as they do not cause interest rate risk to be misstated.

To address consistency of application NCUA plans to issue guidance and training for examiners, including a questionnaire that is tailored specifically to this rule. *See* footnote 4 above. The commentary in the questionnaire emphasizes that the guidance items are not mandatory. Credit unions are encouraged to review and discuss these guidance items with their examiners.

F. *Guidance on IRR Policy and Program.* A number of commenters made observations about the role of the specific guidance in Appendix B to the rule. Of these, one commenter asked whether Appendix B supersedes existing guidance on IRR management. One recommended publishing Appendix B on the NCUA Web site when it is adopted. Another recommended updating the *Examiners Guide* to include the guidance in Appendix B.

NCUA does not intend Appendix B to supplant existing advice on specific aspects of IRR management. Existing NCUA *Letters to Credit Unions* address specific aspects of IRR such as real estate lending, liquidity, rate-sensitive funding sources, and non-maturity shares. These *Letters to Credit Unions* are consistent with the practices set forth in Appendix B and credit unions should continue to heed the advice they give. *See* footnote 3 above. The guidance in Appendix B is also complementary to the 2010 Interagency Advisory on Interest Rate Risk Management and the 2012 Interagency Advisory on Interest Rate Risk Management, Frequently Asked Questions. NCUA will continue to issue *Letters to Credit Unions* relating to IRR management as necessary and will update the *Examiners Guide* accordingly.

A number of commenters addressed technical aspects of IRR measurement methods. Of these, some said Appendix B implied a preference for the valuation of non-maturity shares at par. One said that credit unions should be free to choose their own method. One noted the selection of curves for discounting is debatable. One said a credit union offering rate is the most defensible reinvestment rate. One said that IRR measures using changes in rates might not fully reflect the level of IRR. One said that 300 basis point shocks should not be an industry standard for the rule. One said that parallel shock analysis is not realistic. One recommended semiannual IRR testing in an IRR management program.

NCUA responds to these and similar technical comments by reiterating that it does not seek to endorse certain IRR measures, measurement techniques, or assumptions over others. For example, NCUA does not prescribe valuing non-maturity shares at par but it acknowledges that such measures and the use of historical rate scenarios may provide useful information. Similarly, NCUA does not require discounting on yield curves or endorse any particular discount rate. NCUA does recommend the use of pro forma risk measurement and the discipline of utilizing relevant stress tests to better understand IRR and to be aware of the scenarios that would have the most detrimental impact on earnings, net worth, or net economic value. Base values of balance sheet instruments are as integral to stating risk exposure as stressed results. Testing should be as frequent as needed for a credit union to be fully aware of its IRR exposure and semi-annual IRR testing may not be sufficient to manage IRR.

Several more commenters made observations on the separation of credit union responsibilities with respect to IRR. Of these, two commented on the separation of risk taking and risk management. One of these recommended that NCUA provide examples to suggest appropriate separation of duties, and another one said that separation would be burdensome.

NCUA does not believe this section of Appendix B on policy, board oversight and credit union structure needs to be amended. The proposed rule suggested that credit unions should separate risk-taking and risk measurement functions ''if possible'', particularly in the case of large, complex or high-risk credit unions. In the case of large, complex or high-risk credit unions, the final rule already provides an example of separating the investment function from the IRR measurement function, *e.g.* having the IRR measurement function report to an audit or supervisory committee. However, it is not the function of this rule to prescribe specific organizational structures.

G. *Alternatives to the Proposed Rule.* A number of commenters suggested that NCUA should focus on the 800 credit unions that lack an IRR policy instead of the estimated 75% of credit unions that have such policies in place. NCUA does not agree. The data introduced earlier indicates that IRR overall is at an unprecedented level; it is not limited to a small subset of credit unions.

Attempting to balance flexibility with regulatory concerns, one commenter suggested that an effective IRR program would be one that takes assets and liabilities into account, requires management reports to the board, and performs tests as directed by regulators. NCUA agrees that any rulemaking that addresses IRR should be crafted to not limit credit union flexibility, while still considering regulatory concerns. For this reason, the guidance in Appendix B is flexible. At the same time, shifting interest rates pose a core risk that could jeopardize the liquidity and solvency of credit unions. The steady increase in this exposure to interest rate changes warrants a high level of attention by management and oversight by NCUA and state supervisory authorities. The Board therefore believes that an IRR policy and an effective IRR management program must be implemented by regulation and should not be left solely to the supervisory process.

H. *Effective Date and Implementation of Final Rule.* The proposed rule prescribed a period of three months

between publication of the final rule and its effective date for credit unions to comply with the rule's new requirements. A number of commenters urged making the acclimation period longer than three months and some recommended a phase-in period of as long as one year. In view of these comments, NCUA has reassessed the steps and the time it will take both affected credit unions and itself to acclimate to the final rule.

Balancing its concern for a timely response to interest rate risk issues against its objective to ensure careful implementation of the final rule, the Board has decided to modify the effective date of the final rule to September 30, 2012.

III. Regulatory Procedures

A. *Regulatory Flexibility Act.* The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a rule may have on a substantial number of small entities (primarily those credit unions with less than ten million dollars in assets). By its terms, the final rule's requirement to develop a written IRR management policy and a program to effectively implement the policy do not apply to credit unions with less than $10 million in assets. Accordingly, this final rule will not have a significant economic impact on a substantial number of small credit unions and a Regulatory Flexibility Analysis is not warranted.

B. *Paperwork Reduction Act.* This final rule requires certain credit unions to develop, as prerequisites for insurability of its member deposits, a written IRR management policy (''an IRR policy'') and a program to effectively implement the policy. The Paperwork Reduction Act of 1995 (''PRA'') applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden. 44 U.S.C. 3507(d). For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. NCUA has determined that the requirement to develop an IRR policy creates a new information collection requirement. As required, NCUA has applied to the Office of Management and Budget (''OMB'') for approval of the information collection requirement described below.

The final rule requires two categories of credit unions to develop an IRR policy and program: those having more than $50 million in assets; and those having assets between $10 million and $50 million whose combined first mortgage loans, plus investments with maturities greater than five years, equal or exceed 100% of net worth. As of September 30, 2011, 3,246 FICUs (45% of all FICUs) fell in either of these two categories. NCUA estimates, however, that 2,446 of the affected FICUs (or approximately 75% of them) already have an IRR policy in place; they will need only to review the existing IRR policy, and make appropriate adjustments where necessary, to comply with the final rule. The other 800 affected FICUs (approximately 25% of them) will need to newly develop an IRR policy. Periodic review of an existing IRR policy should require minimal or no additional burden.

The final rule is accompanied by an Appendix setting forth comprehensive guidance on developing both an IRR policy and program. The guidance specifies eight policy items that must be addressed. *See* section II of Appendix B following rule text below. The length of an IRR management policy covering these eight policy elements will vary according to the credit union's business strategies. A credit union offering basic share accounts and short-term loans but no mortgage loans, and that makes relatively simple investments, should be able to develop a basic IRR policy in one to two hours that establishes, for example, maturity limits for loans, the minimum amount of short-term funds, and the range of permissible investments. In contrast, credit unions with more complex balance sheets, especially those containing mortgage loans and complex investments, may warrant a more comprehensive IRR management policy that requires additional time to produce.

NCUA estimates that addressing the eight policy items will each entail an equal time burden of two hours. The maximum time for all segments of an IRR policy is therefore estimated at 16 hours. In turn, the aggregate information collection burden for affected credit unions to comply with the rule is estimated 12,800 hours (800 credit unions × 16 hours).

The proposed rule noted that organizations and individuals wishing to comment on this information collection requirement should direct their comments to the Office of Information and Regulatory Affairs, OMB, Attn: Shagufta Ahmed, Room 10226, New Executive Office Building, Washington, DC 20503, with a copy to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

The sole commenter in response to the proposed rule contended that the estimate of 16 hours to complete an IRR policy understates the time it takes to collect the information, establish limits and review the data. That commenter offered no alternative estimate.

NCUA considers public comments on the collection of information in:

- Evaluating whether the collection of information is necessary for the proper performance of the functions of the NCUA, including whether the information will have a practical use;
- Evaluating the accuracy of the NCUA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of 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.

OMB assigned No. 3133–0184 to this rulemaking.

C. *Executive Order 13132.* Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive Order. This rule 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. Therefore, this rule does not constitute a policy that has federalism implications for purposes of the executive order.

D. *The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families.* The NCUA has determined that this rule will not affect family well-being within the meaning of the Treasury and General Government Appropriations Act, Pub. L. 105–277, 112 Stat. 2681 (1998).

E. *Small Business Regulatory Enforcement Fairness Act.* The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by section 551 of the APA. 5 U.S.C. 551. The Office of

Management and Budget has determined that this rule is not a major rule for purposes of SBREFA. As required by SBREFA, NCUA will file the appropriate reports with Congress and the General Accounting Office so this rule may be reviewed.

List of Subjects in 12 CFR Part 741

Credit unions, Requirements for insurance.

By the National Credit Union Administration Board on January 26, 2012.

Mary F. Rupp,

Secretary of the Board.

For the reasons set forth above, NCUA amends 12 CFR part 741 as follows:

PART 741—REQUIREMENTS FOR INSURANCE

■ 1. The authority citation for part 741 continues to read:

Authority: 12 U.S.C. 1757, 1766(a), 1781–1790 and 1790d; 31 U.S.C. 3717.

■ 2. In § 741.3, add paragraph (b)(5) to read as follows:

§ 741.3 Criteria

* * * * *

(b) * * *

(5)(i) The existence of a written interest rate risk policy (IRR policy'') and an effective interest rate risk management program (''effective IRR program'') as part of asset liability management in all Federally- insured credit unions (''FICU'') as follows. All measurements are based on the most recent Call Report filing of the FICU.

(A) A FICU with assets of more than $50 million must adopt a written IRR policy and implement an effective IRR program;

(B) A FICU with assets of $10 million or more but not greater than $50 million must adopt a written IRR policy and implement an effective IRR program if the total of first mortgage loans it holds combined with total investments with maturities greater than five years, as reported by the FICU on its most recent Call Report, is equal to or greater than 100% of its net worth (*i.e.,* a 1:1 ratio);

(C) A FICU with assets $10 million or more but not greater than $50 million are not required to comply with this paragraph if the total of first mortgage loans it holds, combined with total investments with maturities greater than five years, is less than 100% of its net worth (*i.e.,* a 1:1 ratio); and

(D) A FICU with less than $10 million in assets is not required to comply with this paragraph regardless of the amount of first mortgage loans and total investments with maturities greater than five years it holds.

(ii) For purposes of paragraph (b)(5)(i) of this section—

(A) A FICU is considered to hold a first mortgage loan for its own portfolio when it has not demonstrated the intent and ability to sell the loan to an independent third party within 120 days of origination;

(B) Investments are defined in § 703.2 of this chapter. Investments with maturities greater than five years are defined as those reported by the FICU on the Call Report; and

(C) Appendix B to this Part 741 provides guidance on how to develop an IRR policy and an effective IRR program. The guidance describes widely-accepted best practices in the management of interest rate risk for the benefit of all FICUs.

* * * * *

■ 3. Part 741 is amended by adding Appendix B to read as follows:

Appendix B to Part 741—Guidance for an Interest Rate Risk Policy and an Effective Program

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I. Introduction

This appendix provides guidance to FICUs in developing an interest rate risk (IRR) policy and program that addresses aspects of asset liability management in a single framework. An effective IRR management program identifies, measures, monitors, and controls IRR and is central to safe and sound credit union operations. Given the differences among credit unions, each credit union should use the guidance in this appendix to formulate a policy that embodies its own practices, metrics and benchmarks appropriate to its operations.

These practices should be established in light of the nature of the credit union's operations and business, as well as its complexity, risk exposure, and size. As these elements increase, NCUA believes the IRR practices should be implemented with increasing degrees of rigor and diligence to maintain safe and sound operations in the area of IRR management. In particular, rigor and diligence are required to manage complexity and risk exposure. Complexity relates to the intricacy of financial instrument structure, and to the composition of assets and liabilities on the balance sheet. In the case of financial instruments, the structure can have numerous characteristics that act simultaneously to affect the behavior of the instrument. In the case of the balance sheet, which contains multiple instruments, assets and liabilities can act in ways that are compounding or can be offsetting because their impact on the IRR level may act in the same or opposite directions. High degrees of risk exposure require a credit union to be diligently aware of the potential earnings and net worth exposures under various interest rate and business environments because the margin for error is low.

A. Complexity

In influencing the behavior of instruments and balance sheet composition, complexity is a function of the predictability of the cash flows. As cash flows become less predictable, the uncertainty of both instrument and balance sheet behavior increases. For example, a residential mortgage is subject to prepayments that will change at the option of the borrower. Mortgage borrowers may pay off their mortgage loans due to geographical relocation, or may increase the amount of their monthly payment above the minimum contractual schedule due to other changes in the borrower's circumstances. This cash flow unpredictability is also found in investments, such as collateralized mortgage obligations, because these contain mortgage loans. Additionally, cash flow unpredictability affects liabilities. For example, nonmaturity share balances vary at the discretion of the depositor making deposits and withdrawals, and this may be influenced by a credit union's pricing of its share accounts.

B. IRR Exposure

Exposure to IRR is the vulnerability of a credit union's financial condition to adverse movements in market interest rates. Although some IRR exposure is a normal part of financial intermediation, a high degree of this exposure may negatively affect a credit union's earnings and net economic value. Changes in interest rates influence a credit union's earnings by altering interest-sensitive income and expenses (*e.g.* loan income and share dividends). Changes in interest rates also affect the economic value of a credit union's assets and liabilities, because the present value of future cash flows and, in some cases, the cash flows themselves may change when interest rates change. Consequently, the management of a credit union's pricing strategy is critical to the control of IRR exposure.

All FICUs required to have an IRR policy and program should incorporate the following five elements into their IRR program:

1. Board-approved IRR policy.
2. Oversight by the board of directors and implementation by management.
3. Risk measurement systems assessing the IRR sensitivity of earnings and/or asset and liability values.
4. Internal controls to monitor adherence to IRR limits.

5. Decision making that is informed and guided by IRR measures.

II. IRR Policy

The board of directors is responsible for ensuring the adequacy of an IRR policy and its limits. The policy should be consistent with the credit union's business strategies and should reflect the board's risk tolerance, taking into account the credit union's financial condition and risk measurement systems and methods commensurate with the balance sheet structure. The policy should state actions and authorities required for exceptions to policy, limits, and authorizations.

Credit unions have the option of either creating a separate IRR policy or incorporating it into investment, ALM, funds management, liquidity or other policies. Regardless of form, credit unions must clearly document their IRR policy in writing.

The scope of the policy will vary depending on the complexity of the credit union's balance sheet. For example, a credit union that offers short-term loans, invests in non-complex or short-term bullet investments (*i.e.* a debt security that returns 100 percent of principal on the maturity date), and offers basic share products may not need to create an elaborate policy. The policy for these credit unions may limit the loan portfolio maturity, require a minimum amount of short-term funds, and restrict the types of permissible investments (*e.g.* Treasuries, bullet investments). More complex balance sheets, especially those containing mortgage loans and complex investments, may warrant a comprehensive IRR policy due to the uncertainty of cash flows.

The policy should establish responsibilities and procedures for identifying, measuring, monitoring, controlling, and reporting IRR, and establish risk limits. A written policy should:

- Identify committees, persons or other parties responsible for review of the credit union's IRR exposure;
- Direct appropriate actions to ensure management takes steps to manage IRR so that IRR exposures are identified, measured, monitored, and controlled;
- State the frequency with which management will report on measurement results to the board to ensure routine review of information that is timely (*e.g.* current and at least quarterly) and in sufficient detail to assess the credit union's IRR profile;
- Set risk limits for IRR exposures based on selected measures (*e.g.* limits for changes in repricing or duration gaps, income simulation, asset valuation, or net economic value);
- Choose tests, such as interest rate shocks, that the credit union will perform using the selected measures;
- Provide for periodic review of material changes in IRR exposures and compliance with board approved policy and risk limits;
- Provide for assessment of the IRR impact of any new business activities prior to implementation (*e.g.* evaluate the IRR profile of introducing a new product or service); and
- Provide for at least an annual evaluation of policy to determine whether it is still commensurate with the size, complexity, and risk profile of the credit union.

IRR policy limits should maintain risk exposures within prudent levels. Examples of limits are as follows:

GAP: less than ±I 10 percent change in any given period, or cumulatively over 12 months.

Income Simulation: net interest income after shock change less than 20 percent over any 12-month period.

Asset Valuation: after shock change in book value of net worth less than 50 percent, or after shock net worth of 4 percent or greater.

Net Economic Value: after shock change in net economic value less than 25 percent, or after shock net economic value of 6 percent or greater.

NCUA emphasizes these are only for illustrative purposes, and management should establish its own limits that are reasonably supported. Where appropriate, management may also set IRR limits for individual portfolios, activities, and lines of business.

III. IRR Oversight and Management

A. Board of Directors Oversight

The board of directors is responsible for oversight of their credit union and for approving policy, major strategies, and prudent limits regarding IRR. To meet this responsibility, understanding the level and nature of IRR taken by the credit union is essential. Accordingly, the board should ensure management executes an effective IRR program.

Additionally, the board should annually assess if the IRR program sufficiently identifies, measures, monitors, and controls the IRR exposure of the credit union. Where necessary, the board may consider obtaining professional advice and training to enhance its understanding of IRR oversight.

B. Management Responsibilities

Management is responsible for the daily management of activities and operations. In order to implement the board's IRR policy, management should:

- Develop and maintain adequate IRR measurement systems;
- Evaluate and understand IRR risk exposures;
- Establish an appropriate system of internal controls (*e.g.* separation between the risk taker and IRR measurement staff);
- Allocate sufficient resources for an effective IRR program. For example, a complex credit union with an elevated IRR risk profile will likely necessitate a greater allocation of resources to identify and focus on IRR exposures;
- Develop and support competent staff with technical expertise commensurate with the IRR program;
- Identify the procedures and assumptions involved in implementing the IRR measurement systems; and
- Establish clear lines of authority and responsibility for managing IRR; and
- Provide a sufficient set of reports to ensure compliance with board approved policies.

Where delegation of management authority by the board occurs, this may be to designated committees such as an asset liability committee or other equivalent. In credit unions with limited staff, these responsibilities may reside with the board or management. Significant changes in assumptions, measurement methods, tests performed, or other aspects involved in the IRR process should be documented and brought to the attention of those responsible.

IV. IRR Measurement and Monitoring

A. Risk Measurement Systems

Generally, credit unions should have IRR measurement systems that capture and measure all material and identified sources of IRR. An IRR measurement system quantifies the risk contained in the credit union's balance sheet and integrates the important sources of IRR faced by a credit union in order to facilitate management of its risk exposures. The selection and assessment of appropriate IRR measurement systems is the responsibility of credit union boards and management.

Management should:

- Rely on assumptions that are reasonable and supportable;
- Document any changes to assumptions based on observed information;
- Monitor positions with uncertain maturities, rates and cash flows, such as nonmaturity shares, fixed rate mortgages where prepayments may vary, adjustable rate mortgages, and instruments with embedded options, such as calls; and
- Require any interest rate risk calculation techniques, measures and tests to be sufficiently rigorous to capture risk.

B. Risk Measurement Methods

The following discussion is intended only as a general guide and should not be used by credit unions as an endorsement of a particular method. An IRR measurement system may rely on a variety of different methods. Common examples of methods available to credit unions are GAP analysis, income simulation, asset valuation, and net economic value. Any measurement method(s) used by a credit union to analyze IRR exposure should correspond with the complexity of the credit union's balance sheet so as to identify any material sources of IRR.

GAP Analysis

GAP analysis is a simple IRR measurement method that reports the mismatch between rate sensitive assets and rate sensitive liabilities over a given time period. GAP can only suffice for simple balance sheets that primarily consist of short-term bullet type investments and non mortgage-related assets. GAP analysis can be static, behavioral, or based on duration.

Income Simulation

Income simulation is an IRR measurement method used to estimate earnings exposure to changes in interest rates. An income simulation analysis projects interest cash flows of all assets, liabilities, and off-balance sheet instruments in a credit union's portfolio to estimate future net interest income over a chosen timeframe. Generally, income simulations focus on short-term time horizons (*e.g.* one to three years). Forecasting

income is assumption sensitive and more uncertain the longer the forecast period. Simulations typically include evaluations under a base-case scenario, and instantaneous parallel rate shocks, and may include alternate interest-rate scenarios. The alternate rate scenarios may involve ramped changes in rates, twisting of the yield curve, and/or stressed rate environments devised by the user or provided by the vendor.

NCUA Asset Valuation Tables

For credit unions lacking advanced IRR methods that seek simple valuation measures, the NCUA Asset Valuation Tables are available and prepared quarterly by the NCUA. These are available on the NCUA Web site through *www.ncua.gov.*

These measures provide an indication of a credit union's potential interest rate risk, based on the risk associated with the asset categories of greatest concern—(*e.g.,* mortgage loans and investment securities).

The tables provide a simple measure of the potential devaluation of a credit union's mortgage loans and investment securities that occur during ± 300 basis point parallel rate shocks, and report the resulting impact on net worth.

Net Economic Value (NEV)

NEV measures the effect of interest rates on the market value of net worth by calculating the present value of assets minus the present value of liabilities. This calculation measures the long-term IRR in a credit union's balance sheet at a fixed point in time. By capturing the impact of interest rate changes on the value of all future cash flows, NEV provides a comprehensive measurement of IRR. Generally, NEV computations demonstrate the economic value of net worth under current interest rates and shocked interest rate scenarios.

One NEV method is to discount cash flows by a single interest rate path. Credit unions with a significant exposure to assets or liabilities with embedded options should consider alternative measurement methods such as discounting along a yield curve (*e.g.* the U.S. Treasury curve, LIBOR curve) or using multiple interest rate paths. Credit unions should apply and document appropriate methods, based on available data (*e.g.* utilizing observed market values), when valuing individual or groups of assets and liabilities.

C. Components of IRR Measurement Methods

In the initial setup of IRR measurement, critical decisions are made regarding numerous variables in the method. These variables include but are not limited to the following.

Chart of Accounts

Credit unions using an IRR measurement method should define a sufficient number of accounts to capture key IRR characteristics inherent within their product lines. For example, credit unions with significant holdings of adjustable-rate mortgages should differentiate balances by periodic and lifetime caps and floors, the reset frequency, and the rate index used for rate resets. Similarly, credit unions with significant holdings of fixed-rate mortgages should differentiate at least by original term, *e.g.,* 30 or 15-year, and coupon level to reflect differences in prepayment behaviors.

Aggregation of Data Input

As the credit union's complexity, risk exposure, and size increases, the degree of detail should be based on data that is increasingly disaggregated. Because imprecision in the measurement process can materially misstate risk levels, management should evaluate the potential loss of precision from any aggregation and simplification used in its measurement of IRR.

Account Attributes

Account attributes define a product, including: P\principal type, rate type, rate index, repricing interval, new volume maturity distribution, accounting accrual basis, prepayment driver, and discount rate.

Assumptions

IRR measurement methods rely on assumptions made by management in order to identify IRR. The simplest example is of future interest rate scenarios. The management of IRR will require other assumptions such as: Projected balance sheet volumes; prepayment rates for loans and investment securities; repricing sensitivity, and decay rates of nonmaturity shares. Examples of these assumptions follow.

Example 1. Credit unions should consider evaluating the balance sheet under flat (*i.e.* static) and/or planned growth scenarios to capture IRR exposures. Under a flat scenario, runoff amounts are reinvested in their respective asset or liability account. Conducting planned growth scenarios allows management to assess the IRR impact of the projected change in volume and/or composition of the balance sheet.

Example 2. Loans and mortgage related securities contain prepayment options that enable the borrower to prepay the obligation prior to maturity. This prepayment option makes it difficult to project the value and earnings stream from these assets because the future outstanding principal balance at any given time is unknown. A number of factors affect prepayments, including the refinancing incentive, seasonality (the particular time of year), seasoning (the age of the loan), member mobility, curtailments (additional principal payments), and burnout (borrowers who don't respond to changes in the level of rates, and pay as scheduled). Prepayment speeds may be estimated or derived from numerous national or vendor data sources.

Example 3. In the process of IRR measurement, the credit union must estimate how each account will reprice in response to market rate fluctuations. For example, when rates rise 300 basis points, the credit union may raise its asset or liability rates in a like amount or not, and may choose to lag the timing of its pricing change.

Example 4. Nonmaturity shares include those accounts with no defined maturity such as share drafts, regular shares, and money market accounts. Measuring the IRR associated with these accounts is difficult because the risk measurement calculations require the user to define the principal cash flows and maturity. Credit unions may assume that there is no value when measuring the associated IRR and carry these values at book value or par. Many credit unions adopt this approach because it keeps the measurement method simple.

Alternatively, a credit union may attribute value to these shares (*i.e.* premium) on the basis that these shares tend to be lower cost funds that are core balances by virtue of being relatively insensitive to interest rates. This method generally results in nonmaturity shares priced/valued in a way that will produce an increased net economic value. Therefore, the underlying assumptions of the shares require scrutiny.

Credit unions that forecast share behavior and incorporate those assumptions into their risk identification and measurement process should perform sensitivity analysis.

V. Internal Controls

Internal controls are an essential part of a safe and sound IRR program. If possible, separation of those responsible for the risk taking and risk measuring functions should occur at the credit union.

Staff responsible for maintaining controls should periodically assess the overall IRR program as well as compliance with policy. Internal audit staff would normally assume this role; however, if there is no internal auditor, management, or a supervisory committee that is independent of the IRR process, may perform this role. Where appropriate, management may also supplement the internal audit with outside expertise to assess the IRR program. This review should include policy compliance, timeliness, and accuracy of reports given to management and the board.

Audit findings should be reported to the board or supervisory committee with recommended corrective actions and timeframes. The individuals responsible for maintaining internal controls should periodically examine adherence to the policy related to the IRR program.

VI. Decision-Making Informed by IRR Measurement Systems

Management should utilize the results of the credit union's IRR measurement systems in making operational decisions such as changing balance sheet structure, funding, pricing strategies, and business planning. This is particularly the case when measures show a high level of IRR or when measurement results approach board-approved limits.

NCUA recognizes each credit union has its own individual risk profile and tolerance levels. However, when measures of fair value indicate net worth is low, declining, or even negative, or income simulations indicate reduced earnings, management should be prepared to identify steps, if necessary, to bring risk within acceptable levels. In any case, management should understand and use their IRR measurement results, whether generated internally or externally, in the normal course of business. Management should also use the results proactively as a tool to adjust asset liability management for changes in interest rate environments.

VII. Guidelines for Adequacy of IRR Policy and Effectiveness of Program

The following guidelines will assist credit unions in determining the adequacy of their IRR policy and the effectiveness of their program to manage IRR.

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Policy	
Board oversight	Policy is consistent with credit union strategy and balance sheet complexity, clearly defines board risk tolerances through reasonable interest rate risk limits, and states actions required to address policy exceptions.
Responsible parties identified	A committee or individual(s) is designated as being responsible for IRR management activities, including review and monitoring of IRR.
Direct appropriate action to measure, monitor, control IRR	Policy states all actions that are sufficient to manage IRR, including measurement and monitoring methods, and interest rate risk reduction alternatives.
Reporting frequency specified	Reporting of results is required with sufficient frequency and detail to alert management to emerging IRR.
Risk limits stated with appropriate measures	Clearly defined risk limits are established and are appropriate for the size and complexity of the credit union.
Tests for limits	Tests substantially display the level and range of credit union IRR.
Review of material IRR changes	Any changes beyond a stated level are reported to management and, where appropriate, the Board.
Impact of new business	IRR impact of all business initiatives (new products, lines of business, pricing changes) is required where these will affect future IRR.
Periodic policy review	Review by Board required at least annually to ensure continued relevance and applicability of policy to management of IRR.
IRR Oversight & Management	
Oversight	Board approves policy and strategies and understands IRR faced by its own credit union.
Oversight assessment of program effectiveness	Board periodically evaluates program effectiveness by monitoring management's IRR knowledge. Use of third-party professional advice is acceptable, but does not absolve the Board of its responsibility for informed and knowledgeable oversight and governance.
Choice of IRR measurement systems	Management selects and maintains systems that are able to capture the complexity of IRR risks. The systems used by the credit union must be able to capture IRR (e.g., balance sheet contains material options in investments, mortgage loans or core deposits - calls, prepayments, or administered rates).
Evaluation of IRR risk exposures	Credit union understands all material IRR exposures and evaluates these accordingly relative to credit union strategy. If management relies on outside parties to evaluate credit union's IRR, it must be able to explain the IRR measurement method or the results.
System of internal controls	Internal controls encompass and effectively evaluate programs that manage elements of IRR at the credit union. Internal audit has addressed the correction of IRR deficiencies (e.g. processes for tracking changes in measurement assumptions, such as repricing of core deposits).
IRR resource management	Credit union has allocated initial or additional qualified staff resources sufficient to properly measure and manage IRR by means that address sources of risk.
Expertise of IRR program staff	Staff responsible for IRR measurement and monitoring correctly identifies sources of IRR and can quantify these risks, and is knowledgeable about the operation and limitations of the IRR model, even if modeling is performed by a third party vendor.
Procedures and assumptions of IRR measurement systems	Credit union identifies reasonable procedures and is responsible for supportable assumptions, even if modeling is performed by a third party vendor.
Accountability of IRR management	Responsibility for managing IRR is specific and clearly delineated.
Transparency of changes in assumptions, methods and IRR tests.	Management requires clear disclosure of relevant changes in all material assumptions and methods.
IRR Measurement and Monitoring	
Reasonable and supportable assumptions	Credit union carefully evaluates all assumptions and assesses the sensitivity of results relative to each key assumption. Key assumptions should be demonstrated to be supportable (e.g. mortgage prepayments capture contraction and extension risk and core deposit premiums indicate reasonable maturities).
Assumption changes from observed information	All material changes in assumptions are based on tested internal data or reliable industry sources.
Rigor of calculations and conformity of concepts	Techniques used appropriately capture complexity of balance sheet instruments. Methods to attribute cash flows, and rate sensitivities are based on correct techniques

	(e.g. proper use of statistical correlations).
Positions with uncertain maturities, rates and cash flows	Activity is monitored on a regular basis and compared to projected behavior in order to validate reasonableness of modeling assumptions.
Rigor of interest rate measures and tests	Measures and tests employed capture the material risks embedded in the credit union's balance sheet (e.g., rate shocks trigger the embedded options in some products).
Components of IRR Measurement Methods	
Chart of accounts	A sufficient number of accounts have been defined to capture key IRR characteristics inherent within each product (e.g. 15- and 30-year fixed-rate mortgages are modeled separately in order to capture various coupons and prepayment behaviors).
Data aggregation	The level of data disaggregation is sufficient given the credit union's complexity and risk exposure (e.g. instrument level processing).
Account attributes	Account set-up is appropriate to allow for the capture of key IRR characteristics (e.g. adjustable-rate mortgages are modeled with periodic and lifetime caps and floors).
Discounting methodology	Methodology used properly calculates the value of the asset or liability being modeled (e.g., discount rates or maturities or cash flows are accurate and appropriate in discounting calculations).
Assumptions	Credit union carefully evaluates all assumptions and assesses the sensitivity of results relative to each key assumption (e.g. mortgage prepayments reflect contraction and extension risk and core deposit premiums indicate reasonable maturities).
Internal Controls	
Internal assessment of IRR program	Staff is identified and have annually assessed policy and program to correct any weaknesses.
Compliance with policy	IRR program is evaluated semi-annually for any policy exceptions, including compliance with approved limits.
Timeliness and accuracy of reports	Reports that are routinely provided to management and the Board successfully communicate material IRR exposure of the credit union.
Audit findings reported to board or supervisory committee	IRR program deficiencies and policy exceptions are reported to the Board in accordance with the policy.
Decision-making and IRR	
Use of IRR measurement results in operational decisions	Measured IRR results form part of the credit union's ongoing business decisions and are substantive considerations routinely included in the business decision process.
Escalated use of results when IRR exposure is raised or approaching limits	Procedure specifies review escalation at specific levels with increasing contingency triggers close to limits.
Application to reduce elevated levels of IRR	Credit union utilizes IRR results to clearly define and formulate response (balance sheet structure, funding or pricing strategies) to increased IRR levels.

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NCUA acknowledges both the range of IRR exposures at credit unions, and the diverse means that they may use to accomplish an effective program to manage this risk. NCUA therefore does not stipulate specific quantitative standards or limits for the management of IRR applicable to all credit unions, and does not rely solely on the results of quantitative approaches to evaluate the effectiveness of IRR programs. Assumptions, measures and methods used by a credit union in light of its size, complexity and risk exposure determine the specific appropriate standard. However, NCUA strongly affirms the need for adequate practices for a program to effectively manage IRR. For example, policy limits on IRR exposure are not adequate if they allow a credit union to operate with an exposure that is unsafe or unsound, which means that the credit union may suffer material losses under plausible adverse circumstances as a result of this exposure. Credit unions that do not have a written IRR policy or that do not have an effective IRR program are out of compliance with § 741.3 of NCUA's regulations.

VIII. Additional Guidance for Large Credit Unions With Complex or High Risk Balance Sheets

FICUs with assets of $500 million or greater must obtain an annual audit of their financial statements performed in accordance with generally accepted accounting standards. 12 CFR 715.5, 715.6, 741.202. For purposes of data collection, NCUA also uses $500 million and above as its largest credit union asset range. In order to gather information and to monitor IRR exposure at larger credit unions as it relates to the share insurance fund, NCUA will use this as the criterion for definition of large credit unions for purposes of this section of the guidance. Given the increased exposure to the share insurance fund, NCUA encourages the responsible officials at large credit unions that are complex or high risk to fully understand all aspects of interest rate risk, including but not limited to the credit union's IRR assessment and potential directional changes in IRR exposures. For example, the credit union should consider the following:

- A policy which provides for the use of outside parties to validate the tests and limits commensurate with the risk exposure and complexity of the credit union;
- IRR measurement systems that report compliance with policy limits as shown both by risks to earnings and net economic value of equity under a variety of defined and reasonable interest rate scenarios;
- The effect of changes in assumptions on IRR exposure results (*e.g.* the impact of slower or faster prepayments on earnings and economic value); and,
- Enhanced levels of separation between risk taking and risk assessment (*e.g.* assignment of resources to separate the investments function from IRR measurement, and IRR monitoring and oversight).

IX. Definitions

Basis risk: The risk to earnings and/or value due to a financial institution's holdings

of multiple instruments, based on different indices that are imperfectly correlated.

Interest rate risk: The risk that changes in market rates will adversely affect a credit union's net economic value and/or earnings. Interest rate risk generally arises from a mismatch between the timing of cash flows from fixed rate instruments, and interest rate resets of variable rate instruments, on either side of the balance sheet. Thus, as interest rates change, earnings or net economic value may decline.

Option risk: The risk to earnings and/or value due to the effect on financial instruments of options associated with these instruments. Options are embedded when they are contractual within, or directly associated with, the instrument. An example of a contractual embedded option is a call option on an agency bond. An example of a behavioral embedded option is the right of a residential mortgage holder to vary prepayments on the mortgage through time, either by making additional premium payments, or by paying off the mortgage prior to maturity.

Repricing risk: The repricing of assets or liabilities following market changes can occur in different amounts and/or at different times. This risk can cause returns to vary.

Spread risk: The risk to earnings and/or value resulting from variations through time of the spread between assets or liabilities to an underlying index such as the Treasury curve.

Yield curve risk: The risk to earnings and/or value due to changes in the level or slope of underlying yield curves. Financial instruments can be sensitive to different points on the curve. This can cause returns to vary as yield curves change.

[FR Doc. 2012–2091 Filed 2–1–12; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0691; Directorate Identifier 2011–NE–26–AD; Amendment 39–16909; AD 71–13–01R1]

RIN 2120–AA64

Airworthiness Directives; Lycoming Engines Reciprocating Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; rescission.

SUMMARY: We are rescinding an airworthiness directive (AD) for Lycoming Engines model TIO–540–A series reciprocating engines. The existing AD, AD 71–13–01, was prompted by a report of a failed fuel injector tube assembly. Since we issued AD 71–13–01, we became aware that Lycoming Engines no longer supports Service Bulletin (SB) No. 335A, which was incorporated by reference in AD 71–13–01. The intent of the requirements of that SB is now in Lycoming Engines Mandatory SB No. 342F, which we have incorporated by reference into AD 2008–14–07. The FAA determined, therefore, that this requirement is duplicated by another AD.

DATES: This AD is effective March 8, 2012.

ADDRESSES: For service information identified in this AD, contact Lycoming, 652 Oliver Street, Williamsport, PA 17701; phone: (570) 323–6181; fax: (570) 327–7101; Web site: *www.lycoming.com.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: (800) 647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Norm Perenson, Aerospace Engineer, New York Aircraft Certification Office, FAA, Engine & Propeller Directorate, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7337; fax: (516) 794–5531; email: *Norman.perenson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to rescind an AD that would apply to the specified products. That NPRM published in the **Federal Register** on July 19, 2011 (76 FR 42609). That NPRM proposed to rescind AD 71–13–01 (Amendment number is 39–1231; 36 FR 11512–03, June 15, 1971) for Lycoming Engines model TIO–540–A series reciprocating engines. That AD requires a one-time visual inspection of external fuel injector lines on Lycoming Engines model TIO–540–A series reciprocating engines for fuel stains, cracks, dents, and bend radii under 5/8 inch and, if necessary, removal from service and replacement with serviceable parts. That AD also requires installing, if necessary, fuel injector line support clamps in accordance with Lycoming Engines SB No. 335 or later version of that SB.

Since we issued AD 71–13–01 (Amendment number is 39–1231; 36 FR 11512–03, June 15, 1971), Lycoming Engines has informed us that it no longer supports SB No. 335A. They also pointed out that Lycoming Engines Mandatory SB No. 342F, dated June 4, 2010, or the Instructions for Continued Airworthiness section of the Engine Overhaul Manual is the service information that owners, operators, and certificated repair facilities must use for initial and repetitive visual inspections of external fuel lines on all affected Lycoming Engines reciprocating engines.

We incorporated by reference Lycoming Engines Mandatory SB No. 342E, dated May 18, 2004, into AD 2008–14–07 (73 FR 39574, July 10, 2008). We will supersede AD 2008–14–07 to incorporate by reference Lycoming Engines Mandatory SB No. 342F, dated June 4, 2010.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (76 FR 42609, July 19, 2011).

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require rescinding the AD as proposed.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. 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.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on

products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify that this AD:

(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),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by rescinding airworthiness directive (AD) 71–13–01, Amendment 39–1231:

71–13–01R1 Lycoming Engines (formerly Textron Lycoming Division, AVCO Corporation): Amendment 39–16909; Docket No. FAA–2011–0691; Directorate Identifier 2011–NE–26–AD.

(a) Effective Date

This AD is effective March 8, 2012.

(b) Affected ADs

This AD rescinds AD 71–13–01, Amendment 39–1231.

(c) Applicability

This AD applies to Lycoming Engines model TIO–540–A series reciprocating engines, with serial numbers lower than 1931–61.

(d) Related Information

For more information about this AD, contact Norm Perenson, Aerospace Engineer, New York Aircraft Certification Office, FAA, Engine & Propeller Directorate, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: (516) 228–7337; fax: (516) 794–5531; email: *Norman.perenson@faa.gov.*

(e) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on December 29, 2011.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2012–1130 Filed 2–1–12; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–1357; Airspace Docket No. 11–AGL–26]

Amendment of Class D Airspace; Mount Clemens, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: This action amends Class D airspace within the Mount Clemens, MI, area by updating the geographic coordinates of Selfridge Air National Guard Base (ANGB) and the Selfridge Tactical Air Navigation (TACAN). This action does not change the boundaries or operating requirements of the airspace.

DATES: *Effective date:* 0901 UTC, April 5, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 321–7716.

SUPPLEMENTARY INFORMATION:

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by updating the geographic coordinates of Selfridge Air National Guard Base and the Selfridge TACAN within Class D airspace to coincide with the FAA's aeronautical database. This is an administrative change and does not affect the boundaries, altitudes, or operating requirements of the airspace, therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

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. Therefore, this 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 that this rule, when promulgated, will 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 of 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 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 amends controlled airspace at Selfridge ANGB, Mount Clemens, MI.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 71.1 of the Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective

September 15, 2011, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL MI D Mount Clemens, MI [Amended]

Mount Clemens, Selfridge Air National Guard Base, MI
(Lat. 42°36′30″ N., long. 82°50′08″ W.)
Selfridge TACAN
(Lat. 42°36′47″ N., long. 82°49′55″ W.)

That airspace extending upward from the surface to and including 3,100 feet MSL within a 4.3-mile radius of Selfridge Air National Guard Base, and within 1.5 miles west of the Selfridge TACAN 359° radial extending from the 4.3-mile radius to 5.7 miles north of the airport clockwise to 1.5 miles west of the Selfridge TACAN 191° radial, then north to the 4.3-mile radius. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in Fort Worth, Texas, on January 13, 2012.

Walter L. Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–1787 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–1144; Airspace Docket No. 11–AGL–24]

Amendment of Class D Airspace; Saginaw, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: This action amends Class D airspace within the Saginaw, MI, area by changing the name of the airport from Tri-City International Airport to MBS International Airport, and updating the airport's geographic coordinates. This action does not change the boundaries or operating requirements of the airspace.

DATES: *Effective date:* 0901 UTC, April 5, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 321–7716.

SUPPLEMENTARY INFORMATION:

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by changing the airport formerly known as Tri-City International Airport to MBS International Airport and updating the geographic coordinates within Class D airspace to coincide with the FAA's aeronautical database. This is an administrative change and does not affect the boundaries, altitudes, or operating requirements of the airspace, therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

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. Therefore, this 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 that this rule, when promulgated, will 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 of 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 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 amends controlled airspace at MBS International Airport, Saginaw, MI.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 71.1 of the Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL MI D Saginaw, MI [Amended]

MBS International Airport, MI
(Lat. 43°31′59″ N., long. 84°04′47″ W.)

That airspace extending upward from the surface to and including 3,200 feet MSL within a 4.8-mile radius of MBS International Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in Fort Worth, Texas, on January 13, 2012.

Walter L. Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–1794 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0250; Airspace Docket No. 11–AGL–6]

Amendment of Class E Airspace; South Bend, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace in the South Bend, IN, area. Additional controlled airspace is necessary to accommodate new Area Navigation (RNAV) Standard Instrument Approach Procedures at Jerry Tyler Memorial Airport, Niles, IN. The FAA is taking this action to enhance the safety and management of Instrument Flight Rule (IFR) operations at the airport. The

geographic coordinates and name of a navigation aid also will be corrected.

DATES: *Effective date:* 0901 UTC, April 5, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 321–7716.

SUPPLEMENTARY INFORMATION:

History

On August 10, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E airspace for the South Bend, IN, area, creating additional controlled airspace at Jerry Tyler Memorial Airport (76 FR 49385) Docket No. FAA–2011–0250. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, errors was found in the name of the South Bend ILS Outer Marker and the geographic coordinates of the Gipper VORTAC. This rule will make the corrections to be in concert with the FAAs aeronautical database. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Jerry Tyler Memorial Airport, Niles, IN. This action is necessary for the safety and management of IFR operations at the airport. This action also corrects the name of the South Bend ILS Outer Marker to the Misha Outer Marker, and adjusts the geographic coordinates of the Gipper VORTAC in the airspace designation and regulatory text. With the exception of editorial changes and the changes described above, this action is the same as that proposed in the NPRM.

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. Therefore, this 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 that this rule, when promulgated, will 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 of 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 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 amends controlled airspace in the South Bend, IN, area.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 71.1 of the Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

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

* * * * *

AGL IN E5 South Bend, IN [Amended]

South Bend, South Bend Regional Airport, IN
(Lat. 41°42′30″ N., long. 86°19′02″ W.)
Niles, Jerry Tyler Memorial Airport, IN
(Lat. 41°50′09″ N., long. 86°13′31″ W.)
Gipper VORTAC
(Lat. 41°46′07″ N., long. 86°19′07″ W.)
South Bend ILS Localizer
(Lat. 41°42′15″ N., long. 86°19′59″ W.)
Misha Outer Marker
(Lat. 41°42′20″ N., long. 86°13′09″ W.)

That airspace extending upward from 700 feet above the surface within a 8-mile radius of South Bend Regional Airport, and within 4.4 miles south and 7 miles north of the South Bend ILS Localizer East Course, extending from South Bend Regional Airport to 10.5 miles east of the Misha outer marker, and within 4.4 miles west and 7 miles east of the Gipper VORTAC 001° radial extending from the South Bend Regional Airport to 10.5 miles north of the VORTAC, and within a 6.4-mile radius of Jerry Tyler Memorial Airport, and within 4 miles northwest and 8 miles southeast of the Gipper VORTAC 226° radial extending from the 6.4-mile radius of Jerry Tyler Memorial Airport to 15.4 miles southwest of the airport.

Issued in Fort Worth, Texas, on January 13, 2012.

Walter L. Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–1825 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–1143; Airspace Docket No. 11–AGL–23]

Amendment of Class D Airspace; Jackson, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: This action amends Class D airspace within the Jackson, MI, area by changing the name of the airport from Jackson County-Reynolds Field to Jackson County Airport-Reynolds Field, and updating the geographic coordinates. This action does not change the boundaries or operating requirements of the airspace.

DATES: *Effective date:* 0901 UTC, April 5, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51,

subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 321–7716.

SUPPLEMENTARY INFORMATION:

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by changing the airport formerly known as Jackson County-Reynolds Field to Jackson County Airport-Reynolds Field, and adjusting the geographic coordinates within Class D airspace to coincide with the FAA's aeronautical database. This is an administrative change and does not affect the boundaries, altitudes, or operating requirements of the airspace, therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

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. Therefore, this 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 that this rule, when promulgated, will 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 of 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 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 amends controlled airspace at Jackson County Airport-Reynolds Field, Jackson, MI.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 71.1 of the Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AGL MI D Jackson, MI [Amended]

Jackson County Airport-Reynolds Field, MI (Lat. 42°15′38″ N., long. 84°27′38″ W.)

That airspace extending upward from the surface to and including 3,500 feet MSL within a 4-mile radius of Jackson County Airport-Reynolds Field. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in Fort Worth, Texas, on January 12, 2012.

Walter L. Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2012–1826 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 7, and 16

[Docket No. FDA–2011–N–0121]

RIN 0910–AG60

Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). With these amendments, tobacco products are subject to the same general requirements that apply to other FDA-regulated products.

DATES: This rule is effective April 2, 2012.

FOR FURTHER INFORMATION CONTACT: Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1 (877) CTP–1373, *gerie.voss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 14, 2011 (76 FR 20901), FDA issued a proposed rule seeking to amend several provisions of its general regulations to reflect the Agency's new authority and mandate regarding tobacco products under the Tobacco Control Act (Pub. L. 11–31; 123 Stat. 1776). FDA received substantive comments to its proposal from only one commenter. However, FDA does not believe that these comments warrant making any changes to the regulatory language included in the proposed rule.

Relevant portions of these comments are summarized and responded to in the relevant section(s) of this document. To make it easier to identify comments and FDA's responses, the word ''Comment,'' in brackets, appears before the comment's description, and the word ''Response,'' in brackets, appears before FDA's response. Each comment is numbered to help distinguish among different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance.

II. Legal Authority

FDA is issuing this final rule under provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Tobacco Control Act (21 U.S.C. 321, 331, 333, 371, 381, 387, 387a, 387c, 387f, 387j, and 387k). FDA is also issuing this final rule under section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) as amended by the Tobacco Control Act, and under section 3 of the Comprehensive Smokeless

Tobacco Health Education Act of 1986 (CSTHEA) (15 U.S.C. 4402) as amended by the Tobacco Control Act.

III. Description of Final Regulations

With this rule, FDA is finalizing several amendments to title 21 of the Code of Federal Regulations (CFR), reflecting the Agency's authority over tobacco products under the Tobacco Control Act. The amendments are described in sections III.A, III.B, and III.C of this document.

A. Section 1.21—Failure to Reveal Material Facts

Section 1.21(a) (21 CFR 1.21(a)) states that the labeling of FDA-regulated products shall be deemed misleading if it fails to reveal facts that are: ''* * * Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or [m]aterial with respect to consequences which may result from use of the article under: The conditions prescribed in such labeling or such conditions of use as are customary or usual.'' With this final rule, FDA is amending § 1.21(a) to provide that tobacco product labeling also would be deemed misleading for similar failures to reveal material facts. See section 903(a) of the Tobacco Control Act (21 U.S.C. 387c(a)) (stating that a tobacco product shall be deemed to be misbranded if its labeling is false or misleading). See also section 201(n) of the FD&C Act (21 U.S.C. 321(n)).

Section 1.21(c) describes statements that are not permissible on labeling for FDA-regulated products. For example, paragraph (c)(1) explains that this regulation does not ''[p]ermit a statement of differences of opinion with respect to warnings * * *'' on FDA-regulated products. This final rule amends this section to state that tobacco product labeling, like the labeling of other FDA-regulated products, also may not have a statement of differences of opinion regarding the warnings on tobacco packages or advertisements. This change is in accordance with sections 201 and 204 of the Tobacco Control Act, amending the FCLAA, and the CSTHEA, respectively, as well as section 903(a) generally. FDA already has issued a final rule to implement section 201 of the Tobacco Control Act, amending 15 U.S.C. 1333. See the **Federal Register** of June 22, 2011 (76 FR 36628).

B. Section 1.101—Notification and Recordkeeping

Section 1.101 (21 CFR 1.101) outlines the notification and recordkeeping requirements for exports of FDA-regulated products. Section 1.101(a) pertains to all notifications and records required for FDA-regulated products that may be exported under sections 801 or 802 of the FD&C Act (21 U.S.C. 381 and 382) and section 351 of the Public Health Service Act (42 U.S.C. 262). Because section 103(l) of the Tobacco Control Act specifically amends section 801 of the FD&C Act to include ''tobacco products'' on the list of FDA-regulated products that may be exported under this section, this final rule amends § 1.101(a) and (b) to indicate that tobacco products exported under section 801(e)(1) of the FD&C Act also would be subject to the recordkeeping requirements of this regulation. Please note that this revision to § 1.101(b) does not alter the enforcement policy described in the advance notice of proposed rulemaking that published in the **Federal Register** of June 1, 2004 (69 FR 30842). Thus, with regard to tobacco products, FDA intends to exercise enforcement discretion, as it does with exports generally, regarding the requirement for specific types of records under § 1.101(b)(2) demonstrating that the exported product is not in conflict with the foreign country's laws.

(Comment 1)—One comment requested that FDA provide notice and an opportunity to comment should it propose to end this period of enforcement discretion as it applies to tobacco products.

(Response 1)—We note, previously, that this revision does not alter our exercise of enforcement discretion, including with respect to tobacco products and additional notice and comment with respect to this issue is not necessary.

C. Section 7.3—Definitions

Section 7.3 (21 CFR 7.3) defines the term ''product'' to include all the specific items that are subject to FDA's jurisdiction. This final rule amends § 7.3 of the regulations to define ''product'' to also include tobacco products.

(Comment 2)—One comment stated that FDA's proposed change to § 7.3 did not take into account the fundamental differences between tobacco products and other regulated product categories and, therefore, it should be amended accordingly. This comment also requested that FDA make additional changes to part 7.

(Response 2)—FDA believes that its change to § 7.3 is necessary to ensure that tobacco products are subject to the same general requirements that apply to other FDA-regulated products. The differences between tobacco products and other regulated products do not warrant any additional changes to § 7.3. In circumstances where FDA's requirements apply solely to tobacco products, that is noted in the appropriate sections of the Agency's regulations. Further, FDA believes that the other suggested revisions to part 7 included in this comment are beyond the scope of this rulemaking.

D. Section 16.1—Scope

Section 16.1(b) (21 CFR 16.1(b)) lists the statutory and regulatory provisions that provide for the opportunity for a regulatory hearing. Sections 903(a)(8)(B)(ii), 906(e)(1)(B), 910(d)(1), and 911(j) of the Tobacco Control Act all provide for the opportunity for a hearing. The final rule amends § 16.1 to include certain instances in the Tobacco Control Act where an opportunity for a hearing is provided.

(Comment 3)—One comment requested that FDA also amend part 16 (21 CFR part 16) to provide an opportunity for a regulatory hearing if FDA were to issue a Not Substantially Equivalent (NSE) determination for a tobacco product introduced between February 15, 2007, and March 22, 2011.

(Response 3)—FDA declines to adopt this change. FDA is amending part 16 to incorporate those specific circumstances in which the Tobacco Control Act expressly provides for notice and an opportunity for hearing. Section 910 of the Tobacco Control Act does not specifically provide for notice and an opportunity for hearing with respect to NSE orders; therefore, FDA declines to add section 910(a)(2)(B) to the list of circumstances that provide for a part 16 hearing.

IV. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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 will not be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the requirements are

likely to impose a burden on a substantial number of affected small entities, the Agency anticipates that the final rule will have a significant economic impact on a substantial number of small entities and has conducted a Final Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

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 $136 million, using the most current (2010) 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.

FDA has not quantified the benefits of this final rule. This rule will impose compliance costs on producers of tobacco products as they will be required to comply with recordkeeping requirements according to general regulations that apply to other products that FDA regulates. FDA updates the estimated costs presented in the proposed rule published in the **Federal Register** of April 14, 2011, to incorporate the most recent and publicly available wage rate data. The estimated annual costs of complying with these requirements range from $71,201 to $374,991.

B. Need for the Regulation

The Tobacco Control Act grants FDA authority to regulate tobacco products, thereby enabling FDA to assess the effects of tobacco products on the public health. The final rule ensures tobacco manufacturers adhere to the regulations that apply to other FDA-regulated products sold in the United States and exports of products that are not allowed for sale in the United States. The final rule clarifies FDA's practices and procedures with respect to voluntary recalls of tobacco products. It also guarantees that tobacco product manufacturers have the same rights as other FDA-regulated entities, where appropriate, such as the right to regulatory hearings.

C. Benefits

FDA is unable to quantify the benefits of the amendments. Benefits will derive from FDA's enhanced ability to carry out its obligations and from clarifying certain FDA practices and procedures for tobacco product manufacturers.

D. Costs

Section 7.3(f) clarifies and explains FDA's practices and procedures with respect to recalls of tobacco products. FDA concludes that tobacco product manufacturers follow recall procedures consistent with current regulations and that the amendment to § 7.3(f) will not impose additional burdens on tobacco product manufacturers.[1] The revision to § 16.1(b) allows for an informal hearing when FDA is considering regulatory actions or decisions related to misbranding, good manufacturing practice requirements, or withdrawal of a tobacco product. No additional costs are expected to accrue from amendments to §§ 1.21(c), 7.3(f), and 16.1(b).

Additional costs will derive from recordkeeping requirements as they relate to some tobacco product exports (§ 1.101(a) (b)). The estimated annual costs range is between $0.07 million and $0.37 million, as further explained in table 1 of this document.

TABLE 1—TOTAL ESTIMATED COSTS OF THE FINAL RULE

Cost factor	Annual cost	
	Low	High
Exports of Tobacco Products	$71,201	$374,991

Section 1.101(a)(b) pertain to recordkeeping of documentation that demonstrates that tobacco products not allowed for sale in the United States are exported in accordance with appropriate regulations. In addition, recordkeeping documents must demonstrate that: (1) The product meets the foreign purchaser's specifications, (2) the product does not conflict with the laws of the foreign country, (3) correct labeling is placed outside of the shipping package, and (4) the product is not sold or offered in the United States. These documents are required to be retained (§ 1.101(b)).

1. Number of Affected Entities

The U.S. Department of Commerce International Trade Administration (ITA) reports that the total number of (manufacturing and non-manufacturing) U.S. companies exporting tobacco products (North American Industry Classification System or NAICS code 3122) to the world in 2007 was 158, which includes 30 manufacturers and 125 non-manufacturers of tobacco products.[2] Exporting manufacturers represent approximately 38 percent of all manufacturing companies reported by the 2007 Economic Census in this NAICS category (Ref. 3). FDA takes the total number of exporting manufacturing companies as a lower bound and the total number of exporting (manufacturing and non-manufacturing) companies as an upper bound for the total number of respondents that will be affected by the final rule.

2. Estimated Economic Costs on Affected Entities

In estimating the burden, FDA uses the number of responses per respondent (3), and time per response (22 hours for recordkeeping)[3] from previously reported estimates relating to drugs and medical devices (August 7, 2008, 73 FR 46007). In valuing the time cost, FDA uses the 2010 median hourly wage of $17.98 for Office and Administrative Support Occupations (NAICS code 430000) in the tobacco manufacturing industry (NAICS code 312200) as

[1] In 1995, a major tobacco product manufacturer voluntarily recalled a few tobacco product lines when it was found that the products might be contaminated. After several investigations a Centers for Disease Control and Prevention (CDC) report concluded that it was the use of the tobacco product and not the contaminated product that caused the health complaints (Ref. 1).

[2] As firms sometimes export multiple products, a single firm can be represented in multiple products; thus, exporter counts may not add up to the total (Ref. 2).

[3] The proposed rule inadvertently listed 2 hours for recordkeeping in this section. The total economic effect, however, was accurate and the proper number of 22 hours was listed in the Paperwork Reduction Act (PRA) section.

reported by the Bureau of Labor Statistics (Ref. 4), plus benefits and overhead. Table 2 of this document shows that annual recordkeeping costs for all respondents are estimated to be between $0.07 million and $0.37 million.

TABLE 2—ESTIMATED INCREMENTAL BURDEN FOR EXPORTERS

Cost factor	Number of recordkeepers	Responses per recordkeeper	Total annual records	Hours per recordkeeper	Annual cost low–high
Recordkeeping	30 to 158	3	90 to 474	22	$71,201 to $374,991.

E. Analysis of Alternatives

The simplest alternative is to exempt exporters of tobacco products from the recordkeeping requirements according to general regulations that apply to other exports that FDA regulates. Under this option, there would be no immediate compliance costs or benefits. Compliance costs for exporters of tobacco products are estimated to be between $0.07 million and $0.37 million. The recordkeeping requirements for exporters of tobacco products will have the benefit of allowing FDA to carry out its obligations and to clarify practices and procedures for tobacco product manufacturers.

F. Final Regulatory Flexibility Act Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires Agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. This analysis serves as the Final Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The Small Business Administration (SBA) uses different definitions of what a small entity is for different industries. Using 2009 SBA size standard definitions, a firm categorized in NAICS code 312229 (Other Tobacco Product Manufacturing) is considered small if it hires fewer than 500 employees. On the other hand, firms classified in NAICS code 312221 (Cigarette Manufacturing) are considered small if they hire fewer than 1,000 employees (Ref. 5).

The most current available data on the number of establishments by employee size have not been released for the categories listed previously in this document; thus, FDA uses data from the 2002 Economic Census (Ref. 6) to determine the number of small entities. FDA notes that the data are available at the establishment level rather than at the firm level, and assumes that the typical manufacturing establishment is roughly equivalent to the typical small manufacturing firm. Statistics on the classification of establishments by employment size show that in the year 2002, 67 to 99 percent of tobacco manufacturing entities had fewer than 1,000 employees and will be considered small by SBA. (See table 3 of this document.)

TABLE 3—ESTIMATED NUMBER OF SMALL ENTITIES AFFECTED

	Cigarette manufacturing (NAICS 312221)	Other tobacco product manufacturing (NAICS 312229)
Size Standards in Number of Employees	< 1,000	< 500
Total Number of Establishments	15	83
Percent Considered Small	67%	99%
Estimated Number of Affected Entities	2	12

FDA also estimates the percent of small to medium-sized [4] exporting companies to be 15 percent, using industry trade data for NAICS code 3122 (Tobacco Products) made available by ITA. The estimated number of affected exporting entities is determined by multiplying 0.15 by the total number of establishments. The estimates indicate that the estimated number of affected entities ranges between 2 and 14 exporters. (See table 3 of this document.)

2. Economic Effect on Small Entities

FDA uses the total value of shipments data by employment size from the 2002 Economic Census published by the U.S. Bureau of the Census to determine the unit cost as a percent of the total value of shipment for a typical manufacturer. The analysis of the effect on small versus large entities is limited by the U.S. Bureau of the Census data restrictions imposed to safeguard the confidentially of some establishments in NAICS code 312221. Consequently, the average value of shipments is presented for all establishments in NAICS code 312221 and for establishments employing 1 to 19 and 20 to 99 employees, separately. The average cost per entity is $2,814. It is estimated that this average cost as a percent of average value of shipments for small entities may be between 0.00 and 0.31 percent (see table 4 of this document). The Agency concludes that this final rule will have a significant impact on a substantial number of small entities, but the impact is uncertain.

[4] ITA defines small firms as those with fewer than 100 employees and medium-sized firms as those that employ from 100 to 499 workers (Ref. 7).

TABLE 4—ESTIMATED AVERAGE VALUE OF SHIPMENTS FOR A TYPICAL MANUFACTURER

Description	NAICS		
	31221	31229	
Establishment Employee Size	All	1 to 19	20 to 99.
Value of Shipments ($1,000)	$34,562,900	$35,979	$270,348.
Number of Establishments	15	47	20.
Average Value of Shipments ($1,000)	$2,304,193	$766	$13,517.
Unit Cost as Percent of Average Value of Shipments	0.00%	0.31%	0.02%.

3. Additional Flexibility Considered

In this section, we discuss an alternative to reduce costs for small entities. Exempting exporters of tobacco products from recordkeeping requirements can result in an estimated annual savings of 0.02 to 0.31 percent of the cost of the value of shipments for small-sized firms. However, these recordkeeping requirements will provide evidence that tobacco product manufacturers export according to regulations that apply to other FDA-regulated products.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are given in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Product Issues—21 CFR 1.101.

Description: On June 22, 2009, the President signed the Tobacco Control Act into law. In this rule, FDA is amending certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Tobacco Control Act. The amendments in this rulemaking will subject tobacco products to the same general requirements that apply to other FDA-regulated products, where appropriate.

This rule amends § 1.101(b), among other sections, to require persons who export human drugs, biologics, devices, animal drugs, cosmetics, and tobacco products that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act. Section 801(e)(1) requires exporters to keep records demonstrating that the exported product: (1) Meets with the foreign purchaser's specifications, (2) does not conflict with the laws of the foreign country, (3) is labeled on the outside of the shipping package that is intended for export, and (4) is not sold or offered for sale in the United States. These criteria also could be met by maintaining other documentation, such as letters from a foreign government Agency or notarized certifications from a responsible company official in the United States stating that the exported product does not conflict with the laws of the foreign country.

Description of Respondents: Manufacturers, distributors, and other persons who export tobacco products not intended for sale in the United States.

Comments: A few comments were received which were beyond the scope of this collection of information, did not address PRA issues, and were not addressed in this rule.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN EXPORTERS OF TOBACCO PRODUCTS

21 CFR Section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
1.101(b)	158	3	474	22	10,428

The Agency estimates the number of respondents and burden hours associated with the recordkeeping requirements by reviewing Agency records and using Agency expert resources, and conferring with another Federal Agency with experience and information regarding tobacco product exporters. FDA estimates that between 30 and 158 establishments could be involved in the exporting of tobacco products and, based on previous recordkeeping estimates in OMB control number 0910–0482, ''Export Notification and Recordkeeping Requirements,'' each establishment may have to maintain records up to 3 times per year, at a total of 22 hours per recordkeeper. The Agency estimates between 1,980 and 10,428 burden hours will be needed for tobacco product exporters to create and maintain records demonstrating compliance with section 801(e)(1) of the FD&C Act. Therefore, FDA estimates that 158 respondents will require approximately 10,428 hours to comply with the requirements of section 801(e)(1) of the FD&C Act.

The information collection provisions of this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

VI. Executive Order 13132: Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that this final rule does not contain policies that 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. Accordingly, the Agency concludes that this final rule

does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. References

The following references have been placed on public display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**).

1. CDC, 1996, ''Recall of Philip Morris Cigarettes, May 1995–March 1996,'' *Morbidity and Mortality Weekly Report,* 45(12): 251–254, *http://www.cdc.gov/mmwr/preview/mmwrhtml/00041035.htm,* last accessed November 2010.
2. ITA, 2010, ''Industry Trade Data and Analysis,'' *http://www.trade.gov/mas/ian/EDB/Reports/2007/table14_allmarkets_allcategories.html,* last accessed November 2010.
3. U.S. Census Bureau American FactFinder, 2007, ''Sector 31: EC0731I1: Manufacturing: Industry Series: Detailed Statistics by Industry for the United States: 2007,'' *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0731I1&-_lang=en,* last accessed October 2010.
4. U.S. Bureau of Labor Statistics, 2010, ''Occupational Employment Statistics,'' *http://www.bls.gov/oes/oes_dl.htm,* last accessed June 13, 2011.
5. SBA, 2010, ''Table of Small Business Size Standards Matched to North American Industry Classification System Code,'' *http://www.sba.gov/content/table-small-business-size-standards,* last accessed March 2, 2011.
6. U.S. Census Bureau American FactFinder, 2002, ''2002 Economic Census: Sector 31: Manufacturing: Industry Series: Industry Statistics by Employment Size: 2002,'' *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-ds_name=EC0231I4&-_lang=en,* last accessed October 2010.
7. ITA, *http://www.trade.gov/mas/ian/smeoutlook/edbtechnicalnotes/tg_ian_001929.asp,* last accessed November 2010.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 7

Administrative practice and procedure, Consumer protection, Reporting and recordkeeping requirements.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 7, and 16 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Amend § 1.21 by revising paragraph (a) introductory text and paragraph (c)(1) to read as follows:

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, cosmetic, or tobacco product shall be deemed to be misleading if it fails to reveal facts that are:

* * * * *

(c) * * *

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, cosmetics, or tobacco products under the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 3. Amend § 1.101 by revising paragraph (a) and the heading of paragraph (b) to read as follows:

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act or (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) *Recordkeeping requirements for human drugs, biological products, devices, animal drugs, foods, cosmetics, and tobacco products exported under or subject to section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.* * * *

* * * * *

PART 7—ENFORCEMENT POLICY

■ 4. The authority citation for part 7 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

■ 5. Amend § 7.3(f) by revising the first sentence to read as follows:

§ 7.3 Definitions.

* * * * *

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, any tobacco product intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. * * *

* * * * *

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 6. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 7. Amend § 16.1 by adding new statutory provisions to the end of paragraph (b)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.

Section 906(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act relating to the establishment of good manufacturing practice requirements for tobacco products.

Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.

Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

* * * * *

Dated: January 27, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–2289 Filed 2–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF STATE

22 CFR Parts 22 and 51

[Public Notice: 7779]

RIN 1400–AC58

Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates

AGENCY: Bureau of Consular Affairs, State.

ACTION: Final rule.

SUMMARY: This rule adopts as final the interim final rule published in the **Federal Register** on June 28, 2010 (Public Notice 7068). Specifically, the rule made changes to the Schedule of Fees for Consular Services (Schedule) for a number of different fees. This rulemaking adopts as final the changes to these fees.

DATES: Effective February 2, 2012.

FOR FURTHER INFORMATION CONTACT: Polly Hill, Office of the Comptroller, Bureau of Consular Affairs, Department of State; phone: 202–663–1301, telefax: 202–663–2526; email: *fees@state.gov*.

SUPPLEMENTARY INFORMATION: For the complete explanation of the background of this rule, including the rationale for the change, the authority of the Department of State (''Department'') to make the fee changes in question, and an explanation of the study that produced the fee amounts, consult the prior public notices cited in the ''Background'' section below.

Background

The Department published a proposed rule in the **Federal Register**, 75 FR 6321, on February 9, 2010, proposing to amend sections of 22 CFR part 22. Specifically, the rule proposed changes to the Schedule of Fees for Consular Services and provided 30 days for comments from the public. In response to requests by the public for more information and a further opportunity to submit comments, the Department subsequently published a supplementary notice in the **Federal Register**, 75 FR 14111, on March 24, 2010 (Public Notice 6928). The supplementary notice provided a more detailed explanation of the Cost of Service Model (''CoSM''), previously referred to as the Cost of Service Study or ''CoSS,'' which is the activity-based costing model that the Department used to determine the proposed fees for consular services, and reopened the comment period for an additional 15 days. During this and the previous 30 day comment period, 1,797 comments were received, either by email or through the submission process at *www.regulations.gov*.

The Department analyzed the 1,797 comments in the interim final rule at 75 FR 36522, on June 28, 2010 (Public Notice 7068) and does not reproduce that analysis here. Instead, the current notice addresses only the four additional comments received in the further 60 days during which the comment period for this interim final rule was open (see Analysis of Comments, below). In total, the public was given 105 days to comment on this change to the Schedule of Fees and a total of 1,801 comments were received.

This rule establishes the following fees for the categories below, as determined by the CoSM:

—Passport Book Application Services for Applicants Age 16 or Over (including renewals): from $55 to $70
—Additional Passport Visa Pages: from $0 to $82
—Passport Book Security Surcharge (Enhanced Border Security Fee): from $20 to $40
—File Search and Verification of U.S. Citizenship: from $60 to $150
—Application for Consular Report of Birth Abroad of a Citizen of the United States: from $65 to $100
—Administrative Processing of Formal Renunciation of U.S. Citizenship: from $0 to $450*
—Passport Card Application Services for Applicants Age 16 or Over (including renewals): from $20 to $30
—Passport Card Application Services for Applicants Under Age 16: from $10 to $15
—Making arrangements for a Deceased Non-U.S. Citizen Family Member: from a charge of Consular time spent on the service, previously $265 an hour plus expenses to $200 plus expenses
—Immigrant Visa Application for Immediate Relative and Family Preference Applications: from $355 to $330
—Immigrant Visa Application for Employment-Based Applications: from $355 to $720
—Immigrant Visa Application for Other Visa Classes: from $355 to $305
—Diversity Visa Program Fee: from $375 to $440
—Affidavit of Support Review (only when reviewed domestically): from $70 to $88
—Determining Returning Resident Status: from $400 to $380
—Immigrant Visa Security Surcharge: from $45 to $74
—Providing Notarial Service: First service (seal): from $30 to $50
—Providing Notarial Service: Each additional seal: from $20 to $50
—Certification of a True Copy or That No Record of an Official File Can be Located: First copy: from $30 to $50
—Certification of a True Copy or That No Record of an Official File Can be Located: Each additional copy: from $20 to $50
—Provision of Documents, Certified Copies of Documents, and Other Certifications by the Department of State (domestic): from $30 to $50
—Authentications (by posts abroad): from $30 to $50
—Processing Letters Rogatory and Foreign Sovereign Immunities Act 275 (FSIA) Judicial Assistance Cases: from $735 to $2,275
—Scheduling/Arranging Appointments for Depositions: from $475 to $1,283
—Attending or Taking Depositions, or Executing Commissions to Take Testimony: from $265 per hour plus expenses to $309 per hour plus expenses
—Providing Seal and Certification of Depositions: from $70 to $415
—Consular Time Charges: from $265 to $231

Administrative processing of formal renunciation of U.S. citizenship was previously a no-fee service. Under the new fee structure, the renunciant must now pay a fee for this service. The Department has decided that the renunciant should pay this fee at the visit during which he or she swears the oath of renunciation. The proposed and interim final rules referred to it as ''Documentation of formal renunciation of U.S. citizenship,'' at Item 8 of their respective reproductions of the Schedule of Fees. See 75 FR 36522, 36532; 75 FR 6321, 6328. This final rule makes a technical correction to the title of the service, labeling it ''Administrative processing of formal renunciation of U.S. citizenship.''

Please note there are two additional clarifications the Department of State is making in this final rule. First, the Immigrant Visa application for employment-based applications is based on I–140 and I–526 petitions and also includes investor visas. The interim final rule incorrectly stated that employment-based visas are based on the I–140 petition only. Second, since publishing the interim final rule on June 28, 2010 (75 FR 36522), the Department reexamined the CoSM's inputs to the Diversity Visa Lottery Fee. Upon reexamination, it was decided that the present fee adequately accounts for the costs of processing the immigrant visa application and enhanced security. The Department, therefore, has decided it will not charge the separate Immigrant Visa Application Processing Fee or Immigrant Visa Security Surcharge to

Diversity Visa Lottery selectee-applicants and will amend the Schedule of Fees to so reflect.

Analysis of Comments

In the additional 60 day period since the publication of the interim final rule, four additional comments were received. Three commenters expressed concern over the fee increase for extra passport visa pages. Two of those commenters traveled frequently for work and noted that this would be an additional cost. The third commenter, an American citizen living overseas, expressed concern over the large cost to his family to receive additional visa pages. A suggestion was made by one of the commenters to waive the additional visa pages fee every other year for business people who travel frequently.

As explained in the supplementary notice, 75 FR 14111, 14113, the cost of this service includes not only the pages themselves, but the employee time spent affixing the pages into a passport, endorsing the passport, and performing a quality-control check on the expanded passport; also the costs of trained labor, supervisors, and overhead; of performing a name check of the applicant prior to providing the service; and a share of the overall costs of no-fee emergency services provided to Americans overseas—costs incorporated into and assigned across all passport book services. The Department does offer a larger passport for travelers who anticipate that they will need more visa pages. Any passport applicant may request a larger book (52 pages, instead of the standard 28 pages) at the time of application for no additional fee. Information about this option is widely available to customers both domestically and overseas. Because the Department's passport processing operations must be self-sustaining as much as possible and has accordingly set these fees at a level that will allow cost recovery, the Department is not in a position to grant a fee waiver to frequent business travelers.

The final comment was directed toward the fee increase for the passport book. The commenter stated that the fee increase influenced whether she would renew her passport book and her decision to travel abroad. The Department is aware of the financial impact this fee increase may have on individuals and businesses; however, the Department must recover its costs from the passport services it provides. The Department also maintains that the increase in passport fees is not significant in comparison with the overall costs of international travel.

Conclusion

The Department has adjusted the fees to ensure that sufficient resources are available to meet the costs of providing consular services in light of the CoSM's findings that the U.S. Government was not fully covering its costs for providing these consular services. Pursuant to OMB guidance, the Department endeavors to recover the cost of providing services that benefit specific individuals, as opposed to the general public. *See* OMB Circular A–25, ¶ 6(a)(1), (a)(2)(a). For this reason, the Department has adjusted the Schedule.

Regulatory Findings

For a summary of the regulatory findings and analyses regarding this rulemaking, please refer to the findings and analyses published with the interim final rule, which can be found at 75 FR, at 36529, which are adopted herein. The rule became effective July 13, 2010. As noted above, the Department has considered the comments submitted in response to the interim final rule, and does not adopt them. Thus, the rule remains in effect without modification.

In addition, as noted in the interim final rule, this rule was submitted to and reviewed by OMB pursuant to E.O. 12866. The Department of State has also considered this rule in light of Executive Order 13563, dated January 18, 2011, and affirms that this regulation is consistent with the guidance therein.

Accordingly, the Interim Rule amending 22 CFR parts 22 and 51, which was published in the **Federal Register**, 75 FR 36522, on June 28, 2010 (Public Notice 7068), is adopted as final without change.

Dated: January 23, 2012.

Patrick F. Kennedy,

Under Secretary of State for Management, Department of State.

[FR Doc. 2012–2075 Filed 2–1–12; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 514

Fees

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC or Commission) is amending its fee regulation. The Indian Gaming Regulatory Act (IGRA) requires Tribal gaming operations to pay a fee to the Commission for each gaming operation regulated by IGRA that conducts Class II or Class III gaming activity. IGRA also requires that ''[t]he Commission, by a vote of not less than two of its members, shall annually adopt the rate of the fees authorized by this section which shall be payable to the Commission on a quarterly basis.'' Pursuant to the Commission's authority to ''promulgate such regulations and guidelines as it deems appropriate to implement the provisions of [IGRA],'' the Commission is amending its regulations to provide for the submittal of fees and fee worksheets on a quarterly basis rather than bi-annually; to provide for operations to calculate fees based on the gaming operation's fiscal year rather than a calendar year; to amend certain language in the regulation to better reflect industry usage; to establish an assessment for fees and fee worksheets submitted one to ninety days late; and to establish a fingerprinting fee payment process.

DATES: *Effective Date:* October 1, 2012.

Compliance Date: Submitting fee worksheets and payments on a quarterly basis under §§ 514.5 and 514.6 is not required until January 1, 2013.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig, National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005. Telephone: (202) 632–7009; email: *michael_hoenig@nigc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA) established an agency funding framework whereby gaming operations licensed by tribes pay a fee to the Commission for each gaming operation that conducts Class II or Class III gaming activity that is regulated by IGRA. 25 U.S.C. 2717(a)(1). These fees are used to fund the Commission in carrying out its statutory duties. Fees are based on the gaming operation's assessable gross revenues, which are defined as the annual total amount of money wagered, less any amounts paid out as prizes or paid for prizes awarded and less allowance for amortization of capital expenditures for structures. 25 U.S.C. 2717(a)(6). The rate of fees is established annually by the Commission and shall be payable on a quarterly basis. 25 U.S.C. 2717(a)(3). IGRA limits the total amount of fees imposed during any fiscal year to .08% of the gross gaming revenues of all gaming operations subject to regulation under IGRA. Failure of a gaming operation to pay the fees imposed by the Commission's fee schedule can be grounds for a civil

enforcement action. 25 U.S.C. 2713(a)(1). The purpose of Part 514 is to establish how the NIGC sets and collects those fees, to establish a basic formula for tribes to utilize in calculating the amount of fees to pay, and to advise of the potential consequences for failure to pay the fees.

II. Previous Rulemaking Activity

On November 18, 2010, the National Indian Gaming Commission (NIGC) issued a Notice of Inquiry and Notice of Consultation advising the public that the NIGC was conducting a comprehensive review of its regulations and requesting public comment on which of its regulations were most in need of revision, in what order the Commission should review its regulations, and the process NIGC should utilize to make revisions. 75 FR 70680. On April 4, 2011, after holding eight consultations and reviewing all comments, NIGC published a Notice of Regulatory Review Schedule (NRR) setting out a consultation schedule and process for review. 76 FR 18457. Part 514 was included in the first regulatory group reviewed pursuant to the NRR.

The Commission conducted a total of 16 tribal consultations as part of its review of Part 514. Tribal consultations were held in every region of the country and were attended by many tribal leaders or their representatives. In addition to tribal consultations, on May 10, 2011, the Commission requested public comment on a Preliminary Draft of amendments to Part 514. 76 FR 26967. After considering the comments received from the public and through tribal consultations, the Commission published a Notice of Proposed Rulemaking, proposing five amendments to Part 514: changing the fee calculation from a calendar year to a fiscal year basis; changing the payment schedule to a quarterly payment system; ensuring language is consistent with industry standards; creating a ticketing system for late fee and fee worksheet submissions; and formalizing the fingerprinting fee system. 76 FR 62684.

III. Review of Public Comments

In response to our Notice of Proposed Rulemaking, published October 11, 2011, 76 FR 62684, we received the following comments.

514.3 What is the maximum fee rate?

Comment: One commenter noted that the proposed rule reiterates the maximum fee rate of 5% of amounts in excess of the $1.5 million of assessable gross revenue. The comment acknowledges that the proposed rule does not propose an increase in the fee rate, but states nonetheless that such an increase could have a serious effect on any Tribe's ability to retain revenues. The comment recommends that prior to any amendment in fee rates mandated by the Commission, the Commission should consult with all Tribes paying fees under IGRA.

Response: The National Indian Gaming Commission fee rate is limited by the Indian Gaming Regulatory Act (25 U.S.C. 2717) to 2.5% of the first $1.5 million of a facility's gross gaming revenue, and no more than 5% of amounts in excess of $1.5 million of a facility's gross gaming revenue. Additionally, the Native American Technical Corrections Act of 2006 (Pub. L. 109–221) mandated that fees imposed by the Commission during any fiscal year shall not exceed 0.080% of the gross gaming revenues of all gaming operations subject to regulation under IGRA.

514.4 What are ''assessable gross revenues'' and how does a tribe calculate the amount of the annual fee it owes?

Comment: One commenter suggested that the regulation include a definition of ''gross gaming revenue,'' whether as defined in GAAP or through some other internationally accepted accounting standard.

Response: The GAAP definition of ''Gross Gaming Revenue,'' as well as other internationally accepted standards, may provide a standard definition, but are also subject to change and may be inconsistent with the definition contained in IGRA at 25 U.S.C. 2717(a)(6). The Commission therefore declines to further define ''Gross Gaming Revenue'' through a regulation.

Comment: Another commenter suggests that the regulation should be changed to allow the deduction of promotional items as ''amounts paid out as prizes or paid for prizes awarded.''

Response: Pursuant to IGRA, gross gaming revenue constitutes ''the annual total amount of money wagered, less any amounts paid out as prizes or paid for prizes awarded and less allowance for amortization of capital expenditures for structures.'' In accordance with GAAP and industry standard practices, promotional items given to patrons that are not the result of winning wagers are not considered prizes paid or prizes awarded. The Commission, therefore, declines to allow the deduction of promotional items as prizes paid or prizes awarded as it would be inconsistent with the plain language of IGRA.

Comment: One commenter stated that the computation of gross revenue example in the proposed rule does not reflect the intent of the regulation. In support of this, the commenter cited to the regulation's example that separates gross gaming revenues into two categories—money wagered and entry fees. The commenter suggests that regulation text directing tribes to ''show the amount derived from each type of game'' is inconsistent with the regulation and leads to confusion and potential miscalculation of fees. The Commission should review the examples and promulgate a bulletin providing guidance on the matter.

Response: Although the sub-section referenced in the comment was intended only as an example, and nothing in the regulation requires the segregation of types of games and entry fees, we have removed it from this rule. As for guidance on the computation of gross gaming revenue, the Commission intends to offer a broad array of technical assistance and training in conjunction with this rule.

The Commission also notes that it is amending Part 514 to change the term ''admission fees'' to ''entry fees'' in section 514.4(a). ''Entry fee'' is a term commonly used in the gaming industry and the Commission believes the clarification will eliminate concern that an ''admission fee'' includes admission to concerts or other non-gaming activity.

514.5 When must a tribe pay its annual fees? and 514.6 What are the quarterly statements that must be submitted with the fee payments?

Comment: While two commenters stated their support for changing from a bi-annual submission requirement to a quarterly submission requirement, one commenter opposes the change, stating that it makes it more difficult for Tribes to calculate fees and will result in more instances of late or inaccurate quarterly statements and/or fee payments.

Response: The recommendation to maintain a bi-annual fee was not adopted. The Commission finds that changing the submission requirement back to quarterly is consistent with the requirements of the Indian Gaming Regulatory Act, 25 U.S.C. 2717(f), which states that ''[t]he Commission, by a vote of not less than two of its members, shall annually adopt the rate of the fees authorized by this section which shall be payable to the Commission on a quarterly basis.'' Further, this rule does not prohibit pre-payment of fees. Fee worksheets, however, must be submitted on a quarterly basis, even if the fee has been prepaid.

This rule also changes the timeframe of the fee calculation from a gaming operation's calendar year to its fiscal year. Though there were no comments in opposition to this change, it is important to note that this rule does not mandate that a tribe change its fiscal year, but rather requires that a tribe base its fee calculation on its fiscal year. Thus, if a tribe's fiscal year is based on its calendar year, there is no need to change. The Commission believes that the use of a fiscal year for calculating annual fees and completing fee worksheets will result in fewer inaccuracies in fee calculations.

514.9 What happens if a tribe submits its fee payment or quarterly statement late?

Comment: The Commission is amending Part 514 to add a ''ticket'' system which assesses a fine for a late fee payment. The proposed Rule distinguishes between ''late payments'' and ''failure to pay annual fees.'' A payment received between one and ninety days late is a ''late payment'' and is subject to a late payment fine. A payment received after 90 days constitutes a ''failure to pay annual fees'' and subjects the tribe to a potential notice of violation (NOV) and civil fine assessment. The Chair shall consider any mitigating circumstances surrounding the late payments and, at the Chair's discretion, reduce the late fee or the civil fine due. Per federal law, any fines are payable to U.S. Treasury, not the NIGC.

The comments were overwhelmingly supportive of the proposed rule's implementation of a late payment system. There were, however two comments on how to implement the system. One commenter stated that the proposed late fee structure is too severe. According to the commenter, an assessment of 10% is too harsh, especially for a payment that may only be a few days late. Another commenter stated that the late payment penalties should start at 1% for statements/payments one to thirty days late, 2% for statements/payments thirty-one to sixty days late, 5% for statements/payments sixty-one to ninety days late, and 25% for statements/payments more than ninety days late.

Response: The Commission believes that a late-fee structure of 10%, 15%, and 20% properly emphasizes the importance of annual fees to the continued operation of the NIGC. Timely submission of fee worksheets and payments is vital to the NIGC's ability to fulfill is regulatory duties and provide technical assistance and training to the tribal gaming operations. Accordingly, any late fee must provide incentive to gaming operations to pay fees in a timely manner. The Commission is concerned that setting late fees too low could discourage timely payment. Therefore, it did not adopt the suggestions to lower the late fee percentages.

Comment: Two commenters suggested the Commission consider the inclusion of a grace period, such as no late fees for payments 1–7 days late, and/or reduce the percentage rate for a late payment of thirty days or less.

Response: The recommendation to provide a grace period before a late fee may be assessed is not adopted. The Commission is concerned that the inclusion of a grace period may have the effect of constructively pushing back the fee deadline to the point that the grace period ends. The Commission also notes that the purpose of changing the basis for fee calculation to the fiscal year is to make timely fee payments easier. Further, the Commission's use of the ''mailbox rule'' gives gaming operations the maximum amount of time to prepare and submit fee payments and fee worksheets. According to the mail-box rule, a submission is considered received by the Commission when it is postmarked, not when it is received by the NIGC.

Comment: One commenter asked that the NIGC consider adding language to the effect that the NIGC will take factors such as the size of the tribe's gaming operation, as well as other equitable considerations, into account when assessing late fees.

Response: The suggestion to specify that the above listed factors be considered by the Chair when assessing a late fee is not adopted. Pursuant to this rule, the Chair will take into consideration any information submitted by a tribe in its response to the notice of late fees. See 514.9(b). This information may include the size of the Tribe's gaming operation and other equitable considerations. Specifying what those considerations may be would effectively limit the factors the Chair may consider when determining whether to issue a late fee and the amount of the fee. The Commission does not want to limit what the Chair may consider.

Comment: One commenter stated that the Commission should clarify whether late fees will run concurrently with any enforcement action taken under 514.10 of the proposed rule and, if so, suggests a cap on any late fees assessed in conjunction with a NOV or enforcement action.

Response: The recommendation to further clarify the regulation is not adopted. A late fee and civil fine assessment will likely not be issued concurrently. Under this rule, the first step is to issue a notice of late fee. If the fee payment or fee worksheet is submitted within 90 days of the due date, the Chair may propose a late fee. The proposed late fee will depend on the timeliness of the submission. If, however, the fee or fee worksheet is not submitted within the initial 90 days, the lateness becomes a failure to pay and rather than a late fee, the Chair could instead issue a NOV or closure order. Even if a late fee and civil fine assessment were to issue simultaneously though, the late fee would have to be incorporated into a proposed civil fine. Pursuant to IGRA, the late fee and civil fine cannot collectively exceed the statutory limit.

Comment: One commenter stated that the regulation should require that before the NIGC can find a tribe has failed to pay its fees and issue a NOV or temporary closure order, it must issue two notices to the tribe during the initial 90 days. Another commenter recommended that the NIGC engage in consultation with a tribe before initiating the NOV process.

Response: The recommendations to require two notices or engage in consultation before a NOV or temporary closure order may be issued are not adopted. The Chair and NIGC staff will continue to work with Tribes and gaming operations to ensure that enforcement is the last option, to be used only if assistance and compliance have failed. Typically, the NIGC will have been in informal discussions with a tribe or gaming operation long before a NOV is issued. The Commission chooses not to add to the NOV requirements already mandated by IGRA and NIGC regulations.

Comment: Another commenter stated that the term *proposed late fees* is inaccurate and should be changed to *late fees assessed.*

Response: The recommendation is not adopted. Late fees do not become final unless the recipient of the fee fails to appeal or, on appeal, the fee is upheld by the full Commission.

Comment: One commenter stated that late fees assessed are, in fact, operating expenses. The commenter suggested that if the Commission's intent is to prohibit tribes from deducting the amount of late penalty from the fee calculation, the regulation should be clarified to state as much.

Response: This rule requires late fees to be paid by the person assessed and that they not be treated as an operating expense of a gaming operation. These changes ensure that other parties will

not be responsible for the late fee. Further, the calculation of operating expenses is not relevant to the fee calculation. Fees are based on assessable gross revenues, which are defined by 25 U.S.C. 2717(a)(6) and section 514.4 of this rule as ''the annual total amount of money wagered, less any amounts paid out as prizes or paid for prizes awarded and less allowance for amortization of capital expenditures for structures.'' Because operating expenses are not part of the fee calculation, the suggestion to clarify the rule to prohibit tribes from deducting the late penalty from the fee calculation is not adopted.

514.17 How are fingerprint processing fees collected by the Commission?

Comment: Two commenters objected to fingerprint fees being included as a separate section of the regulation on the grounds that fees should be covered by the annual fee already collected by the Commission.

Response: This comment is not adopted. IGRA does not require the NIGC to process fingerprints and not all tribes utilize the service. The service will continue to be charged as a separate fee only to those tribes that utilize the NIGC's fingerprint processing service. The Commission believes formalizing the procedures for assessing fingerprint card processing fees in a regulation provides transparency and clarity.

IV. Regulatory Matters

Regulatory Flexibility Act

The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions. Nor will the rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

The information collection requirements contained in this rule were previously approved by the Office of Management and Budget (OMB) as required by 44 U.S.C. 3501 *et seq.* and assigned OMB Control Number 3141–0007, which expired in August of 2011. The NIGC is in the process of reinstating that Control Number.

Although the rule changes the collection from bi-annually to quarterly, the proposed rule does not require any significant changes in information collection previously approved under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501 *et seq.* At the time OMB Control Number 3141–0007 was assigned, Part 514 required quarterly submissions. This was changed to a bi-annually submission requirement on August 26, 2009 without obtaining a new OMB Control Number. 74 FR 36926. Accordingly, no significant changes in information will occur since the last OMB Control Number was assigned.

List of Subjects in 25 CFR Part 514

Gambling, Indians—Lands, Indians—Tribal Government, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Commission revises 25 CFR part 514 to read as follows:

PART 514—FEES

Sec.

514.1 What is the purpose of this part?
514.2 When will the annual rates be published?
514.3 What is the maximum fee rate?
514.4 What are ''assessable gross revenues'' and how does a tribe calculate the amount of the annual fees it owes?
514.5 When must a tribe pay its annual fees?
514.6 What are the quarterly statements that must be submitted with the fee payments?
514.7 What should a tribe do if it changes its fiscal year?
514.8 Where should fees, quarterly statements, and other communications about fees be sent?
514.9 What happens if a tribe submits its fee payment or quarterly statement late?
514.10 When does a late payment or quarterly statement submission become a failure to pay?
514.11 Can a tribe or gaming operation appeal a proposed late fee?
514.12 When does a notice of late submission and/or a proposed late fee become a final order of the Commission and final agency action?
514.13 How are late submission fees paid, and can interest be assessed?
514.14 What happens if a tribe overpays its fees or if the Commission does not expend the full amount of fees collected in a fiscal year?
514.15 May tribes submit fingerprint cards to the NIGC for processing?
514.16 How does the Commission adopt the fingerprint processing fee?
514.17 How are fingerprint processing fees collected by the Commission?

Authority: 25 U.S.C. 2706, 2710, 2710, 2717, 2717a.

§ 514.1 What is the purpose of this part?

Each gaming operation under the jurisdiction of the Commission, including a tribe with a certificate of self-regulation, shall pay to the Commission annual fees as established by the Commission. The Commission, by a vote of not less than two of its members, shall adopt the rates of fees to be paid.

§ 514.2 When will the annual rates be published?

(a) The Commission shall adopt preliminary rates for each calendar year no later than March 1st of each year, and, if considered necessary, shall modify those rates no later than June 1st of that year.

(b) The Commission shall publish the rates of fees in a notice in the **Federal Register**.

§ 514.3 What is the maximum fee rate?

(a) The rates of fees imposed shall be—

(1) No more than 2.5% of the first $1,500,000 (1st tier), and

(2) No more than 5% of amounts in excess of the first $1,500,000 (2nd tier) of the assessable gross revenues from

each gaming operation subject to the jurisdiction of the Commission.

(b) If a tribe has a certificate of self-regulation, the rate of fees imposed shall be no more than .25% of assessable gross revenues from self-regulated class II gaming operations.

§ 514.4 What are "assessable gross revenues" and how does a tribe calculate the amount of the annual fee it owes?

(a) For purposes of computing fees, assessable gross revenues for each gaming operation are the annual total amount of money wagered on class II and III games, entry fees (including table or card fees), less any amounts paid out as prizes or paid for prizes awarded, and less an allowance for amortization of capital expenditures for structures as reflected in the gaming operation's audited financial statements.

(b) Each gaming operation subject to these regulations shall calculate the annual fee based on the gaming operation's fiscal year.

(c) Unless otherwise provided by the regulations, generally accepted accounting principles shall be used.

(d) The allowance for amortization of capital expenditures for structures shall be either:

(1) An amount not to exceed 5% of the cost of structures in use throughout the year and 2.5% of the cost of structures in use during only a part of the year; or

(2) An amount not to exceed 10% of the total amount of depreciation expenses for the year.

(e) All class II and III revenues from gaming operations are to be included.

§ 514.5 When must a tribe pay its annual fees?

Each gaming operation shall calculate the amount of fees to be paid and remit them with the quarterly statement required in § 514.6. The fees payable shall be computed using:

(a) The most recent rates of fees adopted by the Commission pursuant to § 514.2,

(b) The assessable gross revenues for the previous fiscal year as calculated using § 514.4, and

(c) The amounts paid and credits received during the fiscal year, if applicable.

§ 514.6 What are the quarterly statements that must be submitted with the fee payments?

(a) Each gaming operation subject to the jurisdiction of the Commission shall file with the Commission quarterly statements showing its assessable gross revenues for the previous fiscal year.

(b) These statements shall show the amounts derived from each type of game, the amounts deducted for prizes, and the amounts deducted for the amortization of structures.

(c) The quarterly statements shall be sent to the Commission within three (3) months, six (6) months, nine (9) months, and twelve (12) months of the end of the gaming operation's fiscal year.

(d) The quarterly statements shall identify an individual or individuals to be contacted should the Commission need to communicate further with the gaming operation. The telephone numbers of the individual(s) shall be included.

(e) Each quarterly statement shall include the computation of the fees payable, showing all amounts used in the calculations. The required calculations are as follows:

(1) Multiply the 1st tier assessable gross revenues, as calculated using § 514.4, by the rate for those revenues adopted by the Commission.

(2) Multiply the 2nd tier assessable gross revenues, as calculated using § 514.4, by the rate for those revenues adopted by the Commission.

(3) Add (total) the results (products) obtained in paragraphs (e)(1) and (2) of this section.

(4) Multiply the total obtained in paragraph (e)(3) of this section by ¼.

(5) The amount computed in paragraph (e)(4) of this section is the amount to be remitted.

(f) Examples of fee computations follow:

(1) Where a filing is made for the first quarter of the fiscal year, the previous year's assessable gross revenues as calculated using section 514.4 of this part are $2,000,000, the fee rates adopted by the Commission are 0.0% on the first $1,500,000 and .08% on the remainder, the amounts to be used and the computations to be made are as follows:

1st tier revenues—$1,500,000 × 0.0% =	0
2nd tier revenues—$500,000 × .08% =	$400
Annual fees	$400
Multiply for fraction of year—¼ or	.25
Fees for first payment	$100
Amount to be remitted	$100

(2) [Reserved]

(g) As required by part 571 of this chapter, quarterly statements must be reconciled with a tribe's audited or reviewed financial statements for each gaming location. These reconciliations must be made available upon the request of any authorized representative of the NIGC.

§ 514.7 What should a tribe do if it changes its fiscal year?

If a gaming operation changes its fiscal year, it shall notify the Commission of the change within thirty (30) days. The Commission may request that the tribe prepare and submit to the Commission the fees and statements required by this subsection for the stub period from the end of the previous fiscal year to the beginning of the new fiscal year. The submission must be sent to the Commission within ninety (90) days of its request.

§ 514.8 Where should fees, quarterly statements, and other communications about fees be sent?

The statements, remittances and communications about fees shall be transmitted to the Commission at the following address: Comptroller, National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005. Checks should be made payable to the National Indian Gaming Commission (do not remit cash).

§ 514.9 What happens if a tribe submits its fee payment or quarterly statement late?

(a) In the event that a gaming operation fails to submit a fee payment or quarterly statement in a timely manner, the Chair of the Commission may issue a notice specifying:

(1) The date the statement and/or payment was due;

(2) The number of calendar days late the statement and/or payment was submitted;

(3) A citation to the federal or tribal requirement that has been or is being violated;

(4) The action being considered by the Chair; and

(5) Notice of rights of appeal pursuant to part 577 of this chapter.

(b) Within fifteen (15) days of service of the notice, a respondent may submit written information about the notice to the Chair. The Chair shall consider any information submitted by the respondent as well as the respondent's history of untimely submissions or failure to file statements and/or fee payments over the preceding five (5) years in determining the amount of the late fee, if any.

(c) When practicable, within thirty (30) days of issuing the notice described in paragraph (a) of this section to a respondent, the Chair of the Commission may assess a proposed late fee against a respondent for each failure to file a timely quarterly statement and/or fee payment:

(1) For statements and/or fee payments one (1) to thirty (30) calendar days late, the Chair may propose a late fee of up to, but not more than 10% of the fee amount for that quarter, as calculated in § 514.6(e);

(2) For statements and/or fee payments thirty-one (31) to sixty (60) calendar days late, the Chair may propose a late fee of up to, but not more than 15% of the fee amount for that quarter, as calculated in § 514.6(e);

(3) For statements and/or fee payments sixty-one (61) to ninety (90) calendar days late, the Chair may propose a late fee of up to, but not more than 20% of the fee amount for that quarter, as calculated in § 514.6(e).

§ 514.10 When does a late payment or quarterly statement submission become a failure to pay?

(a) Statements and/or fee payments over ninety (90) calendar days late constitute a failure to pay the annual fee, as set forth in IGRA, 25 U.S.C. 2717(a)(3), and NIGC regulations, 25 CFR 573.6(a)(2). In accordance with 25 U.S.C. 2717(a)(3), failure to pay fees shall be grounds for revocation of the approval of the Chair of any license, ordinance or resolution required under IGRA for the operation of gaming.

(b) In accordance with § 573.6(a)(2) of this chapter, if a tribe, management contractor, or individually owned gaming operation fails to pay the annual fee, the Chair may issue a notice of violation and, simultaneously with or subsequently to the notice of violation, a temporary closure order.

§ 514.11 Can a tribe or gaming operation appeal a proposed late fee?

(a) Proposed late fees assessed by the Chair may be appealed under part 577 of this chapter.

(b) At any time prior to the filing of a notice of appeal under part 577 of this chapter, the Chair and the respondent may agree to settle the notice of late submission, including the amount of the proposed late fee. In the event a settlement is reached, a settlement agreement shall be prepared and executed by the Chair and the respondent. If a settlement agreement is executed, the respondent shall be deemed to have waived all rights to further review of the notice or late fee in question, except as otherwise provided expressly in the settlement agreement. In the absence of a settlement of the issues under this paragraph, the respondent may contest the proposed late fee before the Commission in accordance with part 577 of this chapter.

§ 514.12 When does a notice of late submission and/or a proposed late fee become a final order of the Commission and final agency action?

If the respondent fails to appeal under part 577 of this chapter, the notice and the proposed late fee shall become a final order of the Commission and final agency action.

§ 514.13 How are late submission fees paid, and can interest be assessed?

(a) Late fees assessed under this part shall be paid by the person or entity assessed and shall not be treated as an operating expense of the operation.

(b) The Commission shall transfer the late fee paid under this subchapter to the U.S. Treasury.

(c) Interest shall be assessed at rates established from time to time by the Secretary of the Treasury on amounts remaining unpaid after their due date.

§ 514.14 What happens if a tribe overpays its fees or if the Commission does not expend the full amount of fees collected in a fiscal year?

(a) The total amount of all fees imposed during any fiscal year shall not exceed the statutory maximum imposed by Congress. The Commission shall credit pro-rata any fees collected in excess of this amount against amounts otherwise due according to § 514.4.

(b) To the extent that revenue derived from fees imposed under the schedule established under this paragraph are not expended or committed at the close of any fiscal year, such funds shall remain available until expended to defray the costs of operations of the Commission.

§ 514.15 May tribes submit fingerprint cards to the NIGC for processing?

Tribes may submit fingerprint cards to the Commission for processing by the Federal Bureau of Investigation (FBI) and the Commission may charge a fee to process fingerprint cards on behalf of the tribes.

§ 514.16 How does the Commission adopt the fingerprint processing fee?

(a) The Commission shall review annually the costs involved in processing fingerprint cards and, by a vote of not less than two of its members, shall adopt preliminary rates for each calendar year no later than March 1st of that year, and, if considered necessary, shall modify those rates no later than June 1st of that year.

(b) The fingerprint fee charge shall be based on fees charged by the Federal Bureau of Investigation and costs incurred by the Commission. Commission costs include Commission personnel, supplies, equipment costs, and postage to submit the results to the requesting tribe.

§ 514.17 How are fingerprint processing fees collected by the Commission?

(a) Fees for processing fingerprint cards will be billed monthly to each Tribe for cards processed during the prior month. Tribes shall pay the amount billed within forty-five (45) days of the date of the bill.

(b) The Chair may suspend fingerprint card processing for a tribe that has a bill remaining unpaid for more than forty-five (45) days.

(c) Fingerprint fees shall be sent to the following address: Comptroller, National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005. Checks should be made payable to the National Indian Gaming Commission (do not remit cash).

Dated: January 27, 2012, Washington, DC.

Tracie L. Stevens,

Chairwoman.

Steffani A. Cochran,

Vice-Chairwoman.

Daniel J. Little,

Associate Commissioner.

[FR Doc. 2012–2254 Filed 2–1–12; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 523

RIN 3141–AA45

Review and Approval of Existing Ordinances or Resolutions; Repeal

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission is repealing obsolete regulations relating to tribal gaming ordinances enacted prior to 1993 that have not yet been submitted to the NIGC Chair. The repealed regulations apply only to gaming ordinances enacted by Tribes prior to January 22, 1993, and not yet submitted to the Chairwoman. Based upon comments received, the Commission believes that all gaming ordinances enacted prior to January 22, 1993, have been submitted to the Chair for review. Therefore, this regulation is no longer necessary, and the Commission removes it in its entirety.

DATES: This rule is effective on March 5, 2012.

FOR FURTHER INFORMATION CONTACT: Jennifer Ward, Staff Attorney, Office of General Counsel, at (202) 632–7003; fax (202) 632–7066.

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* authorizes the NIGC to promulgate such regulations and

guidelines as it deems appropriate to implement certain provisions of the Act. 25 U.S.C. 2706(b)(10). On November 12, 2010, the Commission issued a Notice of Inquiry (NOI) requesting comment on which of its regulations were most in need of revision, in what order the Commission should review its regulations, and the process NIGC should utilize to make revisions. The NOI was published in the **Federal Register** on November 18, 2010. 75 FR 70680. The Commission's regulatory review process established a tribal consultation schedule of 33 meetings over 11 months with a description of the regulation groups to be covered at each consultation. On October 12, 2011, the Commission published a Notice of Proposed Rulemaking (NPRM) indicating its intent to repeal part 523 and requested comment through December 12, 2011. 76 FR 63236.

I. Removal of Part 523—Review and Approval of Existing Ordinances or Resolutions

Part 523 applies only to gaming ordinances or resolutions enacted by Tribes prior to January 22, 1993, and not yet submitted to the Chairwoman. All comments received in response to the NOI, during tribal consultation meetings, or in response to the NPRM indicated that any ordinances or resolutions enacted prior to January 22, 1993 already have been submitted to the Chair for review. Accordingly, comments support the repeal of this part. A review of the Commission documents also did not find any ordinances or resolutions meeting the criteria of this part that require review. Because this regulation appears to be no longer necessary, the Commission removes this part.

II. Specific Comments

Four tribes responded to the NPRM. Of these four, none had effective ordinances that were enacted prior to 1993. Two tribes were supportive of the rule, one had no objection, and the fourth declined comment other than to say the repeal would not affect it..

III. Regulatory Matters

Regulatory Flexibility Act

The proposed rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions, nor will the proposed rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the final rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This rule merely repeals a previous rule, and does not establish, or modify any information reporting or recordkeeping requirements, and therefore is not subject to the requirements of the Paperwork Reduction Act.

Text of the Final Rule

For the reasons stated in the preamble, and under the authority 25 U.S.C. 2701, the National Indian Gaming Commission removes and reserves 25 CFR part 523.

PART 523—[REMOVED AND RESERVED]

Authority: 25 U.S.C. 2701, 2706(b)(10).

Dated: January 27, 2012, in Washington, DC.

Tracie L. Stevens,

Chairwoman.

Steffani A. Cochran,

Vice-Chairwoman.

Daniel J. Little,

Associate Commissioner.

[FR Doc. 2012–2257 Filed 2–1–12; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0018]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Wrightsville Beach, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the S.R. 74 Bridge, across the Atlantic Intracoastal Waterway, mile 283.1, at Wrightsville Beach, NC. This deviation is necessary to accommodate the Quintiles Wrightsville Beach Full and Half Marathon. This deviation allows the bridge to remain in the closed position during the race.

DATES: This deviation is effective from 5 a.m. through 8 a.m. on Sunday, March 18, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2012–0018 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0018 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

email Lindsey Middleton, Coast Guard; telephone (757) 398–6629, email *Lindsey.R.Middleton@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 Quintiles Wrightsville Beach Full and Half Marathon committee on behalf of the North Carolina Department of Transportation (NCDOT) has requested a temporary deviation from the current operating schedule for the S.R. 74 Bascule Drawbridge across the Atlantic Intracoastal Waterway (AIWW), mile 283.1, at Wrightsville Beach, NC. The requested deviation is to accommodate the 2012 Quintiles Wrightsville Beach Full and Half Marathon scheduled for Sunday, March 18, 2012. To facilitate this event, the draw of the bridge will be maintained in the closed-to-navigation position from 5 a.m. until 8 a.m.

The current operating schedule for the bridge is set out in 33 CFR 117.821(a)(4). The regulation requires the bridge to open on signal for vessels at all times except that from 7 a.m. until 7 p.m. the bridge shall open on the hour; every third and fourth Saturday in September the bridge shall remain closed from 7 a.m. until 11 a.m.; and the last Saturday of October or the first or second Saturday of November the bridge shall remain closed from 7 a.m. until 10:30 a.m. The bascule drawbridge has a vertical clearance of 20 feet above mean high water (MHW) in the closed position. Vessels that can pass through the bridge in the closed position may do so at any time.

This race is an annual event; therefore local waterway users should be familiar with the closure. To ensure that waterway users are aware of the closure, the Coast Guard will issue a Local and Broadcast Notice to Mariners to allow mariners to schedule their transits accordingly. There are no alternate routes available to vessels. Most waterway traffic consists of recreational boats with a few barges and tugs in the daytime. The bridge is able to open for emergencies.

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: January 18, 2012.

Waverly W. Gregory, Jr.,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2012–2285 Filed 2–1–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0031]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway Albermarle Sound to Sunset Beach, Scotts Hill, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the Figure Eight Swing Bridge across the Atlantic Intracoastal Waterway North Carolina Cut, mile 278.1, at Scotts Hill, NC. Under this temporary deviation, the drawbridge may remain in the closed position on specific dates and times to facilitate mechanical gear replacement.

DATES: This deviation is effective from 10 a.m. on February 7, 2012, until 3 p.m. on February 8, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket USCG–2012–0031 and are available online by going to *http://www.regulations.gov,* inserting USCG–2012–0031 in the ''Keywords'' box, and then clicking ''Search''. This material is also available for inspection or copying 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 email Mr. Jim Rousseau, Bridge Management Specialist, Fifth Coast Guard District, telephone (757) 398–6557.

Email *James.L.Rousseau2@uscg.mil.* If you have questions on reviewing the docket, call Renee V. Wright, Program Manager, Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Figure Eight Beach Homeowners Association, who owns and operates the Figure Eight Swing Bridge across the Atlantic Intracoastal Waterway (AIWW), North Carolina Cut, mile 278.1, at Scotts Hill, NC, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.821(a)(3), to accommodate mechanical gear replacement.

Under the current operating schedule, the draw shall open on signal for commercial vessels at all times and open on signal for pleasure vessels except need only open for pleasure vessels on the hour and half hour. Figure Eight Swing Bridge, at AIWW mile 278.1, across the North Carolina Cut in Scotts Hill, NC, has a vertical clearance in the closed position to vessels of 20 feet above mean high water. During this time of year approximately two vessels a day transits the area.

To facilitate mechanical gear replacement, the drawbridge will be maintained in the closed-to-navigation position from 10 a.m. to 3 p.m. on February 7 and 8, 2012. The mechanical gear replacement is scheduled for February 7, 2012. Under this temporary deviation, the drawbridge will remain in the closed position to vessels requiring an opening from 10 p.m. to 3 p.m. However, should weather preclude this work from taking place on February 7, 2012, the work will be re-scheduled to take place on February 8, 2012. In that case, the drawbridge will operate as normal on February 7, 2012 and the drawbridge will remain in the closed position to vessels requiring an opening from 10 a.m. to 3 p.m. on February 8, 2012.

Vessels may transit under the drawbridge while it is in the closed position. The Atlantic Intracoastal Waterway caters to a variety of vessels from tug and barge traffic to recreational vessels traveling from Florida to Maine. The Coast Guard will inform unexpected users of the waterway through our local and broadcast Notices to Mariners of the limited operating schedule for the drawbridge so that vessels can arrange their transits to minimize any impacts caused by the temporary deviation. The Atlantic Ocean is the alternate route for vessels and the bridge will not be able to open in the event of an emergency. The Coast Guard will inform the users of the waterway through our Local and Broadcast Notices to Mariners of the opening restrictions of the draw span to minimize transiting delays caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the draw 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: January 20, 2012.

Waverly W. Gregory, Jr.,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2012–2282 Filed 2–1–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1171]

Drawbridge Operation Regulation; Northeast Cape Fear River, Wilmington, NC

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the Isabel S. Holmes Bridge across the Northeast Cape Fear River, mile 1.0, at Wilmington, NC. The deviation restricts the operation of the draw span to accommodate the 100 year Anniversary of the Girl Scout Program Ceremonial walk. The deviation allows the bridge to remain in the closed position to vessels.

DATES: This deviation is effective from 10 a.m. until noon on March 10, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket USCG–2011–1171 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–1171 in the ''Keywords'' box, and then clicking ''Search''. This material is also available for inspection or copying 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 email Mr. Jim Rousseau, Bridge Management Specialist, Fifth Coast Guard District, telephone (757) 398–6557. Email *James.L.Rousseau2@uscg.mil.* If you have questions on reviewing the docket, call Renee V. Wright, Program Manager, Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Event Director for the New Hanover County Girl Scouts, with approval from the North Carolina Department of Transportation, owner of the drawbridge, has requested a temporary deviation from the current operating schedule to accommodate the 100 year Anniversary of the Girl Scout Program Ceremonial walk.

The Isabel S. Holmes Bridge operating regulations are set out in 33 CFR 117.829(a). However on January 10, 2012 (77 FR 1406) the Coast Guard granted a deviation from 33 CFR 117.829(a) to facilitate structural repair on the bridge. Under the current operating deviation schedule, the drawbridge will be closed to navigation from 7 a.m. on January 16, 2012 until and including 11 p.m. on April 30, 2012; except that vessel openings will be provided if at least three hours advance notice is given to the bridge tender at (910) 251–5774 or via marine radio on channel 13 VHF. The Isabel S. Holmes Bridge across the Northeast Cape Fear River, mile 1.0,a bascule lift Bridge, in Wilmington, NC, has a vertical clearance in the closed position of 40 feet, above mean high water.

Under this temporary deviation, the drawbridge will be allowed to remain in the closed-to-navigation position from 10 a.m. to noon on Saturday, March 10, 2012 to accommodate the 100 year Anniversary of the Girl Scout Program Ceremonial walk.

Vessels able to pass under the closed span may transit under the drawbridge while it is in the closed position. Mariners are advised to proceed with caution. The Coast Guard will inform users of the waterway through our local and broadcast Notices to Mariners of the limited operating schedule for the drawbridge so that vessels can arrange their transits to minimize any impacts caused by the temporary deviation. There are no alternate routes for vessels and the bridge will be able to open in the event of an emergency.

In accordance with 33 CFR 117.35(e), when applicable the draw 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: January 13, 2012.

Waverly W. Gregory, Jr.,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2012–2284 Filed 2–1–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AN80

Medical Foster Homes

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) ''Medical'' regulations to add rules relating to medical foster homes. Prior to this final rule, VA's medical foster home program had, whenever possible and appropriate, relied upon regulations governing community residential care facilities; however, those regulations did not cover all aspects of medical foster homes, which provide community based care in a smaller, residential facility and to a more medically complex and disabled population. This final rule reflects current VA policy and practice, and generally conforms to industry standards and expectations.

DATES: *Effective date:* March 5, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this rule as of March 5, 2012.

FOR FURTHER INFORMATION CONTACT: Rick Greene, Office of Patient Care Services (114), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–6786. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: Many veterans who are disabled due to complex chronic disease or traumatic injury may be unable to live safely and independently, or may have health care needs that exceed the capabilities of their families. Many of these veterans are placed in nursing homes. Others, with the proper support, can continue to live in a residential setting and delay, or totally avoid, the need for nursing home care. VA's community residential care program, specifically authorized by 38 U.S.C. 1730 and implemented at 38 CFR 17.61 through 17.72, has provided health care supervision to these veterans.

A medical foster home is a specific type of community residential care facility that provides home-based care to a small number of residents with serious chronic disease and disability. A medical foster home provides a greater level of care than a community residential care facility (and in this respect a medical foster home is more analogous to a nursing home), while allowing veterans to live in a home-like

setting and maintain a greater degree of independence. VA interprets 38 U.S.C. 1730 as authorizing a medical foster home program, as a subset of the community residential care program. In particular, we believe medical foster homes fit within the type of facility authorized by section 1730(f), since they provide ''room and board and * * * limited personal care.''

In a document published in the **Federal Register** on May 19, 2011 (76 FR 28917), VA proposed regulations to govern medical foster homes. We provided a 60 day comment period, which ended on July 18, 2011. We received one comment.

The commenter sought clarification regarding whether a veteran would ''have the option of receiving approved care in their own home rather than being forced into a local nursing home'' if there were no approved medical foster home in their area. The proposed rule stated in § 17.73(a) that the purpose of the medical foster home program is to ''approve[] certain medical foster homes for the placement of veterans'' and that placement in a medical foster home is voluntary on the part of the veteran. If the veteran is interested in this care option, VA will try to refer the veteran to a medical foster home as close to his or her residence as possible.

However, VA is aware that a medical foster home may not be located in the immediate vicinity of the veteran's residence. If a veteran is unable or unwilling to accept placement in a medical foster home that is located outside the immediate vicinity of the veteran's residence, VA offers several alternate health care programs that may better suit the veteran's needs. These alternate programs include home based primary care, where the veteran receives primary care in his home; community residential care, which provides care similar to that of the medical foster home; and nursing home care. Home Based Primary Care provides long-term primary care to chronically ill veterans in their own homes. Home Based Primary Care is appropriate for veterans with complex, chronic, and long-term conditions that would make it difficult to come to a VA facility for treatment. A VA treatment team coordinates the plan of care for each veteran and comes to the veteran's home to provide services. Home Based Primary Care provides primary care, palliative care, therapy, disease management, and coordination of care services.

The commenter noted that § 17.74(d)(3) requires the veteran to be placed in a single-occupancy bedroom, unless the veteran agrees to a multi-occupant bedroom. The commenter asked whether the spouse of a married veteran ''[c]an * * * move into the home with the veteran[,] or will the couple be forced to live apart?'' Nothing in the regulation would preclude the spouse of a veteran from living in the same medical foster home as the veteran. Such an arrangement would be a matter of agreement between the spouse of the veteran and the medical foster home caregiver. If the spouse of the veteran also requires medical care in addition to lodging, then the spouse of the veteran must be included in the total number of residents receiving care in the medical foster home, which § 17.73(b) limits to no more than three. The medical foster home would not be able to provide adequate care to all of its residents if the total number of residents receiving care exceeds three. If VA recommends a medical foster home that was unable to accommodate the veteran and his or her spouse, VA could provide the veteran an alternate location that would accommodate the veteran and the spouse's needs. However, any agreement between the medical foster home caregiver for the lodging and/or care of veteran's spouse in such home is beyond the scope of this rulemaking. Also, as noted above, if the option of a medical foster home does not adequately address the veteran's and the veteran's family's needs, the veteran may consider an alternate health care option. Therefore, no veteran will be ''forced to live apart'' from his or her spouse. Because the agreement for lodging and/or medical care for the spouse of the veteran is outside the scope of this rulemaking, except where it may impact compliance with § 17.73(b), we are not making any changes based on this comment.

The commenter also stated that, in the commenter's view, the proposed rule contained language that seemed to indicate that only elderly veterans were eligible to be placed in a medical foster home. The commenter further stated that ''there are a growing number of young military veterans who are severely injured and in need of daily medical assistance'' and questioned whether placement in a medical foster home would be an option for these veterans. We agree with the commenter that placement in a medical foster home should not be restricted based on the age of the veteran, and this final rulemaking does not place any such restriction. Age is referenced only in the proposed rulemaking in the supplementary information discussing § 17.73(c)(2), where we discussed the eligibility criteria for referral to a medical foster home. We had stated that one criterion is the veteran's enrollment in either the VA Home Based Primary Care or VA Spinal Cord Injury Homecare program. The proposed rule notice explained that ''VA Home Based Primary Care (HBPC) is a home care program designed to meet the longitudinal, primary care needs of an aging veteran population with complex, chronic, disabling disease.'' However, the HBPC program is not limited to elderly veterans. The program is designed to serve the chronically ill through the months and years before death, providing primary care, palliative care, rehabilitation, disease management and coordination of care services. The proposed rulemaking did not place any age restrictions on eligibility for placement in a medical foster home within the regulation text. We are, therefore, not making any changes based on this comment.

The proposed rule cited 38 U.S.C. 501, 1721, and as noted in specific sections as the authority for 38 CFR part 17. However, the correct authority for part 17 is 38 U.S.C. 501, and as noted in specific sections. We are amending the final rule to reflect the correct authority for part 17.

Based on the rationale set forth in the proposed rule and in this document, VA adopts the proposed rule as a final rule, with the above noted change.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rule, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary rules or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this final rule if possible or, if not possible, such guidance is superseded by this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant

regulatory action,'' which requires review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) 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; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined not to be a significant regulatory action under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

OMB assigns a control number for each collection of information it approves. Except for emergency approvals under 44 U.S.C. 3507(j), VA 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.

In the proposed rule, we stated that proposed § 17.74(q) contains collection of information provisions under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), and that we had requested public comment on those provisions in the notice published in the **Federal Register** on May 19, 2011 (76 FR 28917). We did not receive any comments on the proposed collection of information, which OMB has approved without an expiration date, under control number 2900–0777. Following § 17.74(q) in this final rule, we set out an information collection approval parenthetical displaying OMB control number 2900–0777.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. In addition to having an effect on individuals (veterans), the final rule will have an insignificant economic impact on a few small entities. Most of the minimum standards that will be established by this rulemaking are already required by state and local regulations, and medical foster homes should already be in compliance with those regulations or with the current NFPA codes. Any additional costs for compliance with this final rule would constitute an inconsequential amount of the operational cost for most facilities. Accordingly, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.005, Grants to States for Construction of State Home Facilities; 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on January 9, 2012, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Incorporation by reference, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: January 26, 2012.

Robert C. McFetridge,

Director of Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Revise § 17.1(b) to read as follows:

§ 17.1 Incorporation by reference.

* * * * *

(b) The following materials are incorporated by reference into this part.

(1) NFPA 10, Standard for Portable Fire Extinguishers (2010 edition), Incorporation by Reference (IBR) approved for §§ 17.63, 17.74, and 17.81.

(2) NFPA 101, Life Safety Code (2009 edition), IBR approved for §§ 17.63, 17.74 (chapters 1 through 11, 24, and section 33.7), 17.81, and 17.82.

(3) NFPA 101A, Guide on Alternative Approaches to Life Safety (2010 edition), IBR approved for § 17.63.

(4) NFPA 13, Standard for the Installation of Sprinkler Systems (2010 edition), IBR approved for § 17.74.

(5) NFPA 13D, Standard for the Installation of Sprinkler Systems in One- and Two-Family Dwellings and Manufactured Homes (2010 edition), IBR approved for § 17.74.

(6) NFPA 13R, Standard for the Installation of Sprinkler Systems in Residential Occupancies Up To and Including Four Stories in Height (2010 edition), IBR approved for § 17.74.

(7) NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems (2008 edition), IBR approved for § 17.74.

(8) NFPA 30, Flammable and Combustible Liquids Code (2008 edition), IBR approved for § 17.74.

(9) NFPA 72, National Fire Alarm and Signaling Code (2010 edition), IBR approved for § 17.74.

(10) NFPA 720, Standard for the Installation of Carbon Monoxide (CO)

Detection and Warning Equipment (2009 edition), IBR approved for § 17.74.

* * * * *

■ 3. Sections 17.73 and 17.74 are added to read as follows:

§ 17.73 Medical foster homes—general.

(a) *Purpose.* Through the medical foster home program, VA recognizes and approves certain medical foster homes for the placement of veterans. The choice to become a resident of a medical foster home is a voluntary one on the part of each veteran. VA's role is limited to referring veterans to approved medical foster homes. When a veteran is placed in an approved home, VA will provide inspections to ensure that the home continues to meet the requirements of this part, as well as oversight and medical foster home caregiver training. If a medical foster home does not meet VA's criteria for approval, VA will not refer any veteran to the home or provide any of these services. VA may also provide certain medical benefits to veterans placed in medical foster homes, consistent with the VA program in which the veteran is enrolled.

(b) *Definitions.* For the purposes of this section and § 17.74:

Labeled means that the equipment or materials have attached to them a label, symbol, or other identifying mark of an organization recognized as having jurisdiction over the evaluation and periodic inspection of such equipment or materials, and by whose labeling the manufacturer indicates compliance with appropriate standards or performance.

Medical foster home means a private home in which a medical foster home caregiver provides care to a veteran resident and:

(i) The medical foster home caregiver lives in the medical foster home;

(ii) The medical foster home caregiver owns or rents the medical foster home; and

(iii) There are not more than three residents receiving care (including veteran and non-veteran residents).

Medical foster home caregiver means the primary person who provides care to a veteran resident in a medical foster home.

Placement refers to the voluntary decision by a veteran to become a resident in an approved medical foster home.

Veteran resident means a veteran residing in an approved medical foster home who meets the eligibility criteria in paragraph (c) of this section.

(c) *Eligibility.* VA health care personnel may assist a veteran by referring such veteran for placement in a medical foster home if:

(1) The veteran is unable to live independently safely or is in need of nursing home level care;

(2) The veteran must be enrolled in, or agree to be enrolled in, either a VA Home Based Primary Care or VA Spinal Cord Injury Homecare program, or a similar VA interdisciplinary program designed to assist medically complex veterans living in the home; and

(3) The medical foster home has been approved in accordance with paragraph (d) of this section.

(d) *Approval of medical foster homes.* Medical foster homes will be approved by a VA Medical Foster Homes Coordinator based on the report of a VA inspection and on any findings of necessary interim monitoring of the medical foster home, if that home meets the standards established in § 17.74. The approval process is governed by the process for approving community residential care facilities under §§ 17.65 through 17.72 except as follows:

(1) Where §§ 17.65 through 17.72 reference § 17.63.

(2) Because VA does not physically place veterans in medical foster homes, VA also does not assist veterans in moving out of medical foster homes as we do for veterans in other community residential care facilities under § 17.72(d)(2); however, VA will assist such veterans in locating an approved medical foster home when relocation is necessary.

(e) *Duties of Medical foster home caregivers.* The medical foster home caregiver, with assistance from relief caregivers, provides a safe environment, room and board, supervision, and personal assistance, as appropriate for each veteran.

(Authority: 38 U.S.C. 501, 1730)

§ 17.74 Standards applicable to medical foster homes.

(a) *General.* A medical foster home must:

(1) Meet all applicable state and local regulations, including construction, maintenance, and sanitation regulations.

(2) Have safe and functioning systems for heating, hot and cold water, electricity, plumbing, sewage, cooking, laundry, artificial and natural light, and ventilation. Ventilation for cook stoves is not required.

(3) Except as otherwise provided in this section, meet the applicable provisions of chapters 1 through 11 and 24, and section 33.7 of NFPA 101 (incorporated by reference, see § 17.1), and the other codes and chapters identified in this section, as applicable.

(b) *Community residential care facility standards applicable to medical foster homes.* Medical foster homes must comply with § 17.63(c), (d), (f), (h), (j) and (k).

(c) *Activities.* The facility must plan and facilitate appropriate recreational and leisure activities.

(d) *Residents' bedrooms.* Each veteran resident must have a bedroom:

(1) With a door that closes and latches;

(2) That contains a suitable bed and appropriate furniture; and

(3) That is single occupancy, unless the veteran agrees to a multi-occupant bedroom.

(e) *Windows.* VA may grant provisional approval for windows used as a secondary means of escape that do not meet the minimum size and dimensions required by chapter 24 of NFPA 101 (incorporated by reference, see § 17.1) if the windows are a minimum of 5.0 square feet (and at least 20 inches wide and at least 22 inches high). The secondary means of escape must be brought into compliance with chapter 24 no later than 60 days after a veteran resident is placed in the home.

(f) *Special locking devices.* Special locking devices that do not comply with section 7.2.1.5 of NFPA 101 (incorporated by reference, see § 17.1) are permitted where the clinical needs of the veteran resident require specialized security measures and with the written approval of:

(1) The responsible VA clinician; and

(2) The VA fire/safety specialist or the Director of the VA Medical Center of jurisdiction.

(g) *Smoke and carbon monoxide (CO) detectors and smoke and CO alarms.* Medical foster homes must comply with this paragraph (g) no later than 60 days after the first veteran is placed in the home. Prior to compliance, VA inspectors will provisionally approve a medical foster home for the duration of this 60-day period if the medical foster home mitigates risk through the use of battery-operated single station alarms, provided that the alarms are installed before any veteran is placed in the home.

(1) Smoke detectors or smoke alarms must be provided in accordance with sections 24.3.4.1 or 24.3.4.2 of NFPA 101 (incorporated by reference, see § 17.1); section 24.3.4.3 of NFPA 101 will not be used. In addition, smoke alarms must be interconnected so that the operation of any smoke alarm causes an alarm in all smoke alarms within the medical foster home. Smoke detectors or smoke alarms must not be installed in the kitchen or any other location subject to causing false alarms.

(2) CO detectors or CO alarms must be installed in any medical foster home with a fuel-burning appliance, fireplace,

or an attached garage, in accordance with NFPA 720 (incorporated by reference, see § 17.1).

(3) Combination CO/smoke detectors and combination CO/smoke alarms are permitted.

(4) Smoke detectors and smoke alarms must initiate a signal to a remote supervising station to notify emergency forces in the event of an alarm.

(5) Smoke and/or CO alarms and smoke and/or CO detectors, and all other elements of a fire alarm system, must be inspected, tested, and maintained in accordance with NFPA 72 (incorporated by reference, see § 17.1) and NFPA 720 (incorporated by reference, see § 17.1).

(h) *Sprinkler systems.* (1) If a sprinkler system is installed, it must be inspected, tested, and maintained in accordance with NFPA 25 (incorporated by reference, see § 17.1), unless the sprinkler system is installed in accordance with NFPA 13D (incorporated by reference, see § 17.1). If a sprinkler system is installed in accordance with NFPA 13D, it must be inspected annually by a competent person.

(2) If sprinkler flow or pressure switches are installed, they must activate notification appliances in the medical foster home, and must initiate a signal to the remote supervising station.

(i) *Fire extinguishers.* At least one 2–A:10–B:C rated fire extinguisher must be visible and readily accessible on each floor, including basements, and must be maintained in accordance with the manufacturer's instructions. Portable fire extinguishers must be inspected, tested, and maintained in accordance with NFPA 10 (incorporated by reference, see § 17.1).

(j) *Emergency lighting.* Each occupied floor must have at least one plug-in rechargeable flashlight, operable and readily accessible, or other approved emergency lighting. Such emergency lighting must be tested monthly and replaced if not functioning.

(k) *Fireplaces.* A non-combustible hearth, in addition to protective glass doors or metal mesh screens, is required for fireplaces. Hearths and protective devices must meet all applicable state and local fire codes.

(l) *Portable heaters.* Portable heaters may be used if they are maintained in good working condition and:

(1) The heating elements of such heaters do not exceed 212 degrees Fahrenheit (100 degrees Celsius);

(2) The heaters are labeled; and

(3) The heaters have tip-over protection.

(m) *Oxygen safety.* Any area where oxygen is used or stored must not be near an open flame and must have a posted ''No Smoking'' sign. Oxygen cylinders must be adequately secured or protected to prevent damage to cylinders. Whenever possible, transfilling of liquid oxygen must take place outside of the living areas of the home.

(n) *Smoking.* Smoking must be prohibited in all sleeping rooms, including sleeping rooms of non-veteran residents. Ashtrays must be made of noncombustible materials.

(o) *Special/other hazards.* (1) Extension cords must be three-pronged, grounded, sized properly, and not present a hazard due to inappropriate routing, pinching, damage to the cord, or risk of overloading an electrical panel circuit.

(2) Flammable or combustible liquids and other hazardous material must be safely and properly stored in either the original, labeled container or a safety can as defined by section 3.3.44 of NFPA 30 (incorporated by reference, see § 17.1).

(p) *Emergency egress and relocation drills.* Operating features of the medical foster home must comply with section 33.7 of NFPA 101 (incorporated by reference, see § 17.1), except that section 33.7.3.6 of NFPA 101 does not apply. Instead, VA will enforce the following requirements:

(1) Before placement in a medical foster home, the veteran will be clinically evaluated by VA to determine whether the veteran is able to participate in emergency egress and relocation drills. Within 24 hours after arrival, each veteran resident must be shown how to respond to a fire alarm and evacuate the medical foster home, unless the veteran resident is unable to participate.

(2) The medical foster home caregiver must demonstrate the ability to evacuate all occupants within three minutes to a point of safety outside of the medical foster home that has access to a public way, as defined in NFPA 101 (incorporated by reference, see § 17.1).

(3) If all occupants are not evacuated within three minutes or if a veteran resident is either permanently or temporarily unable to participate in drills, then the medical foster home will be given a 60-day provisional approval, after which time the home must have established one of the following remedial options or VA will terminate the approval in accordance with § 17.65.

(i) The home is protected throughout with an automatic sprinkler system in accordance with section 9.7 of NFPA 101 (incorporated by reference, see § 17.1) and whichever of the following apply: NFPA 13 (incorporated by reference, see § 17.1); NFPA 13R (incorporated by reference, see § 17.1); or NFPA 13D (incorporated by reference, see § 17.1).

(ii) Each veteran resident who is permanently or temporarily unable to participate in a drill or who fails to evacuate within three minutes must have a bedroom located at the ground level with direct access to the exterior of the home that does not require travel through any other portion of the residence, and access to the ground level must meet the requirements of the Americans with Disabilities Act. The medical foster home caregiver's bedroom must also be on ground level.

(4) The 60-day provisional approval under paragraph (p)(3) of this section may be contingent upon increased fire prevention measures, including but not limited to prohibiting smoking or use of a fireplace. However, each veteran resident who is temporarily unable to participate in a drill will be permitted to be excused from up to two drills within one 12-month period, provided that the two excused drills are not consecutive, and this will not be a cause for VA to not approve the home.

(5) For purposes of paragraph (p), the term *all occupants* means every person in the home at the time of the emergency egress and relocation drill, including non-residents.

(q) *Records of compliance with this section.* The medical foster home must comply with § 17.63(i) regarding facility records, and must document all inspection, testing, drills and maintenance activities required by this section. Such documentation must be maintained for 3 years or for the period specified by the applicable NFPA standard, whichever is longer. Documentation of emergency egress and relocation drills must include the date, time of day, length of time to evacuate the home, the name of each medical foster home caregiver who participated, the name of each resident, whether the resident participated, and whether the resident required assistance.

(r) *Local permits and emergency response.* Where applicable, a permit or license must be obtained for occupancy or business by the medical foster home caregiver from the local building or business authority. When there is a home occupant who is incapable of self-preservation, the local fire department or response agency must be notified by the medical foster home within 7 days of the beginning of the occupant's residency.

(s) *Equivalencies.* Any equivalencies to VA requirements must be in

accordance with section 1.4.3 of NFPA 101 (incorporated by reference, see § 17.1), and must be approved in writing by the appropriate Veterans Health Administration, Veterans Integrated Service Network (VISN) Director. A veteran living in a medical foster home when the equivalency is granted or who is placed there after it is granted must be notified in writing of the equivalencies and that he or she must be willing to accept such equivalencies. The notice must describe the exact nature of the equivalency, the requirements of this section with which the medical foster home is unable to comply, and explain why the VISN Director deemed the equivalency necessary. Only equivalencies that the VISN Director determines do not pose a risk to the health or safety of the veteran may be granted. Also, equivalencies may only be granted when technical requirements of this section cannot be complied with absent undue expense, there is no other nearby home which can serve as an adequate alternative, and the equivalency is in the best interest of the veteran.

(t) *Cost of medical foster homes.* (1) Payment for the charges to veterans for the cost of medical foster home care is not the responsibility of the United States Government.

(2) The resident or an authorized personal representative and a representative of the medical foster home facility must agree upon the charge and payment procedures for medical foster home care.

(3) The charges for medical foster home care must be comparable to prices charged by other assisted living and nursing home facilities in the area based on the veteran's changing care needs and local availability of medical foster homes. (The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0777.)

(Authority: 38 U.S.C. 501, 1730)

[FR Doc. 2012–2063 Filed 2–1–12; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0913; FRL–9625–5]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Regional Haze State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving the District of Columbia Regional Haze Plan, a revision to the District of Columbia State Implementation Plan (SIP) addressing Clean Air Act (CAA) requirements and EPA's rules for states to prevent and remedy future and existing anthropogenic impairment of visibility in mandatory Class I areas through a regional haze program. EPA is also approving this revision since it meets the infrastructure requirements relating to visibility protection for the 1997 8-hour ozone National Ambient Air Quality Standard (NAAQS) and the 1997 and 2006 fine particulate matter ($PM_{2.5}$) NAAQS.

DATES: *Effective Date:* This final rule is effective on March 5, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2011–0913. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (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 electronically through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the District Department of the Environment, 1200 First Street NE., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Jacqueline Lewis, (215) 814–2037, or by email at *lewis.jacqueline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Throughout this document, whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. On November 16, 2011 (76 FR 70929), EPA published a notice of proposed rulemaking (NPR) for the District of Columbia. The NPR proposed approval of the District of Columbia's regional haze plan for the first implementation period, through 2018. EPA proposed to approve this revision since it assures reasonable progress toward the national goal of achieving natural visibility conditions in Class I areas for the first implementation period. This revision also meets the infrastructure requirements of 110(a)(2)(D)(i)(II) and 110 (a)(2)(J), relating to visibility protection for the 1997 8-hour ozone NAAQS and the 1997 and 2006 $PM_{2.5}$ NAAQS.

II. Summary of SIP Revision

The revision includes a long term strategy with enforceable measures ensuring reasonable progress towards meeting the reasonable progress goals for the first planning period, through 2018. The District of Columbia's Regional Haze Plan contains the emission reductions needed to achieve the District of Columbia's share of emission reductions agreed upon through the regional planning process. Other specific requirements of the CAA and EPA's Regional Haze Rule and the rationale for EPA's proposed action are explained in the NPR and will not be restated here. No public comments were received on the NPR.

III. Final Action

EPA is approving a revision to the District of Columbia State Implementation Plan submitted by the District of Columbia, through the District Department of the Environment (DDOE), on October 27, 2011, that addresses regional haze for the first implementation period. EPA is making a determination that the District of Columbia Regional Haze SIP contains the emission reductions needed to achieve the District of Columbia's share of emission reductions agreed upon through the regional planning process. Furthermore, the District of Columbia's Regional Haze Plan ensures that emissions from the District will not interfere with the reasonable progress goals for neighboring states' Class I areas. In addition, EPA is approving this revision because it meets the applicable visibility related requirements of the CAA section 110(a)(2) including, but not limited to 110(a)(2)(D)(i)(II) and 110(a)(2)(J), relating to visibility protection for the 1997 8-hour ozone NAAQS and the 1997 and 2006 $PM_{2.5}$ NAAQS.

IV. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting

Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the District, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by April 2, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action pertaining to the District of Columbia's Regional Haze Plan for the first implementation period, through 2018 may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: January 24, 2012.

W. C. Early,

Acting, Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart J—District of Columbia

■ 2. In § 52.470, the table in paragraph (e) is amended by adding the entry for Regional Haze Plan at the end of the table to read as follows:

§ 52.470 Identification of plan.

* * * * *

(e) * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional explanation
*	*	*	*	*
Regional Haze Plan	Statewide	10/27/11	2/2/12 [*Insert page number where the document begins*]	

[FR Doc. 2012–2197 Filed 2–1–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Parts 251, 252, 276, 280, 281, 282, and 283

[Docket No. MARAD 2012–0004]

RIN 2133–AB80

Retrospective Review Under E.O. 13563: Shipping—Removal of Obsolete Regulations

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Final rule.

SUMMARY: In accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' the Maritime Administration (MarAd) is evaluating the continued validity of its rules and determining whether they effectively address current issues. As part of this review, MarAd has decided to remove parts of its regulations. The Maritime Security Act of 1996, established the Maritime Security Program, which replaced the Operating-Differential Subsidy (ODS) Program. Therefore, the regulations pertaining to the ODS Program and the Construction-Differential (CDS) Program are no longer in use. In addition, the disuse of regulations pertaining to the CDS program, have rendered these regulations obsolete. This rulemaking, deleting these obsolete regulations, will have no substantive effect on the regulated public.

DATES: This final rule is effective on February 2, 2012.

ADDRESSES: This final rule is available for inspection and copying between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays, at the Docket Clerk, U.S. DOT Dockets, W12–140, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. An electronic version of this document is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: T. Mitchell Hudson, Jr., Division of Legislation and Regulations, Office of Chief Counsel, Maritime Administration, 1200 New Jersey Avenue SE., Room W24–220, Washington, DC 20590–0001; telephone: (202) 366–9373.

SUPPLEMENTARY INFORMATION:

Background

On January 18, 2011, President Obama issued Executive Order 13563, which outlined a plan to improve regulation and regulatory review (76 FR 3821, 1/21/11). Executive Order 13563 reaffirms and builds upon governing principles of contemporary regulatory review, including Executive Order 12866, ''Regulatory Planning and Review,'' (58 FR 51735, 10/4/1993), by requiring Federal agencies to design cost-effective, evidence-based regulations that are compatible with economic growth, job creation, and competitiveness. The President's plan recognizes that these principles should not only guide the Federal government's approach to new regulations, but to existing ones as well. To that end, Executive Order 13563 requires agencies to review existing significant rules to determine if they are outmoded, ineffective, insufficient, or excessively burdensome.

Accordingly, the Maritime Administration (MarAd) is deleting regulations 46 CFR parts 251, 252, 276, 280, 281,282, and 283. The regulations related to the ODS Program are no longer needed because they have been superseded by the Maritime Security Program established in the Maritime Security Act of 1996, Public Law 104–239. Section 3 of the Maritime Security Act of 1996 prohibits the Secretary of Transportation from entering into any new ODS contracts. Additionally, all previously awarded ODS contracts have expired and no further payments will be made. Therefore, the existing regulations do not serve any useful purpose.

The regulations governing the CDS Program are being deleted because the program has not been funded for approximately thirty years and, as a practical matter of disuse, the existing regulations are outdated. If funds were to be appropriated for CDS in the future, contracts will be awarded under new regulations or under existing or modified policies and procedures for awarding grants.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review) and Department of Transportation (DOT) Regulatory Policies and Procedures; Public Law 104–121

Under Executive Order 12866 (58 FR 51735, October 4, 1993), supplemented by E.O. 13563 (76 FR 3821, January 18, 2011) and DOT policies and procedures, MarAd must determine whether a regulatory action is ''significant,'' and therefore subject to OMB review and the requirements of the E.O. The Order defines ''significant regulatory action'' as one likely to result in a rule that may:

(1) 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 government or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

MarAd has determined that this final rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. This final rule will not result in an annual effect on the economy of $100 million or more. It also is not considered a major rule for purposes of Congressional review under Public Law 104–121. This final rule is also not significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034, February 26, 1979). The costs and overall economic impact of this rulemaking are so minimal that no further analysis is necessary.

Administrative Procedure Act

The Administrative Procedure Act (5 U.S.C. 553) provides an exception to notice and comment procedures when they are unnecessary or contrary to the public interest. MarAd finds that under 5 U.S.C. 553(b)(3)(B) good cause exists for not providing notice and comment since this final rule deletes regulations that no longer serve the public interest as a result of having been superseded or as a matter of disuse. Under 5 U.S.C. 553(d)(3), MarAd finds that, for the same reasons, good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Executive Order 13132 (Federalism)

We analyzed this rulemaking in accordance with the principles and criteria contained in E.O. 13132 (''Federalism'') and have determined that it does not have sufficient Federalism implications to warrant the preparation of a Federalism summary

impact statement. This rule has no substantial effect on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. Nothing in this document preempts any State law or regulation. Therefore, MarAd did not consult with State and local officials because it was not necessary.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

MarAd does not believe that this final rule will significantly or uniquely affect the communities of Indian tribal governments when analyzed under the principles and criteria contained in Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments). Therefore, the funding and consultation requirements of this Executive Order do not apply.

E.O. 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires MarAd to assess whether this rule would have a significant economic impact on a substantial number of small entities and to minimize any adverse impact. The Maritime Administrator certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule only deletes obsolete Parts in title 46 of the CFR, which have no substantive effect on the regulated public.

Environmental Assessment

We have analyzed this final rule for purposes of compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and have concluded that under the categorical exclusions provision in section 4.05 of Maritime Administrative Order (MAO) 600–1, ''Procedures for Considering Environmental Impacts,'' 50 FR 11606 (March 22, 1985), neither the preparation of an Environmental Assessment, an Environmental Impact Statement, nor a Finding of No Significant Impact for this rulemaking is required. This rulemaking has no environmental impact.

Executive Order 13211 (Energy Supply, Distribution, or Use)

MarAd has determined that the proposed rule would not significantly affect energy supply, distribution, or use. Therefore, no Statement of Energy Effects is required.

Executive Order 12630 (Taking of Private Property)

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

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. This rulemaking contains no new or amended information collection or recordkeeping requirements that have been approved or require approval by the Office of Management and Budget.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 requires Agencies to evaluate whether an Agency action would result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $141.3 million or more (as adjusted for inflation) in any 1 year, and if so, to take steps to minimize these unfunded mandates. This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $141.3 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objectives of the rule.

Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

46 CFR Part 251

Application for Subsidies and Other Direct Financial Aid.

46 CFR Part 252

Operating-Differential Subsidy for Bulk Cargo Vessels Engaged in World-Wide Services.

46 CFR Part 276

Construction-Differential Subsidy Repayment

46 CFR Part 280

Limitations on the Award and Payment of Operating-Differential Subsidy for Liner Operators.

46 CFR Part 281

Information and Procedure Required under Liner Operating-Differential Subsidy Agreements.

46 CFR Part 282

Operating-Differential Subsidy for Liner Vessels Engaged in Essential Services in the Foreign Commerce of the United States.

46 CFR Part 283

Dividend Policy for Operators Receiving Operating-Differential Subsidy.

For the reasons set forth in the preamble, and under the authority of the Merchant Marine Act of 1936, codified at 46 U.S.C. chapter 501, MarAd amends 46 CFR chapter II, subchapter C by removing parts 251, 252, 276, 280, 281, 282, and 283. All contracts for Operating-Differential Subsidy, not previously closed out, are hereby terminated, and no further payments shall be owning or payable. Parts 251, 252, 276, 280, 281 and 283, of title 46, CFR, are removed and reserved for future use by MarAd.

PART 251—[REMOVED]

PART 252—[REMOVED]

PART 276—[REMOVED]

PART 280—[REMOVED]

PART 281—[REMOVED]

PART 282—[REMOVED]

PART 283—[REMOVED]

Dated: January 27, 2012.

By Order of the Maritime Administrator and Maritime Subsidy Board.

Julie Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–2256 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–81–P

Proposed Rules

Federal Register
Vol. 77, No. 22
Thursday, February 2, 2012

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.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0607; Directorate Identifier 2009–NM–024–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (NPRM); reopening of comment period.

SUMMARY: We are revising an earlier proposed airworthiness directive (AD) for all Model 747–100B SUD, 747–300, 747–400, and 747–400D series airplanes; and Model 747–200B series airplanes having a stretched upper deck. The original NPRM would have superseded an existing AD that currently requires repetitively inspecting for cracking or discrepancies of the fasteners in the tension ties, shear webs, and frames at body stations 1120 through 1220; and related investigative and corrective actions if necessary. The original NPRM proposed to require modifying the frame-to-tension-tie joints at body stations 1120 through 1220 (including related investigative actions and corrective actions if necessary), which would provide a terminating action for the repetitive inspections. The original NPRM also proposed to require new repetitive inspections after the modification, corrective actions if necessary, and additional modification requirements at a specified time after the first modification. The original NPRM also proposed to remove certain airplanes from the applicability. The original NPRM was prompted by reports of cracked and severed tension ties, broken fasteners, and cracks in the frame, shear web, and shear ties adjacent to tension ties for the upper deck. This action revises the original NPRM by adding repetitive open hole high frequency eddy current (HFEC) inspections for cracking in the forward and aft tension tie channels, and repair if necessary. For certain airplanes, this supplemental NPRM also requires a one-time angle inspection to determine if the angle is installed correctly, and re-installation if necessary; and a one-time open hole HFEC inspection at the fastener locations where the tension tie previously attached to the frame prior to certain modifications, and repair if necessary. This supplemental NPRM also, for the Stage 2 inspections, reduces the initial compliance times for those inspections. We are proposing this supplemental NPRM to detect and correct cracking of the tension ties, shear webs, and frames of the upper deck, which could result in rapid decompression and reduced structural integrity of the airplane.

DATES: We must receive comments on this supplemental NPRM by March 19, 2012.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* 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:* 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.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone (206) 544–5000, extension 1; fax (206) 766–5680; email *me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call (425) 227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 917–6428; fax (425) 917–6590; email: *nathan.p.weigand@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2009–0607; Directorate Identifier 2009–NM–024–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We issued an NPRM to amend 14 CFR part 39 to include an AD (the ''original NPRM'') to supersede AD 2007–23–18, amendment 39–15266 (72 FR 65655, November 23, 2007). The original NPRM applied to all Boeing Model 747–100B SUD, 747–300, 747–400, and 747–400D series airplanes; and Model 747–200B series airplanes having a stretched upper deck. The original NPRM was published in the **Federal Register** on July 13, 2009 (74 FR 33377). The

original NPRM proposed to supersede an existing AD that currently requires repetitively inspecting for cracking or discrepancies of the fasteners in the tension ties, shear webs, and frames at body stations 1120 through 1220; and related investigative and corrective actions if necessary. The original NPRM proposed to require modifying the frame-to-tension-tie joints at body stations (STA) 1120 through 1220 (including related investigative actions and corrective actions if necessary), which would provide a terminating action for the repetitive inspections. The original NPRM also proposed to require new repetitive inspections after the modification, corrective actions if necessary, and additional modification requirements at a specified time after the first modification. The original NPRM also proposed to remove certain airplanes from the applicability.

Actions Since Previous NPRM was Issued

Since we issued the original NPRM (74 FR 33377, July 13, 2009), we have received reports from one operator that three adjacent tension ties were found severed on a Model 747–300 series airplane with approximately 18,400 flight cycles. Another operator reported that two adjacent tension ties were found cracked or severed on a 747–300 series airplane with approximately 14,000 flight cycles. In addition, operators have reported finding cracks in the tension ties and frames during the inspection required by the existing AD and done in accordance with Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005. We have received revised service information, as described below, and included it in the supplemental NPRM as the appropriate source of service information for accomplishing certain actions.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010. Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005, was referred to as the appropriate source of service information for accomplishing certain actions specified in the original NPRM (74 FR 33377, July 13, 2009). Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, adds procedures for the following inspections:

- For all airplanes: Repetitive open hole HFEC inspections for cracking in the forward and aft tension tie channels at 12 fastener locations inboard of the aluminum straps at STA 1140, and repair if necessary by doing an oversize hole repair or repairing the tension tie.
- For certain airplanes: A one-time detailed inspection to determine if the angle is installed correctly, and re-install if necessary.
- A one-time open-hole HFEC inspection for cracks at the fastener locations (STA 1120, 1160, 1200, and 1220) where the tension tie previously attached to the frame, before modification to the Boeing special freighter or Boeing converted freighter configuration, and repair if necessary by doing an oversize hole repair or repairing the frame.

The initial compliance times specified in Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, for the new inspections at STA 1140 is before the accumulation of 10,000 total flight cycles or within 3,000 flight cycles after the issue date of Revision 1 of the service bulletin, whichever is later; with a repetitive interval not to exceed 3,000 flight cycles.

The compliance time for the new one-time inspection for mislocated angles is within 3,000 flight cycles after the issue date of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010.

The compliance time for the new one-time inspection for tie frames at previous tension tie locations is within 3,000 flight cycles after the issue date of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010.

We have also reviewed Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011. Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, was referred to as the appropriate source of service information for accomplishing the actions in the original NPRM (74 FR 33377, July 13, 2009). No more work is necessary for airplanes on which Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, was used to accomplish the actions. Certain procedures specified in Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011, have been clarified to provide additional instructions. We have revised paragraph (k) of this AD to refer to Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011, and added a new paragraph to give credit for actions done before the effective date of the AD in accordance with Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009.

Comments

We have considered the following comments on the original NPRM (74 FR 33377, July 13, 2009).

Support for Proposed Actions

United Parcel Service Co. (UPS) supports mandating the Stage 2 inspections specified in the original NPRM (74 FR 33377, July 13, 2009).

Requests To Extend the Modification Compliance Time

Lufthansa and KLM requested that we revise the original NPRM (74 FR 33377, July 13, 2009) to extend the compliance time for the proposed modification.

Lufthansa requested a detailed explanation about the decision making that resulted in the compliance threshold of 17,000 flight cycles (damage tolerance analysis, calculations, findings) for the proposed modification, which seems inconsistent in light of the Stage 2 inspection threshold of 16,000 flight cycles. Lufthansa requested that the FAA revise the compliance threshold for the proposed modification to 20,000 total flight cycles.

KLM also stated that AD 2007–23–18, Amendment 39–15266 (72 FR 65655, November 23, 2007), mandates Stage 2 inspections at 16,000 total flight cycles, while the original NPRM (74 FR 33377, July 13, 2009) mandates the modification at 17,000 total flight cycles, and it does not change the Stage 2 total flight cycles. KLM stated it believes many other operators (in addition to KLM) have started the AD 2007–23–18 Stage 2 inspections before the 16,000 total flight cycles. KLM stated that even though defects were found with the Stage 2 inspections, most of the defects have not propagated to such an extent where they would have been found with Stage 1 inspections. Furthermore, KLM stated that the repair methods/procedures used to repair defects found during the Stage 2 inspections have the same intent (partial frame/tension tie replacement) as the modification, and that the only difference is that the design of the modification is more durable, given the fact that it has an 8,000 total flight cycle threshold.

KLM stated that the Stage 2 inspection in AD 2007–23–18 amendment 39–15266 (72 FR 65655, November 23, 2007) provides an acceptable level of safety to at least 20,000 flight cycles, and therefore proposes that the modification be an optional terminating action for the Stage 1 and Stage 2 inspection in AD 2007–23–18. KLM stated that if the FAA still

wants to mandate the modification, it would like the FAA to consider re-evaluating the modification threshold to a more realistic threshold given the fact that the Stage 2 inspection threshold is 16,000 flight cycles.

We agree with Lufthansa and KLM that it seems inconsistent to have a modification threshold of 17,000 total flight cycles, which is just 1,000 cycles more than the inspection threshold. However, after issuance of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005, the manufacturer completed additional analysis and determined the new inspection threshold should be lowered to 10,000 total flight cycles. The new inspection threshold can be found in Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010. We have determined this reduced compliance time is necessary to address the identified unsafe condition and added it to paragraph (i)(2) of this AD.

Since the issuance of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005, further cracking in the fleet has occurred resulting in thresholds being further reduced in Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010. The modification threshold and new inspection threshold are appropriate given the quantity and nature of cracks found on Model 747 airplanes, which are based on extensive analysis. Due in part to the reporting requirement of AD 2007–23–18, Amendment 39–15266 (72 FR 65655, November 23, 2007), the manufacturer received a significant number of inspection findings. The findings include numerous cases of single or dual tension tie failure and one airplane with three adjacent severed tension ties. Because the findings constituted multiple site damage, a damage tolerance analysis alone was no longer appropriate. Rather, a widespread fatigue damage analysis had to be employed to properly analyze the risk of cracked and severed tension ties, and to set inspection and modification thresholds appropriately. The manufacturer performed widespread fatigue analysis and the FAA accepted its findings.

The analysis, combined with the empirical data, supported an inspection threshold of 10,000 total flight cycles, as reflected in Revision 1 of the Stage 2 inspection, and a modification threshold of 17,000 total flight cycles. Therefore, based upon crack reports received, material analysis completed, and widespread fatigue damage analysis performed, the inspection and modification thresholds contained in this supplemental NPRM are appropriate.

Request for an Optional Modification

UPS agreed that the modification will strengthen the area and protect against widespread fatigue damage. UPS stated that the current Stage 2 inspections and repetitive timeline are effectively locating and repairing the discrepant areas prior to any damages reaching a critical length. Therefore, UPS proposed the modification specified in paragraph (m) of the original NPRM (74 FR 33377, July 13, 2009) not be mandated. UPS instead recommended that paragraph (m) be offered as an alternative to the existing Stage 2 inspections assigned per paragraph (j). UPS stated it supports the modification of the frames and tension ties for the upper deck as proposed in the original NPRM, but suggested that the current Stage 2 inspections be allowed to continue as an alternative to performing the modification.

Airlines for America (A4A), formerly known as the Air Transport Association of America (ATA), on behalf of its member United Airlines (UAL), and Japan Airlines (JAL) both stated that the modification is expensive. JAL noted the expense is due to kit cost, labor cost and the lack of warranty coverage. We infer the commenters are requesting that the modification be made optional due to its cost. UAL also noted that even after accomplishing the modification, the original NPRM (74 FR 33377, July 13, 2009) would still require post modification inspections.

We disagree with the requests to make the required modification optional. As we stated previously, the crack finding data and analysis performed support the inspection and modification thresholds in this supplemental NPRM. We have not changed the supplemental NPRM in this regard.

Request for Alternative Terminating Modification

Lufthansa requested we allow alternative terminating modifications. Lufthansa stated that it is seeking alternative solutions and intervals for relief in view of the huge design deficiency driven modification work necessary for its Model 747 airplanes. Lufthansa asked that an alternative modification be allowed using new parts with existing part numbers, instead of mandating a modification using new parts and new part numbers. KLM noted that no alternative to the proposed modification has been considered.

We disagree with the request for an alternative modification of the frame-to-tension-tie joints proposed in this supplemental NPRM. An alternative method of compliance approving a modification using new parts with existing part numbers does not remove all of the unsafe condition. The modification in this supplemental NPRM includes reinforcing the fuselage frames; therefore ''* * * using new parts with existing part numbers instead of mandating a modification using new parts and new part numbers'' does not reinforce the fuselage tension ties or frames, and would not address the identified unsafe condition. We are mandating the overall reinforcement modification to achieve a long-term acceptable level of safety. We have not changed the supplemental NPRM in this regard.

Request To Correct Errors in Service Information

All Nippon Airways (ANA) and JAL noted that Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, contains typographical errors. JAL asks that these errors be corrected before an AD is issued. ANA stated that Boeing issued Service Bulletin Information Notice 747–53A2559 IN 01, to correct the typographical errors in Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009. ANA asks that Boeing Service Bulletin Information Notice 747–53A2559 IN 01 be included in this supplemental NPRM.

Paragraph (m) of the original NPRM (74 FR 33377, July 13, 2009) refers to Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, as the appropriate source of service information for the proposed requirements. Boeing corrected the errors in Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, by issuing Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011. We have replaced all references to Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, with Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011, in this supplemental NPRM.

JAL stated that there are also errors in the effectivity section of Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, and added that Model 747–400 Boeing Converted Freighter (BCF) airplanes are not identified correctly. Boeing added that the effectivity should exclude airplane RT743, which was converted to a Large Cargo Freighter (LCF) airplane on which the subject tension ties were removed. Boeing stated that the airplane is therefore not subject to the unsafe condition. Boeing also noted that there are currently no plans to revise this

service bulletin to remove that airplane from the effectivity.

We do not agree to reidentify Model 747–400 BCF airplanes in the applicability of this supplemental NPRM. BCF airplanes continue to be modified and as such, the applicability in this supplemental NPRM follows the group categorization of airplanes using the Group/Configuration/Description table in paragraph 1.A., ''Effectivity'' of Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009. We have not changed the supplemental NPRM in this regard.

We agree to exclude airplanes that have been converted to a Model 747–400 LCF configuration from the applicability of this supplemental NPRM. That airplane configuration no longer has the subject tension ties to inspect or modify, so is not subject to the unsafe condition. We have changed paragraph (c) of this supplemental NPRM to exclude those airplanes.

Request To Clarify Additional Modification

ANA stated that paragraph (m) of the original NPRM (74 FR 33377, July 13, 2009), proposed to require modification and post-modification inspections in accordance with Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009. ANA noted that the additional modification as specified in this service bulletin is an open-hole HFEC inspection, not a modification. ANA asked that we revise paragraph (m)(2) of the NPRM to clarify the term ''additional modification'' as an open-hole inspection.

We disagree that the additional modification is an open-hole HFEC inspection. Paragraph (m)(2) of the supplemental NPRM (also paragraph (m)(2) of the original NPRM (74 FR 33377, July 13, 2009)) requires doing an additional modification using a method approved in accordance with the procedures in the alternative methods of compliance (AMOC) paragraph. At this time, we have not approved a method that meets the conditions for the additional modification. However, under the provisions of paragraph (s)(1) of this AD, we will consider requests for accomplishing a modification if data are submitted to substantiate that it would provide an acceptable level of safety.

Request To Change Cost Information

ANA stated that its work hour estimate, based on the time it took to do a modification identical to that in Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, exceeded 2,000 work hours. ANA added that the estimated costs in the original NPRM (74 FR 33377, July 13, 2009) are based on the work hours addressed in this service bulletin. ANA asked that the actual work hours be considered to estimate the costs.

We disagree with the request. The cost information in this supplemental NPRM describes only the direct costs of the specific required actions. Based on the best data available, the manufacturer provided the number of work hours necessary to do the required actions. This number represents the time necessary to perform only the actions actually required by this supplemental NPRM. We recognize that, in doing the actions required by an AD, operators might incur incidental costs in addition to the direct costs. But the cost analysis in AD rulemaking actions typically does not include incidental costs such as the time necessary for planning, airplane down time, or time necessitated by other administrative actions. Those incidental costs, which might vary significantly among operators, are almost impossible to calculate. We have not changed the supplemental NPRM regarding this issue.

FAA's Determination

We are proposing this supplemental NPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs. Certain changes described above expand the scope of the original NPRM. As a result, we have determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this supplemental NPRM.

Proposed Requirements of the Supplemental NPRM

This supplemental NPRM would require accomplishing the actions specified in the service information described previously.

Costs of Compliance

There are about 561 airplanes of the affected design in the worldwide fleet, which includes 67 U.S.-registered airplanes. The following table provides the estimated costs for U.S. operators to comply with this proposed AD. The average labor rate is $85 per work hour.

ESTIMATED COSTS

Action	Work hours	Parts	Cost per airplane	Fleet cost
Stage 1 inspections (required by AD 2007–23–18, Amendment 39–15266 (72 FR 65655, November 23, 2007)).	19	$0	$1,615 per inspection cycle.	$108,205 per inspection cycle.
Stage 2 inspections (required by AD 2007–23–18, Amendment 39–15266 (72 FR 65655, November 23, 2007)).	83	$0	$7,055	$472,685 per inspection cycle.
Modification (new proposed action)	257 to 263	$341,334 to $345,490.	$363,179 to $367,845	$24,332,993 to $24,645,615.[1]
Post-modification inspections (new proposed action)	6	$0	$510 per inspection cycle	$34,170 per inspection cycle.

[1] Depending on airplane configuration.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. 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.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on

products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing amendment 39–15266 (72 FR 65655, November 23, 2007) and adding the following new AD:

The Boeing Company: Docket No. FAA–2009–0607; Directorate Identifier 2009–NM–024–AD.

(a) Comments Due Date

We must receive comments by March 19, 2012.

(b) Affected ADs

This AD supersedes AD 2007–23–18, Amendment 39–15266 (72 FR 65655, November 23, 2007).

(c) Applicability

This AD applies to all The Boeing Company Model 747–100B SUD, 747–300, 747–400, and 747–400D series airplanes; and Model 747–200B series airplanes having a stretched upper deck; certificated in any category; excluding airplanes that have been converted to a large cargo freighter configuration.

(d) Subject

Air Transport Association (ATA) of America Code 53: Fuselage.

(e) Unsafe Condition

This AD results from reports of cracked and severed tension ties, broken fasteners, and cracks in the frame, shear web, and shear ties adjacent to tension ties for the upper deck. We are issuing this AD to detect and correct cracking of the tension ties, shear webs, and frames of the upper deck, which could result in rapid decompression and reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Restatement of Requirements of AD 2007–23–18, Amendment 39–15266 (72 FR 65655, November 23, 2007), With Revised Compliance Times and New Service Information: Repetitive Stage 1 Inspections With Reduced Repetitive Interval

For all airplanes: Do detailed inspections for cracking or discrepancies of the fasteners in the tension ties, shear webs, and frames at body stations 1120 through 1220, and related investigative and corrective actions as applicable, by doing all actions specified in and in accordance with ''Stage 1 Inspection'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005, except as provided by paragraph (k) of this AD; or Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010. As of the effective date of this AD only Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, may be used. Do the Stage 1 inspections at the applicable times specified in paragraphs (h) and (i) of this AD, except as provided by paragraphs (g)(1) and (g)(2) of this AD. Accomplishment of the initial Stage 2 inspection required by paragraph (j) of this AD terminates the requirements of this paragraph. Any applicable related investigative and corrective actions must be done before further flight. Doing the modification required by paragraph (l) of this AD terminates the repetitive inspection requirements of this paragraph.

(1) Where paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005, specifies a compliance time relative to ''the original issue date on this service bulletin,'' this AD requires compliance before the specified compliance time after April 26, 2006 (the effective date of AD 2006–06–11).

(2) For any airplane that reaches the applicable compliance time for the initial Stage 2 inspection (as specified in Table 1, Compliance Recommendations, under paragraph 1.E. of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005) before reaching the applicable compliance time for the initial Stage 1 inspection: Accomplishment of the initial Stage 2 inspection eliminates the need to do the Stage 1 inspections.

(h) Compliance Time for Initial Stage 1 Inspection

Do the initial Stage 1 inspection at the earlier of the times specified in paragraphs (h)(1) and (h)(2) of this AD.

(1) At the earlier of the times specified in paragraphs (h)(1)(i) and (h)(1)(ii) of this AD.

(i) At the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005.

(ii) Before the accumulation of 10,000 total flight cycles, or within 250 flight cycles after November 28, 2007 (the effective date of AD 2007–23–18, amendment 39–15266 (72 FR 65655, November 23, 2007)), whichever occurs later.

(2) At the later of the times specified in paragraphs (h)(2)(i) and (h)(2)(ii) of this AD.

(i) Before the accumulation of 12,000 total flight cycles.

(ii) Within 50 flight cycles or 20 days, whichever occurs first, after November 28, 2007.

(i) Compliance Times for Repetitive Stage 1 Inspections

Repeat the Stage 1 inspection specified in paragraph (g) of this AD at the time specified in paragraph (i)(1) or (i)(2) of this AD, as applicable. Repeat the inspection thereafter at intervals not to exceed 250 flight cycles, until the initial Stage 2 inspection required by paragraph (j) of this AD has been done.

(1) For airplanes on which the initial Stage 1 inspection has not been accomplished as of November 28, 2007: Do the next inspection before the accumulation of 10,000 total flight cycles, or within 250 flight cycles after the initial Stage 1 inspection done in accordance with paragraph (j) of this AD, whichever occurs later.

(2) For airplanes on which the initial Stage 1 inspection has been accomplished as of November 28, 2007: Do the next inspection at the applicable time specified in paragraph (i)(2)(i) or (i)(2)(ii) of this AD.

(i) For airplanes that have accumulated fewer than 12,000 total flight cycles as of November 28, 2007: Do the next inspection before the accumulation of 10,000 total flight cycles, or within 250 flight cycles after November 28, 2007, whichever occurs later.

(ii) For airplanes that have accumulated 12,000 total flight cycles or more as of November 28, 2007: Do the next inspection at the later of the times specified in paragraphs (i)(2)(ii)(A) and (i)(2)(ii)(B) of this AD.

(A) Within 250 flight cycles after accomplishment of the initial Stage 1 inspection.

(B) Within 50 flight cycles or 20 days, whichever occurs first, after November 28, 2007.

(j) Repetitive Stage 2 Inspections With Reduced Initial Compliance Time

For all airplanes: Do detailed and high frequency eddy current inspections for cracking or discrepancies of the fasteners in the tension ties, shear webs, and frames at body stations 1120 through 1220, and related investigative and corrective actions as

applicable, by doing all actions specified in and in accordance with ''Stage 2 Inspection'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005; or Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010; except as provided by paragraph (j) of this AD. Do the initial inspections at the earlier of the times specified in paragraphs (j)(1) and (j)(2) of this AD. Repeat the Stage 2 inspection thereafter at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005. As of the effective date of this AD only Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, may be used. Any applicable related investigative and corrective actions must be done before further flight. Accomplishment of the initial Stage 2 inspection ends the repetitive Stage 1 inspections. Doing the modification required by paragraph (m) of this AD terminates the repetitive inspection requirements of this paragraph.

(1) Before the accumulation of 16,000 total flight cycles, or within 1,000 flight cycles after November 28, 2007; whichever occurs later.

(2) Before the accumulation of 10,000 total flight cycles, or within 1,000 flight cycles after the effective date of this AD.

(k) Exception to Corrective Action Instructions

If any discrepancy including but not limited to any crack, broken fastener, loose fastener, or missing fastener is found during any inspection required by paragraph (g), (h) or (i) of this AD, and Boeing Alert Service Bulletin 747–53A2507, dated April 21, 2005; or Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010; specifies to contact Boeing for appropriate action: Before further flight, repair the discrepancy using a method approved in accordance with the procedures specified in paragraph (s) of this AD.

(l) Reporting Requirement

At the applicable time specified in paragraph (l)(1) or (l)(2) of this AD, submit a report of the findings (both positive and negative) of each Stage 1 inspection required by paragraph (g) of this AD to Boeing Commercial Airplanes; Attention: Manager, Airline Support; P.O. Box 3707 MC 04–ER; Seattle, Washington 98124–2207; fax (425) 266–5562. The report must include the inspection results, a description of any discrepancies found, the inspections performed, the airplane serial number, and the number of total accumulated flight cycles on the airplane. Under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120–0056.

(1) For any inspection done after November 28, 2007: Submit the report within 30 days after the inspection.

(2) For any inspection done before November 28, 2007: Submit the report within 30 days after November 28, 2007.

(m) New Requirements of This AD: Modification

Except as provided by paragraphs (m)(1) and (m)(2) of this AD: At the times specified in paragraph 1.E, ''Compliance,'' of Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011, modify the frame-to-tension-tie joints at body stations (STA) 1120 through 1220; do all related investigative and applicable corrective actions; do the repetitive post-modification detailed inspections for cracking of the tension tie and frame structure and all applicable corrective actions; and do the additional modification. Do all actions in accordance with the Accomplishment Instructions of Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011. Modifying the frame-to-tension-tie joints at body stations 1120 through 1220 terminates the repetitive inspection requirements of paragraphs (g) and (j) of this AD.

(1) Where paragraph 1.E., ''Compliance,'' of Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011, specifies a compliance time relative to ''the original issue date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Where Boeing Service Bulletin 747–53A2559, Revision 1, dated August 4, 2011, specifies to contact Boeing for repair instructions or additional modification requirements: Before further flight, repair the cracking or do the modification using a method approved in accordance with the procedures specified in paragraph (s) of this AD.

(n) Credit for Actions Accomplished in Accordance With Previous Service Information

Actions done before the effective date of this AD in accordance with Boeing Alert Service Bulletin 747–53A2559, dated January 8, 2009, are acceptable for compliance with the corresponding actions required by this AD.

(o) Stage 2 Inspection: Additional Work at STA 1140

For all airplanes: Except as provided by paragraph (r) of this AD; at the time specified in paragraph 1.E, ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010; do an open hole high frequency eddy current (HFEC) inspection for cracking in the forward and aft tension tie channels at 12 fastener locations inboard of the aluminum straps at STA 1140, and before further flight do all applicable repairs. Do all actions in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010. Repeat the inspections thereafter at the time specified in paragraph 1.E., ''Compliance.''

(p) One-Time Inspection for Mis-Located Angles

For Group 1, Configuration 1, airplanes as identified in Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010: Except as provided by paragraph (r) of this AD; at the time specified in paragraph 1.E, ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, do a detailed inspection to determine if the angle is installed correctly, and before further flight re-install all angles installed incorrectly. Do all actions in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010.

(q) One-Time Inspection for Cracks in Frames at Previous Tension Tie Locations

For Group 1, Configuration 2 airplanes; and Group 2 and 3 airplanes; as identified in Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010: Except as provided by paragraph (r) of this AD; at the time specified in paragraph 1.E, ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, do an open hole HFEC inspection for cracks at the fastener locations (STA 1120, 1160, 1200, and 1220) where the tension tie previously attached to the frame prior to modification to the Boeing special freighter or Boeing Converted Freighter configuration, and before further flight do all applicable repairs. Do all actions in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010.

(r) Exception to Boeing Alert Service Bulletin 747–53A2507, Revision 1, Dated January 14, 2010

Where paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 747–53A2507, Revision 1, dated January 14, 2010, specifies a compliance time relative to ''the Revision 1 date of this service bulletin,'' this AD requires compliance within the specified compliance time after the effective date of this AD.

(s) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov*.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization

Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously in accordance with AD 2007–23–18, amendment 39–15266 (72 FR 65655, November 23, 2007), are approved as AMOCs for the corresponding requirements of paragraphs (g), (h), and (i) of this AD.

(t) Related Information

(1) For more information about this AD, contact Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; phone: (425) 917–6428; fax: (425) 917–6590; email: *nathan.p.weigand@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone (206) 544–5000, extension 1; fax (206) 766–5680; email *me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call (425) 227–1221.

Issued in Renton, Washington, on January 12, 2012.

Michael J. Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–2301 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. FDA–2011–F–0853]

Ecolab, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ecolab, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium dodecylbenzenesulfonate as an antimicrobial agent in produce wash water without the requirement of a potable water rinse.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by March 5, 2012.

ADDRESSES: 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.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, (240) 402–1282.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2A4785) has been filed by Ecolab, Inc., 370 North Wabasha St., St. Paul, MN 55102–1390. The petition proposes to amend the food additive regulations in 21 CFR part 173, *Secondary Direct Food Additives Permitted in Food for Human Consumption,* to provide for the safe use of sodium dodecylbenzenesulfonate as an antimicrobial agent in produce wash water without the requirement of a potable water rinse.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of 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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the Agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: January 19, 2012.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2012–2279 Filed 2–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1062]

RIN 1625–AA09

Drawbridge Operation Regulation; Bear Creek, Dundalk, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of the Baltimore County highway bridge at Wise Avenue across Bear Creek, mile 3.4, between Dundalk and Sparrows Point, MD. The proposed change will alter the four hour advance notice requirement for a bridge opening to a 48-hour advance notice requirement for a bridge opening. Due to the lack of openings, it is not necessary to have personnel available on a four-hour notice. The operating regulation change will allow Baltimore County to more efficiently utilize the maintenance personnel who are responsible for the operation of the bridge.

DATES: Comments and related material must reach the Coast Guard on or before April 2, 2012.

ADDRESSES: You may submit comments identified by docket number USCG–2011–1062 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* (202) 493–2251.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section

below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Lindsey Middleton, Fifth Coast Guard District Bridge Administration Division, Coast Guard; telephone (757) 398–6629, email *Lindsey.R.Middleton@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–1062), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov,* it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rules'' and insert ''USCG–2011–1062'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2011–1062'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the four methods specified under **ADDRESSES**. Please explain why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Basis and Purpose

Baltimore County has requested a change to the operating regulation for the bascule Baltimore County highway bridge at Wise Avenue across Bear Creek, mile 3.4 between Dundalk and Sparrows Point, MD. This change would require the draw to open if at least 48 hours of notice is given.

Draw tender logs provided by the County show that this bridge has had fewer than 12 openings every year since 2008. The majority of these openings have been to test or maintain the bridge. When a request is made, the County contacts the ''on call'' maintenance contractor who relays the message to their electrical subcontractor. This subcontractor is the person that operates the bridge. The qualified subcontractors are normally at other work locations making it difficult, logistically, to arrive at the bridge site for an opening within the current four hour notice period. This change would allow the County to utilize its maintenance personnel more efficiently.

The current regulation, set out in 33 CFR 117.543(b), requires the bridge to open if at least four hours of notice is given. Section 117.543 was last amended on October 20, 2011, which was to remove a bridge operating regulation for a bridge that has been replaced with a fixed bridge.

Discussion of Proposed Rule

The Coast Guard proposes to amend 33 CFR 117.543(b) for the Baltimore County highway bridge, mile 3.4 at Wise Avenue between Dundalk and Sparrows Point, MD. This regulation would change to allow the bridge to open on signal if at least 48 hours notice is given. There is no alternate route. The majority of vessels that use this waterway are recreational boats that can travel through the bridge without requiring a bridge opening; the vertical clearance of the bridge in the closed position is 14 feet at mean high water. For those vessels, this regulation will not impact their waterway transit because they are able to transit through the bridge at any time. There are few larger vessels that may require a bridge opening. This regulation change should not have an adverse effect on their transit because the bridge is able to open if the mariner provides at least 48 hours of advance notice.

Regulatory Analyses

We developed this proposed 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 proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that Order. The proposed change is expected to have only a minimal impact on maritime traffic transiting the bridge. Most mariners utilizing this waterway

do not require a bridge opening. The few mariners that may need a bridge opening can plan their trips in accordance with the 48-hour scheduled advance notice requirement for a bridge opening to minimize delay.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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 proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels requiring a bridge opening.

This action will not have a significant economic impact on a substantial number of small entities because the rule adds minimal restrictions to the movement of navigation by requiring mariners to give at least 48 hours of notice when requesting a bridge opening. The majority of vessels utilizing this waterway is shorter than 14 feet and is able to safely transit under the bridge in the closed position at any time.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lindsey Middleton, Bridge Management Specialist, Fifth Coast Guard District, (757) 398–6629 or *Lindsey.R. Middleton@uscg.mil.* The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

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

Protection of Children

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

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed 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 proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for

drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. Revise § 117.543(b) to read as follows:

§ 117.543 Bear Creek

* * * * *

(b) The draw of the Baltimore County highway bridge, mile 3.4 at Wise Avenue between Dundalk and Sparrows Point, shall open on signal if at least 48 hours of notice is given.

Dated: January 19, 2012.

William D. Lee,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2012–2283 Filed 2–1–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

[Docket No. FWS–R7–SM–2011–0015; FXFR13350700640L6–123–FF07J00000]

RIN 1018–AX64

Subsistence Management Regulations for Public Lands in Alaska—2013–14 and 2014–15 Subsistence Taking of Fish and Shellfish Regulations

AGENCY: Forest Service, Agriculture; Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish regulations for fish and shellfish seasons, harvest limits, methods and means related to taking of fish and shellfish for subsistence uses during the 2013–2014 and 2014–2015 regulatory years. The Federal Subsistence Board (Board) is on a schedule of completing the process of revising subsistence taking of fish and shellfish regulations in odd-numbered years and subsistence taking of wildlife regulations in even-numbered years; public proposal and review processes take place during the preceding year. The Board also addresses customary and traditional use determinations during the applicable cycle. When final, the resulting rulemaking will replace the existing subsistence fish and shellfish taking regulations. This proposed rule would also amend the general regulations on subsistence taking of fish and wildlife.

DATES: *Public meetings:* The Subsistence Regional Advisory Councils (Councils) will hold public meetings to receive comments and make proposals to change this proposed rule on several dates between February 7 and March 23, 2012, and then hold another round of public meetings to discuss and receive comments on the proposals, and make recommendations on the proposals to the Board, on several dates between August 14 and October 17, 2012. The Board will discuss and evaluate proposed regulatory changes during a public meeting in Anchorage, AK, in January 2013. See **SUPPLEMENTARY INFORMATION** for specific information on dates and locations of the public meetings.

Public comments: Comments and proposals to change this proposed rule must be received or postmarked by March 30, 2012.

ADDRESSES: *Public meetings:* The Federal Subsistence Board and the Subsistence Regional Advisory Councils' public meetings will be held at various locations in Alaska. See **SUPPLEMENTARY INFORMATION** for specific information on dates and locations of the public meetings.

Public comments: You may submit comments by one of the following methods:

- *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov* and search for FWS–R7–SM–2011–0015, which is the docket number for this rulemaking.
- *By hard copy:* U.S. mail or hand-delivery to: USFWS, Office of Subsistence Management, 1011 East Tudor Road MS 121, Attn: Theo Matuskowitz, Anchorage, AK 99503–6199, or hand delivery to the Designated Federal Official attending any of the Federal Subsistence Regional Advisory Council public meetings. See **SUPPLEMENTARY INFORMATION** for additional information on locations of the public meetings.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Review Process section below for more information).

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o U.S. Fish and Wildlife Service, Attention: Peter J. Probasco, Office of Subsistence Management; (907) 786–3888 or *subsistence@fws.gov.* For questions specific to National Forest System lands, contact Steve Kessler, Regional Subsistence Program Leader, USDA, Forest Service, Alaska Region; (907) 743–9461 or *skessler@fs.fed.us.*

SUPPLEMENTARY INFORMATION:

Background

Under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 3111–3126), the Secretary of the Interior and the Secretary of Agriculture (Secretaries) jointly implement the Federal Subsistence Management Program. This program provides a preference for take of fish and wildlife resources for subsistence uses on Federal public lands and waters in Alaska. The Secretaries published temporary regulations to carry out this program in the **Federal Register** on June 29, 1990 (55 FR 27114), and final regulations were published in the **Federal Register** on May 29, 1992 (57 FR 22940). The Program has subsequently amended these regulations a number of times. Because this program is a joint effort between Interior and Agriculture, these regulations are located in two titles of the Code of Federal Regulations (CFR): Title 36, ''Parks, Forests, and Public Property,'' and Title 50, ''Wildlife and Fisheries,'' at 36 CFR 242.1–28 and 50 CFR 100.1–28, respectively. The regulations contain subparts as follows: Subpart A, General Provisions; Subpart B, Program Structure; Subpart C, Board Determinations; and Subpart D, Subsistence Taking of Fish and Wildlife.

Consistent with subpart B of these regulations, the Secretaries established a Federal Subsistence Board to administer the Federal Subsistence Management Program. The Board is currently made up of:

- A Chair appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture;
- The Alaska Regional Director, U.S. Fish and Wildlife Service;
- The Alaska Regional Director, U.S. National Park Service;
- The Alaska State Director, U.S. Bureau of Land Management;
- The Alaska Regional Director, U.S. Bureau of Indian Affairs;

• The Alaska Regional Forester, U.S. Forest Service; and

• Two public members appointed by the Secretary of the Interior with concurrence of the Secretary of Agriculture.

Through the Board, these agencies and public members participate in the development of regulations for subparts C and D, which, among other things, set forth program eligibility and specific harvest seasons and limits.

In administering the program, the Secretaries divided Alaska into 10 subsistence resource regions, each of which is represented by a Subsistence Regional Advisory Council (Council). The Councils provide a forum for rural residents with personal knowledge of local conditions and resource requirements to have a meaningful role in the subsistence management of fish and wildlife on Federal public lands in Alaska. The Council members represent varied geographical, cultural, and user interests within each region.

Public Review Process—Comments, Proposals, and Public Meetings

The Regional Advisory Councils have a substantial role in reviewing this proposed rule and making recommendations for the final rule. The Federal Subsistence Board, through the Councils, will hold meetings on this proposed rule at the following locations in Alaska, on the following dates:

Region 1—Southeast Regional Council	Juneau	March 20, 2012.
Region 2—Southcentral Regional Council	Anchorage	March 13, 2012.
Region 3—Kodiak/Aleutians Regional Council	Kodiak	March 21, 2012.
Region 4—Bristol Bay Regional Council	Naknek	March 6, 2012.
Region 5—Yukon–Kuskokwim Delta Regional Council	Bethel	February 23, 2012.
Region 6—Western Interior Regional Council	McGrath	February 28, 2012.
Region 7—Seward Peninsula Regional Council	Nome	February 7, 2012.
Region 8—Northwest Arctic Regional Council	Kotzebue	March 7, 2012.
Region 9—Eastern Interior Regional Council	Fairbanks	February 29, 2012.
Region 10—North Slope Regional Council	Barrow	February 15, 2012.

During April 2012, the written proposals to change the subpart D, take of fish and shellfish regulations, and subpart C, customary and traditional use determinations, will be compiled and distributed for public review. During the 30-day public comment period, which is presently scheduled to end on May 28, 2012, written public comments will be accepted on the distributed proposals.

The Board, through the Councils, will hold a second series of meetings in August through October 2012, to receive comments on specific proposals and to develop recommendations to the Board at the following locations in Alaska, on the following dates:

Region 1—Southeast Regional Council	Sitka	September 26, 2012.
Region 2—Southcentral Regional Council	TBA	October 2, 2012.
Region 3—Kodiak/Aleutians Regional Council	Sand Point	September 5, 2012.
Region 4—Bristol Bay Regional Council	TBA	TBA XX, 2012.
Region 5—Yukon–Kuskokwim Delta Regional Council	Quinhagak	October 10, 2012.
Region 6—Western Interior Regional Council	Aniak	October 10, 2012.
Region 7—Seward Peninsula Regional Council	Nome	October 3, 2012.
Region 8—Northwest Arctic Regional Council	TBA	August 21, 2012.
Region 9—Eastern Interior Regional Council	Tanana	October 16, 2012.
Region 10—North Slope Regional Council	TBA	August 14, 2012.

A notice will be published of specific dates, times, and meeting locations in local and statewide newspapers prior to both series of meetings. Locations and dates may change based on weather or local circumstances. The amount of work on each Council's agenda determines the length of each meeting.

The Board will discuss and evaluate proposed changes to the subsistence management regulations during a public meeting scheduled to be held in Anchorage, AK, in January 2013. The Council Chairs, or their designated representatives, will present their respective Councils' recommendations at the Board meeting. Additional oral testimony may be provided on specific proposals before the Board at that time. At that public meeting, the Board will deliberate and take final action on proposals received that request changes to this proposed rule.

Proposals to the Board to modify the general fish and wildlife regulations, fish and shellfish harvest regulations, and customary and traditional use determinations must include the following information:

a. Name, address, and telephone number of the requestor;

b. Each section and/or paragraph designation in this proposed rule for which changes are suggested, if applicable;

c. A description of the regulatory change(s) desired;

d. A statement explaining why each change is necessary;

e. Proposed wording changes; and

f. Any additional information that you believe will help the Board in evaluating the proposed change.

The Board immediately rejects proposals that fail to include the above information, or proposals that are beyond the scope of authorities in § ___.24, subpart C (the regulations governing customary and traditional use determinations), and §§ ___.25, ___.27, and ___.28, subpart D (the general and specific regulations governing the subsistence take of fish and shellfish). During the January 2013 meeting, the Board may defer review and action on some proposals to allow time for cooperative planning efforts, or to acquire additional needed information. The Board may elect to defer taking action on any given proposal if the workload of staff, Councils, or the Board becomes excessive. These deferrals may be based on recommendations by the affected Council(s) or staff members, or on the basis of the Board's intention to do least harm to the subsistence user and the resource involved. A proponent of a proposal may withdraw the proposal provided it has not been presented to a Council for action. The Board may consider and act on

alternatives that address the intent of a proposal while differing in approach.

Tribal Consultation and Comment

As expressed in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' the Federal officials that have been delegated authority by the Secretaries are committed to honoring the unique government-to-government political relationship that exists between the Federal Government and Federally Recognized Indian Tribes (Tribes) as listed in 75 FR 60810 (October 1, 2010). Consultation with Alaska Native corporations is based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Alaska National Interest Lands Conservation Act does not provide rights to Tribes for the subsistence taking of wildlife, fish, and shellfish. However, because tribal members are affected by subsistence fishing, hunting, and trapping regulations, the Secretaries, through the Board, will provide Federally recognized Tribes and Alaska Native corporations an opportunity to consult on this proposed rule.

The Board will engage in outreach efforts for this proposed rule, including a notification letter, to ensure that Tribes and Alaska Native corporations are advised of the mechanisms by which they can participate. The Board provides a variety of opportunities for consultation: Proposing changes to the existing rule; commenting on proposed changes to the existing rule; engaging in dialogue at the Regional Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process. The Board will commit to efficiently and adequately providing an opportunity to Tribes and Alaska Native corporations for consultation in regard to subsistence rulemaking.

The Board will consider Tribes' and Alaska Native corporations' information, input, and recommendations, and address their concerns as much as practicable.

Prior to the start of the public regulatory meeting in January, 2013, the Board will provide Federally recognized Tribes and Alaska Native corporations a specific opportunity to consult on this proposed rule. Federally recognized Tribes and Alaska Native corporations will be notified by mail and telephone and will be given the opportunity to attend the consultation in person or via teleconference.

Developing the 2013–14 and 2014–15 Fish/Shellfish Seasons and Harvest Limit Regulations

Subpart C and D regulations are subject to periodic review and revision. The Board currently completes the process of revising subsistence take of fish and shellfish regulations in odd-numbered years and wildlife regulations in even-numbered years; public proposal and review processes take place during the preceding year. The Board also addresses customary and traditional use determinations during the applicable cycle.

The text of the final rule published March 8, 2011 (76 FR 12564) for the 2011–13 subparts C and D regulations is the text of this proposed rule. These regulations will remain in effect until subsequent Board action changes elements as a result of the public review process outlined above in this document.

Compliance With Statutory and Regulatory Authorities

National Environmental Policy Act

A Draft Environmental Impact Statement that described four alternatives for developing a Federal Subsistence Management Program was distributed for public comment on October 7, 1991. The Final Environmental Impact Statement (FEIS) was published on February 28, 1992. The Record of Decision (ROD) on Subsistence Management for Federal Public Lands in Alaska was signed April 6, 1992. The selected alternative in the FEIS (Alternative IV) defined the administrative framework of an annual regulatory cycle for subsistence regulations.

A 1997 environmental assessment dealt with the expansion of Federal jurisdiction over fisheries and is available at the office listed under **FOR FURTHER INFORMATION CONTACT**. The Secretary of the Interior, with concurrence of the Secretary of Agriculture, determined that expansion of Federal jurisdiction does not constitute a major Federal action significantly affecting the human environment and, therefore, signed a Finding of No Significant Impact.

Section 810 of ANILCA

An ANILCA § 810 analysis was completed as part of the FEIS process on the Federal Subsistence Management Program. The intent of all Federal subsistence regulations is to accord subsistence uses of fish and wildlife on public lands a priority over the taking of fish and wildlife on such lands for other purposes, unless restriction is necessary to conserve healthy fish and wildlife populations. The final § 810 analysis determination appeared in the April 6, 1992, ROD and concluded that the Federal Subsistence Management Program, under Alternative IV with an annual process for setting subsistence regulations, may have some local impacts on subsistence uses, but will not likely restrict subsistence uses significantly. During the subsequent environmental assessment process for extending fisheries jurisdiction, an evaluation of the effects of the periodic subparts C and D rules was conducted in accordance with § 810; that evaluation also supported the Secretaries' determination that these rules will not reach the ''may significantly restrict'' threshold that would require notice and hearings under ANILCA § 810(a).

Paperwork Reduction Act

An agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. This proposed rule does not contain any new collections of information that require OMB approval. OMB has reviewed and approved the following collections of information associated with the subsistence regulations at 36 CFR part 242 and 50 CFR part 100: Subsistence hunting and fishing applications, permits, reports, and Federal Subsistence Regional Advisory Council Membership Application/Nomination and Interview Forms (OMB Control No. 1018–0075 expires January 31, 2013).

Regulatory Planning and Review (Executive Order 12866)

The Office of Management and Budget has determined that this proposed rule is not significant and has not reviewed this proposed rule under Executive Order 12866. OMB bases its determination upon the following four criteria:

(a) Whether the rule will have an annual effect of $100 million or more on the economy or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government.

(b) Whether the rule will create inconsistencies with other agencies' actions.

(c) Whether the rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) Whether the rule raises novel legal or policy issues.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations, or governmental jurisdictions. In general, the resources to be harvested under this proposed rule are already being harvested and consumed by the local harvester and do not result in an additional dollar benefit to the economy. Therefore, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*), this proposed rule is not a major rule. It does not have an effect on the economy of $100 million or more, will not cause a major increase in costs or prices for consumers, and does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Executive Order 12630

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority on public lands. The scope of this program is limited by definition to certain public lands. Likewise, these regulations have no potential takings of private property implications as defined by Executive Order 12630.

Unfunded Mandates Reform Act

The Secretaries have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. The implementation of this proposed rule is by Federal agencies and there is no cost imposed on any State or local entities or tribal governments.

Executive Order 12988

The Secretaries have determined that these regulations meet the applicable standards provided in §§ 3(a) and 3(b)(2) of Executive Order 12988, regarding civil justice reform.

Executive Order 13132

In accordance with Executive Order 13132, the proposed rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

Executive Order 13175

The Alaska National Interest Lands Conservation Act does not provide rights to tribes for the subsistence taking of wildlife, fish, and shellfish. However, the Board will provide Federally recognized Tribes and Alaska Native corporations an opportunity to consult on this proposed rule. Consultation with Alaska Native corporations are based on Public Law 108–199, div. H, Sec. 161, Jan. 23, 2004, 118 Stat. 452, as amended by Public Law 108–447, div. H, title V, Sec. 518, Dec. 8, 2004, 118 Stat. 3267, which provides that: ''The Director of the Office of Management and Budget and all Federal agencies shall hereafter consult with Alaska Native corporations on the same basis as Indian tribes under Executive Order No. 13175.''

The Secretaries, through the Board, will provide a variety of opportunities for consultation: commenting on proposed changes to the existing rule; engaging in dialogue at the Council meetings; engaging in dialogue at the Board's meetings; and providing input in person, by mail, email, or phone at any time during the rulemaking process.

Executive Order 13211

This Executive Order requires agencies to prepare Statements of Energy Effects when undertaking certain actions. However, this proposed rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no Statement of Energy Effects is required.

Drafting Information

Theo Matuskowitz drafted these regulations under the guidance of Peter J. Probasco of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional assistance was provided by:

- Daniel Sharp, Alaska State Office, Bureau of Land Management;
- Sandy Rabinowitch and Nancy Swanton, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen, Alaska Regional Office, Bureau of Indian Affairs;
- Jerry Berg, Alaska Regional Office, U.S. Fish and Wildlife Service; and
- Steve Kessler, Alaska Regional Office, U.S. Forest Service.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

Proposed Regulation Promulgation

For the reasons setout in the preamble, the Federal Subsistence Board proposes to amend 36 CFR part 242 and 50 CFR part 100 for the 2013–14 and 2014–15 regulatory years. The text of the proposed amendments to 36 CFR 242.24, 242.27, and 242.28 and 50 CFR 100.24, 100.27, and 100.28 is the finalrule for the 2011–13 regulatory period (76 FR 12564; March 8, 2011), and the text of the proposed amendments to 36 CFR242.25 and 50 CFR 100.25 is the final rule for the 2010–11 and 2011–12wildlife regulatory period (75 FR 37918; June 30, 2010), as modified by anysubsequent Federal Subsistence Board action during meetings held February 7 through March 23, 2012.

Dated: January 12, 2012.

Peter J. Probasco,

Acting Chair, Federal Subsistence Board.

Dated: January 12, 2012.

Steve Kessler,

Subsistence Program Leader, USDA–Forest Service.

[FR Doc. 2012–2008 Filed 2–1–12; 8:45 am]

BILLING CODE 3410–11–P; 4310–55–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2011–0998; FRL–9625–9]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Amendments to the Handling, Storage, and Disposal of Volatile Organic Compounds Emissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Delaware. This SIP revision amends the control of volatile organic compound (VOC) emissions from industrial cleaning solvents facilities, automobile and light-duty truck coating operations, paper, film, foil coating units, flat wood paneling products, and flexible packaging printing presses. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before March 5, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2011–0998 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2011–0998, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. 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–R03–OAR–2011–0998. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *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 *www.regulations.gov* or email. The *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 email comment directly to EPA without going through *www.regulations.gov,* your email 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.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* 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 electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19903.

FOR FURTHER INFORMATION CONTACT: Gregory Becoat, (215) 814–2036, or by email at *becoat.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: On June 20, 2011, EPA received a revision to the Delaware SIP submitted by the Delaware Department of Natural Resources and Environmental Control (DNREC). The SIP revision updates regulations in 7 DE Admin. Code 1124—Control of Volatile Organic Compound Emissions to implement reasonably available control technology (RACT) controls on emission sources covered by EPA's control techniques guidelines (CTG).

I. Background

Section 182(b)(2) of the CAA requires all ozone nonattainment areas, including Delaware, to update relevant regulations for RACT controls for emission sources covered by EPA's CTG and to submit the regulations to EPA as SIP revisions. The SIP revision amends section 8.0, ''Handling, Storage, and Disposal of Volatile Organic Compounds,'' section 13.0, ''Automobile and Light-Duty Truck Coating Operations,'' section 16.0, ''Paper Coating,'' section 23.0, ''Coating of Flat Wood Paneling,'' section 37.0, ''Graphic Art Systems,'' and section 45.0, ''Industrial Cleaning Solvents,'' to reflect technology developments and expand VOC emission controls.

Sections 8.0, 13.0, 16.0, 23.0, 37.0, and 45.0 of 7 DE Admin. Code 1124 were originally developed in the 1990's based on EPA's CTGs. From September 2006 to September 2008, EPA updated relevant CTGs affecting these sections to reflect technology developments and expand VOC emission controls. As a result, DNREC revised these to reflect the new requirements in EPA's CTGs into existing Delaware Regulation 1124.

II. Summary of SIP Revision

DNREC's SIP revision to section 8.0 establishes a (1) new VOC content limit applicable for cleaning solvents used in facilities regulated under Regulation 1124; (2) adds definitions and terms; (3) establishes exemptions; (4) updates existing work practice standards; (5) establishes control requirements; and (6) establishes test methods, procedures and recordkeeping requirements based on EPA CTGs.

Amendments to section 13.0 establish (1) applicability for specific automobile and light-duty truck coating operations; (2) specify a transition period for existing permitted sources for every owner or operator of any automobile or light-duty truck assembly plant; (3) add and update definitions and terms; (4) update daily-weighted average limitation and control devices; (5) update compliance procedures; (6) and update test methods, procedures and recordkeeping requirements.

The SIP revision amends section 16.0 to (1) add ''Film, and Foil,'' now entitled ''Paper, Film, and Foil Coating; (2) establish applicability to any paper, film, or foil coating unit; (3) add exemptions for any coating unit in-line with any offset lithographic, screen, letterpress, flexographic, rotogravure, or digital printing operations; (4) add a transition period for existing permitted sources for every owner or operator of any paper coating unit; (5) add and update definitions and terms; (6) set VOC content limit standards; (7) update daily-weighted average limitation and control devices; (8) and update recordkeeping and reporting requirements.

DNREC's SIP revision to section 23.0 adds (1) tileboard panels and exterior sidings to the flat wood paneling product category and establishes VOC emission limits; (2) establishes more stringent emission limits to previously existing flat wood paneling products: Printed interior panels, natural finish panels, and Class II finish panels; (3) sets requirements that no owner or operator of a flat wood paneling coating line subject to the regulation for flat wood paneling coating shall allow VOC emissions in excess of the emission limits in Table 1 below; (4) deletes a regulation that did not require Class I

hardboard paneling finishes, particle board used in furniture, insulation board, exterior siding, tileboard, and softwood plywood coating lines to apply to flat wood paneling coating standards; (5) adds work practice standards; (6) updates control devices; and (7) updates test methods and efficiency of control systems, and recordkeeping and reporting requirements.

TABLE 1—VOC EMISSION LIMITS FROM FLAT WOOD PANELING COATINGS

Flat wood paneling product category	VOC content limits in coatings, inks, or adhesives being applied	
	pounds/gallon (lb/gal)	grams/liter (g/L)
Printed interior panels made of hardwood, plywood, or thin particleboard	*2.1	250
Natural finish hardwood plywood panels	2.1	250
Class II finishes on hardboard panels	2.1	250
Tileboard	2.1	250
Exterior siding	2.1	250

* This limit of 2.1 lb/gal is equivalent to 5.0 lb VOC per 1,000 square feet coating area.

Amendments to section 37.0 establish (1) provisions for flexible packaging printing presses; (2) add a transition period for existing permitted sources for every owner or operator of any flexible package printing facility; (3) add definitions and terms; (4) establish efficiency requirements for control systems to be installed on the flexible packaging printing presses; and (5) update recordkeeping and reporting requirements.

The SIP revision amends section 45.0 to update the applicability for the industrial use of organic cleaning solvents and clarify that the requirements of section 45.0 are triggered based on a limit of VOC emissions rather than cleaning solvent used. A detailed summary of EPA's review and rationale for proposing to approve this SIP revision may be found in the Technical Support Document (TSD) for this action which is available on-line at *www.regulations.gov,* Docket number EPA–R03–OAR–2011–0998.

III. Proposed Action

EPA is proposing to approve the Delaware SIP revision for the control of VOC emissions from industrial cleaning solvents facilities, automobile and light-duty truck coating operations, paper, film, foil coating units, flat wood paneling products, and flexible packaging printing presses. (7 DE Admin Code 1124, sections 8.0, 13.0, 16.0, 23.0, 37.0, and 45.0) submitted on June 20, 2011. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, pertaining to Delaware's Regulation 7 DE Admin. Code 1124—Control of Volatile Organic Compound Emissions, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 17, 2012.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2012–2333 Filed 2–1–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2012–0053; FRL–9625–7]

Approval and Promulgation of Implementation Plans and Designations of Areas for Air Quality Planning Purposes; Missouri and Illinois; St. Louis; Determination of Attainment by Applicable Attainment Date for the 1997 Ozone National Ambient Air Quality Standard (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to determine, pursuant to the Clean Air Act (CAA), that the bi-state St. Louis (MO–IL) ozone nonattainment area (''St. Louis area'') attained the 1997 8-hour ozone National Ambient Air Quality Standards (NAAQS) by the applicable attainment date of June 15, 2010. This proposed determination is based upon complete, quality-assured, and certified ambient air quality data from the 2007–2009 monitoring period which show that the St. Louis area has monitored attainment of the 1997 8-hour ozone NAAQS as of the applicable date.

DATES: Comments must be received on or before March 5, 2012.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2012–0053, by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *Email: kemp.lachala@epa.gov*.
3. *Fax:* (913) 551–9214.
4. *Mail:* Lachala Kemp, Air Planning and Development Branch, Environmental Protection Agency Region 7, 901 North 5th Street, Kansas City, Kansas 66101.
5. *Hand Delivery or Courier:* Lachala Kemp, Air Planning and Development Branch, Environmental Protection Agency Region 7, 901 North 5th Street, Kansas City, Kansas 66101. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2012–0053. 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 email. 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 email comment directly to EPA without going through *www.regulations.gov*, your email 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.

Docket. All documents in the electronic 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 in *http://www.regulations.gov* or in hard copy at the U.S. Environmental Protection Agency Region 7, 901 North 5th Street, Kansas City, Kansas 66101, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Lachala Kemp, Air Planning and Development Branch, U.S. Environmental Protection Agency Region 7, 901 N. 5th Street, Kansas City, Kansas 66101, at (913) 551–7214 or by email at *kemp.lachala@epa.gov*. In Region 5 contact Edward Doty, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), 77 West Jackson Boulevard, Chicago, Illinois 60604, at (312) 886–6057 or by email at *doty.edward@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' or ''our'' refer to EPA. This section provides additional information by addressing the following questions:

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I. What action is EPA taking?
II. What is the background for this action?
III. What was the air quality in the St. Louis area for the 1997 8-hour ozone NAAQS for the 2007–2009 monitoring period?
IV. What is the proposed action?
V. Statutory and Executive Order Reviews

I. What action is EPA taking?

Pursuant to section 181(b)(2) of the CAA, EPA is proposing to determine that the St. Louis area attained the 1997 8-hour ozone NAAQS by its applicable attainment date of June 15, 2010. The St. Louis area is composed of Jefferson County, Franklin County, St. Louis County, St. Louis City, and St. Charles County in Missouri, and Madison, Monroe, Jersey, and St. Clair Counties in Illinois. This proposed determination is based upon complete, quality-assured and certified ambient air monitoring data from 2007–2009 which show that the St. Louis area monitored attainment of the 1997 8-hour ozone NAAQS as of its applicable attainment date.

On June 9, 2011, EPA published in the **Federal Register** a final determination that the St. Louis area has attained the 1997 8-hour ozone NAAQS based on complete, quality-assured ozone monitoring data for 2008–2010, and the effect of that determination pursuant to 40 CFR 51.918. *See* 76 FR 33647–50. Today's proposed action is separate from and independent of EPA's June 9, 2011 determination, and it does not affect or modify that rulemaking. Today's proposed determination concerns an earlier period of air quality monitoring, and it addresses only EPA's obligation under CAA section 181(b)(2) to determine whether the area attained the 8-hour ozone standard by its applicable June 15, 2010 attainment date.

II. What is the background for this action?

On July 18, 1997 (62 FR 38856), EPA promulgated an 8-hour ozone standard of 0.08 parts per million (ppm). On April 30, 2004 (69 FR 23858), EPA published a final rule designating and classifying areas under the 8-hour ozone NAAQS. These designations and

classifications became effective June 15, 2004. EPA designated as nonattainment any area that was violating the 8-hour ozone NAAQS based on the three most recent years of air quality data, 2001–2003. Under EPA's implementation rule for the 1997 8-hour ozone standard (69 FR 23951, April 30, 2004), an area was classified under subpart 2 of the CAA based on its 8-hour ozone design value (i.e. the three-year average annual fourth-highest daily maximum 8-hour average ozone concentration), if it had a 1-hour design value at the time of designation at or above 0.121 ppm. *See* 40 CRF 51.902(a). All other nonattainment areas were covered under subpart 1, based upon their 8-hour design values (69 FR 23958). The St. Louis area was classified as a subpart 2, 8-hour ozone moderate nonattainment area by EPA on April 30, 2004 (69 FR 23858, 23898, and 23915), based on the three most recent years of monitoring data (2001–2003), consistent with 40 CFR 51.903(a).

As a moderate nonattainment area for the 1997 8-hour ozone NAAQS, the St. Louis (MO–IL) area had an applicable attainment date of June 15, 2010, as required by 40 CFR 51.903(a) Table 1. Pursuant to section 181(b)(2) of the CAA, EPA is required to make a determination as to whether the St. Louis area attained the standard as of its applicable attainment date. This determination is based on the area's design value as of the attainment date, which in turn is based on the three most recent years of air quality data (2007–2009) prior to the attainment date.

III. What was the air quality in the St. Louis area for the 1997 8-hour ozone NAAQS for the 2007–2009 monitoring period?

Today's rulemaking assesses whether the St. Louis area attained the 1997 8-hour ozone NAAQS by its applicable attainment date of June 15, 2010. Under EPA regulations at 40 CFR 50.15, the 1997 8-hour primary and secondary ozone ambient air quality standards are met at an ambient air quality monitoring site when the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentration is less than or equal to 0.08 ppm, as determined in accordance with 40 CFR part 50, Appendix I. Based on the rounding convention set forth in section 2.3 of Appendix I, the smallest value that is greater than 0.08 ppm is 0.085 ppm.

EPA has reviewed the ambient air monitoring data for the St. Louis area for the 1997 8-hour ozone NAAQS, consistent with requirements contained at 40 CFR part 50. EPA's review focused primarily on data recorded in the EPA Air Quality System (AQS) database for the St. Louis area for 2007–2009.

Table 1 shows the 2007–2009 and 2008–2010 ozone design values for the St. Louis area monitors with complete, quality-assured and certified data for that period. All data values are expressed in ppm. As shown in Table 1, all of these monitors recorded ozone design values less than 0.085 ppm for 2007–2009 and 2008–2010, with the highest value at any monitor in the area, 0.078 ppm, recorded at the West Alton monitor.

TABLE 1—ANNUAL FOURTH-HIGHEST DAILY MAXIMUM 8-HOUR OZONE CONCENTRATIONS AND 3-YEAR AVERAGES IN PPM FOR THE ST. LOUIS AREA MONITORS WITH COMPLETE DATA (2007–2009) AND (2008–2010)

State	County	Monitor	2007 4th High (ppm)	2008 4th High (ppm)	2009 4th High (ppm)	2010 4th High (ppm)	2007–2009 Design value (ppm)	2008–2010 Design value (ppm) *
Illinois	Jersey	Jerseyville 17–083–1001.	0.075	0.069	0.068	0.072	0.070	0.069
	Madison	Alton 17–119–0008.	0.081	0.068	0.067	0.080	0.072	0.071
		Maryville 17–119–1009.	0.087	0.070	0.074	0.074	0.077	0.072
		Wood River 17–119–3007.	0.086	0.067	0.066	0.070	0.073	0.067
	St. Clair	East St. Louis 17–163–0010.	0.077	0.064	0.069	0.072	0.070	0.068
Missouri	St. Charles	West Alton 29–183–1002.	0.089	0.076	0.071	0.084	0.078	0.077
		Orchard Farm 29–183–1004.	0.083	0.072	0.073	0.077	0.076	0.074
	St. Louis	Maryland Heights 29–189–0014.	0.094	0.069	0.070	0.076	0.077	0.071
		Pacific 29–189–0005.	0.085	0.064	0.064	0.069	0.071	0.065
	St. Louis City	Blair Street 29–510–0085.	0.087	0.073	0.065	0.071	0.075	0.069

*Although the determination here is whether the area attained the 1997 8-hour ozone NAAQS based on 2007–2009 data, the 2010 data shows that all monitors in the St. Louis area continued to attain the NAAQS in 2008–2010.

As shown above in Table 1, there were ten monitoring sites with complete data during the 2007–2009 monitoring period. Data are considered to be sufficient for comparison to the NAAQS if three consecutive complete years of

data exist. These ten monitoring sites with complete data provide an adequate basis for EPA to determine that the area has attained the NAAQS. See 40 CFR Part 58, Appendix D for network design criteria.[1]

Based on its evaluation of complete quality assured and certified data from the relevant monitoring sites for the 2007–2009 monitoring period, EPA believes that the St. Louis area attained the 1997 8-hour ozone NAAQS by the June 15, 2010 attainment date.

Two additional monitors have recorded data that are not considered as complete for the 2007–2009 monitoring period. Pertinent data from these sites are shown in Table 2.

TABLE 2—ANNUAL FOURTH-HIGHEST DAILY MAXIMUM 8-HOUR OZONE CONCENTRATIONS AND 3-YEAR AVERAGES IN PPM FOR THE ST. LOUIS AREA MONITORS WITH INCOMPLETE DATA

State	County	Monitor	2007 4th high (ppm)	2008 4th high (ppm)	2009 4th high (ppm)	2010 4th high (ppm)	2008–2010 average (ppm)
Missouri	Jefferson	Arnold & Tenbrook 29–099–0012.	0.087	.....	.....	.....	.....
		Arnold West 29–099–0019	.....	0.070	0.070	0.077	0.072

The Arnold and Tenbrook site was discontinued after the 2007 ozone season because it no longer met siting criteria in 40 CFR 58.14(c)(6) and section 5 of Appendix E to Part 58, due to trees in the immediate vicinity of the site. The Arnold West site replaced the discontinued monitor and began operation in the 2008 ozone season. The Missouri Department of Natural Resources requested, and EPA approved, the discontinuation of the Arnold & Tenbrook monitor. The siting of the replacement monitor at the Arnold West site was approved in the 2008 annual network plan as a more optimal location with respect to meeting the siting criteria in 40 CFR Part 58, including the criteria in section 5 of Appendix E.[2] The two sites are located within two miles of each other, and if data from the Arnold and Tenbrook monitor was combined with data from the Arnold West monitor, the resulting 2007–2009 design value would attain the 1997 8-hour ozone NAAQS at 0.075 ppm.

TABLE 3—DESIGN VALUES FOR INCOMPLETE DATA MONITORS COMPARED TO HIGHEST MONITORS IN THE ST. LOUIS AREA, 2000–2010

		2000–2002 Design value (ppm)	2001–2003 Design value (ppm)	2002–2004 Design value (ppm)	2003–2005 Design value (ppm)	2004–2006 Design value (ppm)	2005–2007 Design value (ppm)	2006–2008 Design value (ppm)	2007–2009 Design value (ppm)	2008–2010 Design value (ppm)
Incomplete Data Monitors	Arnold & Tenbrook 29–099–0012.	0.086	0.087	0.081	0.081	0.080	0.086	.....	.....	.....
	Arnold West 29–099–0019	.....	.....	.....	.....	.....	.....	.....	.....	0.072
Design Value Monitors	West Alton 29–183–1002	0.090	0.091	0.089	0.085	0.085	0.089	0.085	0.078	0.077
	Orchard Farm 29–183–1004.	0.090	0.092	0.088	0.086	0.086	0.089	0.082	0.076	0.074

Table 3 lists data over the last ten years for the monitors with incomplete data in comparison with the monitors that determine the design value for the St. Louis area. The design value monitor for any three year period is the monitor recording the highest levels out of all the monitors in the nonattainment area. The design values are used to compare against the NAAQS. Table 3 illustrates that the Arnold and Tenbrook and Arnold West monitor's three year monitoring averages in all cases have been below the design value monitor for the area. It also shows the continued decrease in overall ozone levels over this period. Although the data from these monitors are used for comparison to the 8-hour ozone NAAQS, the table demonstrates they are not the monitors that would set the design value for the area. The other monitors for the area, including the monitors which have historically set the design value for the area, all have complete data and recorded attainment of the 1997 8-hour ozone NAAQS during the 2007–2009 period, as discussed above and shown in Table 1. Therefore, EPA believes it is reasonable to conclude that the area met the NAAQS based on complete data from the ten monitors recording values during the 2007–2009 period.

EPA finds that Missouri and Illinois have exercised diligence in monitoring in the St. Louis area, and have worked cooperatively with EPA in evaluating and seeking approval for monitor closures and moves.

EPA's review of monitoring data from the 2007–2009 monitoring period is supported by corroborating data from 2010 and shows that the St. Louis area attained the 1997 8-hour ozone NAAQS by its applicable attainment date of June 15, 2010.

IV. What is the proposed action?

This action proposes to determine that the St. Louis area attained the 1997 8-hour ozone NAAQS by its applicable attainment date of June 15, 2010, pursuant to CAA section 181(b)(2).

[1] The monitoring network for the 2007–2009 monitoring period met and exceeded the minimum criteria for ozone monitoring in 40 CFR part 58, Appendix D.

[2] The MDNR did not request that the data from the discontinued monitor and the replacement monitor be combined.

V. Statutory and Executive Order Reviews

This action proposes to make a determination of attainment based on air quality, and would not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed determination that the St. Louis area attained the 1997 8-hour ozone NAAQS by its applicable attainment date does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIPs are not approved to apply in Indian country located in the states, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, ozone, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 19, 2012.

Karl Brooks,

Regional Administrator, Region 7.

Dated: January 25, 2012.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2012–2336 Filed 2–1–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 489

[CMS–1350–NC]

RIN 0938–AQ51

Medicare Program; Emergency Medical Treatment and Labor Act (EMTALA): Applicability to Hospital Inpatients and Hospitals With Specialized Capabilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for comments.

SUMMARY: This request for comments addresses the applicability of the Emergency Medical Treatment and Labor Act (EMTALA) to hospital inpatients.

DATES: *Comment Date:* To be assured consideration, comments on the Applicability of EMTALA to Hospitals with Specialized Capabilities (section II.B. of this document) must be received at one of the addresses provided below, no later than 5 p.m. EST on April 2, 2012.

ADDRESSES: In commenting, please refer to file code CMS–1350–NC. 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 ''Submit a comment'' instructions.

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–1350–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

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–1350–NC, 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) 786–1066 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 information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Renate Dombrowski, (410) 786–4645, Ankit Patel, (410) 786–4537.

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

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Social Security Act (the Act) were enacted as parts of the Emergency Medical Treatment and Labor Act (EMTALA). These statutory provisions impose specific obligations on certain Medicare-participating hospitals and critical access hospitals (CAHs). (Throughout this document, when we reference the obligation of a ''hospital'' under these sections of the Act and in our regulations, we mean to include CAHs as well.) These obligations concern individuals who come to a hospital's ''dedicated emergency department'' (as defined at 42 CFR 489.24(b)) and request examination or treatment for a medical condition and apply to all of these individuals regardless of whether they are beneficiaries of any program under the Act.

EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272. Congress incorporated these antidumping provisions within the Social Security Act to ensure that any individual with an emergency medical condition (EMC), regardless of the individual's insurance coverage, is not denied essential lifesaving services. Under section 1866(a)(1)(I)(i) of the Act, a hospital that fails to fulfill its EMTALA obligations under these provisions may be subject to termination of its Medicare provider agreement which would result in the loss of Medicare and Medicaid payments. In addition, section 1867(d) of the Act provides for the imposition of civil monetary penalties on a hospital or physician who negligently violates a requirement of EMTALA under section 1867 of the Act.

Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the emergency department of a hospital and request examination or treatment for a medical condition. The statute further provides that, if a hospital finds that such an individual has an EMC, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility where stabilization can occur. The EMTALA statute also separately outlines the obligation of hospitals to receive appropriate transfers from other hospitals. Section 1867(g) of the Act states that ''A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.'' The regulations implementing section 1867 of the Act are found at 42 CFR 489.24. The regulations at 42 CFR 489.20(l), (m), (q), and (r) also refer to certain EMTALA requirements outlined in section 1866 of the Act. The Interpretive Guidelines concerning EMTALA are found at Appendix V of the CMS State Operations Manual: *http://www.cms.gov/manuals/Downloads/som107ap_v_emerg.pdf.*

A. Applicability of EMTALA to Hospital Inpatients

The focus of EMTALA routinely involves the treatment of individuals who ''come to the emergency department,'' as we have defined that term at 42 CFR 489.24(b); that is, the individual is in a hospital-owned and operated ambulance or ''has presented at a hospital's dedicated emergency department * * * and requests examination or treatment for a medical condition, or has such a request made on his or her behalf [or] [h]as presented on hospital property * * * other than the dedicated emergency department, and requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf.''

However, concerns have also arisen about the continuing applicability of EMTALA to hospital inpatients. We have previously discussed the applicability of EMTALA to hospital inpatients in the May 9, 2002 (67 FR 31475) Hospital Inpatient Prospective Payment System (IPPS) proposed rule entitled ''Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates'' (hereinafter referred to as the FY 2003 IPPS proposed rule) and the September 9, 2003 (68 FR 53243) stand-alone final rule on EMTALA entitled ''Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions'' (hereinafter referred to as the 2003 EMTALA final rule). As we noted in these prior proposed and final rules, in 1999, the United States Supreme Court considered a case (*Roberts* v. *Galen of Virginia,* 525 U.S. 249 (1999)) that involved, in part, the question of whether EMTALA applies to hospital inpatients. In the context of that case, the United States Solicitor General advised the Court that HHS would develop a regulation clarifying its position on this issue. In the FY 2003 IPPS proposed rule, we proposed that EMTALA continues to apply to admitted individuals who are not stabilized (who presented under EMTALA), but that it would not otherwise apply to inpatients. We indicated that individuals whose conditions go in and out of apparent stability rapidly and frequently would not be considered ''stabilized'' and the hospital would continue to have an obligation to such individuals even after they are admitted. However, for all other inpatients we stated that EMTALA was intended to provide protection to individuals coming to a hospital to seek care for an EMC. Therefore, we stated that we believe the EMTALA requirements do not extend to stabilized inpatients even if they subsequently become unstable because those inpatients are protected by a number of Medicare conditions of participation (CoPs) as well as the hospital's other legal, licensing, and professional obligations with respect to the continued proper care and treatment of its patients.

In the 2003 EMTALA final rule, we refined this position to state that a hospital's obligation under EMTALA ends either when the individual is stabilized or when that hospital, in good faith, admits an individual with an EMC as an inpatient in order to provide stabilizing treatment. That is, we stated that EMTALA does not apply to any inpatient, even one who was admitted through the dedicated emergency department and for whom the hospital had initially incurred an EMTALA obligation to stabilize an EMC, and who remained unstabilized after admission as an inpatient. We noted that other patient safeguards protect all inpatients, including the hospital CoPs as well as State malpractice law. In addition, we noted that judicial interpretation of the matter and comments we received on the proposed rule helped shape the policy articulated in the final rule. However, we also stated in the rule that a hospital could not escape liability under EMTALA by admitting an individual with no intention of treating the individual and then inappropriately

transferring or discharging that individual without having met the stabilization requirement.

B. EMTALA Technical Advisory Group Recommendation Regarding Responsibilities of Hospitals With Specialized Capabilities

Section 945 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108–173, required the Secretary to establish a Technical Advisory Group (TAG) to advise the Secretary on issues related to the regulations and implementation of EMTALA. The EMTALA TAG's functions, as identified in the charter for the EMTALA TAG, were as follows:

- Review EMTALA regulations.
- Provide advice and recommendations to the Secretary concerning these regulations and their application to hospitals and physicians.
- Solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations.
- Disseminate information concerning the application of these regulations to hospitals, physicians, and the public.

The TAG met 7 times during its 30-month term, which ended on September 30, 2007. At its meetings, the TAG heard testimony from representatives of physician groups, hospital associations, and others regarding EMTALA issues and concerns. During each meeting, recommendations developed by subcommittees established by the TAG were discussed and voted on by members of the TAG. One of these recommendations, presented by the TAG to CMS during its September 2007 meeting, called for CMS to revise its regulations to address the situation of an individual who: (1) Presents to a hospital that has a dedicated emergency department and is determined to have an EMC; (2) is admitted to the hospital as an inpatient for purposes of stabilizing the EMC; and (3) subsequently needs a transfer to a hospital with specialized capabilities to receive stabilizing treatment that cannot be provided by the referring hospital that originally admitted the individual. This recommendation can be found at the following Web site: *http://www.cms.gov/EMTALA/Downloads/EMTALA_Final_Report_Summary.pdf.*

C. Applicability of EMTALA to Hospital Inpatients and Responsibilities of Hospitals With Specialized Capabilities

To further clarify our position on the applicability of EMTALA and the responsibilities of hospitals with specialized capabilities to accept appropriate transfers, the agency included as part of the April 30, 2008 Hospital IPPS proposed rule (73 FR 23669) entitled, ''Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians'' (hereinafter referred to as the FY 2009 IPPS proposed rule), two proposals that addressed the issue of hospital inpatients. First, we stated that we believe that the obligation of EMTALA does not end for all hospitals once an individual is admitted as an inpatient to the hospital where the individual first presented with a medical condition that was determined to be an EMC. Rather, once the individual is admitted, the admission only affects the EMTALA obligation of the hospital where the individual first presented (the admitting hospital). In the FY 2009 IPPS proposed rule (73 FR 23670), we stated that section 1867(g) of the Act (which refers to responsibilities of hospitals with specialized capabilities)

> * * * requires a receiving hospital with specialized capabilities to accept a request to transfer an individual with an unstable emergency medical condition as long as the hospital has the capacity to treat that individual, regardless of whether the individual had been an inpatient at the admitting hospital.

We stated that we believe that permitting inpatient admission at the admitting hospital to end EMTALA obligations for another hospital would seemingly contradict the intent of section 1867(g) of the Act to ensure that hospitals with specialized capabilities provide medical treatment to individuals with EMCs in order to stabilize those conditions. We further noted that while a hospital inpatient is protected under Medicare CoPs and may also have additional protections under State law, the obligations of another hospital under the CoPs apply only to that hospital's patients, and there is no CoP that requires a hospital to accept the transfer of a patient from another facility. We proposed to interpret section 1867(g) of the Act as creating an obligation on hospitals with specialized capabilities to accept appropriate transfers of individuals for whom the admitting hospital originally had an EMTALA obligation under section 1867 of the Act, if the hospital with specialized capabilities has the capacity to treat the individuals. Thus, in the FY 2009 IPPS proposed rule (73 FR 23670), we proposed to amend the regulations

> * * * to add a provision to state that when an individual covered by EMTALA was admitted as an inpatient and remains unstabilized with an emergency medical condition, a receiving hospital with specialized capabilities has an EMTALA obligation to accept that individual, assuming that the transfer of the individual is an appropriate transfer and the participating hospital with specialized capabilities has the capacity to treat the individual.

We received many comments opposing the proposal concerning hospitals with specialized capabilities included in the FY 2009 IPPS proposed rule. The commenters stated that the proposed rule would effectively ''reopen'' EMTALA for the admitting hospital by extending EMTALA's requirements for an ''appropriate transfer'' despite the fact that the admitting hospital's general EMTALA obligations ended, under regulation, when it admitted an individual as an inpatient. The commenters also stated that, because the original admitting hospital may claim that it lacks the capability to stabilize the individual's EMC, finalizing the proposed policy would result in an increase in patient dumping and inappropriate transfers, especially to teaching hospitals, tertiary care centers, and urban safety net hospitals. Commenters further asserted that finalizing CMS' policy as proposed would exacerbate confusion surrounding the determination of whether an individual is considered stable. That is, the hospital would be required to continuously monitor the individual to determine if at any point in the emergency department or even as an inpatient, the individual experienced a period of stability since such stability would end EMTALA obligations for all hospitals that might otherwise have obligations under the law. Under this scenario, the commenters asserted that the hospital with specialized capabilities would be forced to accept the transfer of an individual, potentially increasing the number of inappropriate or unnecessary transfers, because that hospital would be unable, with complete certainty, to determine whether the individual being transferred had ever experienced a period of stability.

As a result, in the August 19, 2008 IPPS final rule (73 FR 48659) entitled, ''Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of

Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals'' (hereinafter referred to as the FY 2009 IPPS final rule) we stated that,

> Due to the many concerns that the commenters raised which are noted above, we believe it is appropriate to finalize a policy to state that if an individual with an unstable emergency medical condition is admitted, the EMTALA obligation has ended for the admitting hospital and even if the individual's emergency medical condition remains unstabilized and the individual requires special services only available at another hospital, the hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual.

Put another way, we finalized a policy that a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of an individual who has been admitted in good faith as an inpatient at the first hospital. In the FY 2009 IPPS final rule (73 FR 48659), we stated that we believe that,

> * * * finalizing the policy as proposed may negatively impact patient care, due to an increase in inappropriate transfers which could be detrimental to the physical and psychological health and well-being of patients [and we were] concerned that finalizing our proposed rule could further burden the emergency services system and may force hospitals providing emergency care to limit their services or close, reducing access to emergency care.

In addition, we stated that we were concerned about the possible disparate treatment of inpatients under the proposed policy because an individual who presented to a hospital under EMTALA might have different transfer rights than an inpatient who was admitted for an elective procedure. In the FY 2009 IPPS final rule (73 FR 48659) we stated—

> [W]e believe that, in the case where an individual is admitted and later found to be in need of specialized care not available at the admitting hospital, hospitals with specialized capabilities generally do accept the transfer, even in the absence of a legal requirement to do so.

Finally, while we adopted a final rule that limits the EMTALA responsibilities of a hospital with specialized capabilities (73 FR 48661), we

> * * * encourage[d] the public to make CMS aware if this interpretation of section 1867(g) of the Act should result in harmful refusals by hospitals with specialized capabilities to accept the transfer of inpatients whose emergency medical condition remains unstabilized, or any other unintended consequences.

D. Litigation Related to the Applicability of EMTALA to Hospital Inpatients

We are aware that there continues to be a range of opinions, even at the Federal circuit court level, on the topic of EMTALA's application to inpatients. For example, in *Thornton* v. *Southwest Detroit Hospital,* 895 F.2d 1131, 1134 (6th Cir. 1990), the Sixth Circuit stated that, ''once a patient is found to suffer from an [EMC] in the emergency room, she cannot be discharged until the condition is stabilized * * *.'' However, other courts have concluded that a hospital's obligations under EMTALA end at the time that a hospital admits an individual to the facility as an inpatient. (See *Bryan* v. *Rectors and Visitors of the University of Virginia,* 95 F.3d 349 (4th Cir. 1996) and *Bryant* v. *Adventist Health System/West,* 289 F.3d 1162 (9th Cir. 2002)). More recently, in *Moses* v. *Providence Hospital and Medical Centers Inc.,* 561 F.3d 573 (6th Cir. 2009), the Sixth noted that the policy articulated in the 2003 EMTALA final rule that a hospital's obligation under EMTALA would end when that hospital, in good faith, admits an individual with an EMC as an inpatient was contrary to the plain language of the EMTALA statute. Rather, the court stated that a hospital's EMTALA obligations to an individual continue until that individual's EMC is stabilized regardless of the individual's status as an inpatient or outpatient.

E. Advance Notice of Proposed Rulemaking: Applicability of EMTALA to Hospital Inpatients and Hospitals With Specialized Capabilities

In 2010, United States Solicitor General advised the Supreme Court that HHS had committed to initiating a rulemaking process to reconsider the policy articulated in its current regulations, which state that a hospital's EMTALA obligations end upon the good faith admission as an inpatient of an individual with an EMC. In the December 23, 2010 **Federal Register** (75 FR 80762), we published an advance notice of proposed rulemaking (ANPRM) entitled ''Medicare Program; Emergency Medical Treatment and Labor Act: Applicability to Hospital and Critical Access Hospital Inpatients and Hospitals With Specialized Capabilities'' to solicit comments regarding whether we should revisit the policies established in the 2003 EMTALA final rule and the FY 2009 IPPS final rule. In addition, we sought real world examples that would inform our understanding of the current policy's impact on patients' access to care for an EMC. We noted that we would find it particularly helpful whether commenters could submit specific real-world examples that demonstrate if it would be beneficial to revisit these policies. We stated (75 FR 80765) that we—

> * * * are interested in hearing whether commenters are aware of situations where an individual who presented under EMTALA with an unstable EMC was admitted to the hospital where he or she first presented and was then transferred to another facility, even though the admitting hospital had the capacity and capability to treat that individual's EMC.

We further stated (75 FR 80765) that we were ''* * * interested in receiving information regarding the accuracy of our statement in the August 19, 2008 IPPS final rule that a hospital with specialized capabilities would accept the transfer of an inpatient with an unstabilized EMC absent an EMTALA obligation.'' Lastly, we stated (75 FR 80765) that we were interested in learning whether commenters were ''* * * aware of situations where an individual with an unstabilized EMC was admitted as an inpatient and continued to have an unstabilized EMC requiring the services of a hospital with specialized capabilities that refused to accept the transfer of the individual because current policy does not obligate hospitals with specialized capabilities to do so.''

II. Provisions of the Request for Comments

A. Applicability of EMTALA to Hospital Inpatients

In the 2003 EMTALA final rule, we took the position that a hospital's obligation under EMTALA ends when that hospital, in good faith, admits an individual with an unstable emergency medical condition as an inpatient to that hospital. In that rule, we noted that other patient safeguards including the CoPs as well as State malpractice law protect inpatients. In response to our request for comments in the ANPRM as to whether we should revisit the policies that were established in the 2003 EMTALA final rule, very few commenters took the position that the admitting hospital should continue to have an EMTALA obligation after the individual is admitted as an inpatient. While some commenters advocated extending EMTALA to inpatients who do not experience a period of stability, the commenters did not provide any evidence that the existing policy has resulted in patients being admitted and then subsequently discharged before

they were stable, adversely affecting the clinical outcome of those patients. Most commenters expressed support for the current policy that EMTALA does not apply to any inpatient of a hospital, even a patient who was admitted through that hospital's dedicated emergency department and continues to be unstable. These commenters referred to our 2003 EMTALA final rule and concurred with our assessment that, under our existing policy, the numerous hospital CoPs that protect inpatients as well as inpatients' rights under State law afford individuals admitted to a hospital with sufficient protection. Moreover, commenters appreciated the clarity and predictability of a bright line policy. Commenters also noted that our current policy regarding inpatients is achieving Congress' intent by ensuring that every individual, regardless of their ability to pay for emergency services, should have access to hospital services provided in hospitals with emergency departments.

Therefore, in light of the comments we received regarding the extension of the EMTALA obligations for hospitals admitting an individual through their dedicated emergency departments, we are not proposing to change the current EMTALA requirements for these hospitals. That is, we are maintaining our current policy that, if an individual ''comes to the [hospital's] emergency department,'' as we have defined that term in regulation, and the hospital provides an appropriate medical screening examination and determines that an EMC exists, and then admits the individual in good faith in order to stabilize the EMC, that hospital has satisfied its EMTALA obligation towards that patient. We continue to believe that this policy is a reasonable interpretation of the EMTALA statute and is supported by several Federal courts that have held that an individual's EMTALA protections end upon admission as a hospital inpatient. For further explanation, we refer readers to the 2003 EMTALA final rule (68 FR 53244), in which we finalized the policy that a hospital's EMTALA obligations end upon admission.

B. Applicability of EMTALA to Hospitals With Specialized Capabilities

The second issue upon which the ANPRM solicited comment was, whether EMTALA should apply to situations where a hospital seeks to transfer an individual, who was admitted by that hospital as an inpatient after coming to the hospital's dedicated emergency department with an EMC, to a hospital with specialized capabilities because the admitted inpatient continues to have an unstabilized EMC that requires specialized treatment not available at the admitting hospital. Under current regulations, if an individual comes to the hospital's dedicated emergency department, is determined to have an EMC, is admitted as an inpatient, and continues to have an unstabilized EMC which requires the specialized capabilities of another hospital, the EMTALA obligation for the admitting hospital has ended and a hospital with specialized capabilities also does not have an EMTALA obligation towards that individual.

Although we received some comments that supported amending the current regulations to require hospitals with specialized capabilities to accept the appropriate transfer of an inpatient who had presented to the admitting hospital under EMTALA and requires specialized capabilities to stabilize his or her EMC not available at the admitting hospital, most comments supported making no change to the current policies regarding the applicability of EMTALA to hospitals with specialized capabilities.

Therefore, at this time, we are making no proposals with respect to our policies regarding the applicability of EMTALA to hospitals with specialized capabilities. However, we will continue to monitor whether it may be appropriate in the future to reconsider this issue. Thus, we are providing a 60-day comment period to allow the public to submit data or real world examples that are relevant to this issue.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble. If we proceed to issue a subsequent document on the issues raised therein, we will respond to those comments in the preamble to that document.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774)

Dated: January 9, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: January 26, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–2287 Filed 1–31–12; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 327

[Docket No. MARAD 2012–0005]

RIN 2133–AB79

Retrospective Review Under E.O. 13563: Seamen's Claims; Admiralty Extension Act Claims; and Admiralty Claims

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: In accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' the Maritime Administration (MarAd) is evaluating the continued validity of its rules and determining whether they effectively address current issues. As part of this review, MarAd is soliciting public comment concerning clarification of its regulations pertaining to seamen's claims, administrative action taken against MarAd, and litigation pertaining to such matters. Specifically, MarAd proposes to update and modernize the existing regulations and to adopt a procedural process to more effectively address claims arising under the Suits in Admiralty Act, the Admiralty Extension Act and the Clarification Act. The revised regulations implement the Clarification Act and implement a process to resolve administrative claims arising under the Admiralty Extension Act, and both the Suits in Admiralty Act and the Public Vessels Act, respectively. MarAd will consider the comments it receives and determine whether any changes should be made to the proposed regulation.

DATES: Written comments are requested, and must be received on or before May 2, 2012.

ADDRESSES: You may submit comments [identified by Docket Number MARAD–2012–0005] by any of the following methods:

- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Room W12–140 on the plaza level of the U.S. Department of Transportation at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the

online instructions for submitting comments.

To avoid duplication, please use only one of these four methods. *See* the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments, including collection of information comments, if any for the Office of Information and Regulatory Affairs (OIRA), OMB. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: You may contact Jay Gordon, Assistant Chief Counsel for Litigation and General Law, at (202) 366–5173. You may send mail to Mr. Gordon at Office of Chief Counsel, MAR–221, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. You may send electronic mail to *jay.gordon@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

On January 18, 2011, President Obama issued Executive Order 13563, which outlined a plan to improve regulation and regulatory review (76 FR 3821, 1/21/11). Executive Order 13563 reaffirms and builds upon governing principles of contemporary regulatory review, including Executive Order 12866, ''Regulatory Planning and Review,'' (58 FR 51735, 10/4/1993), by requiring Federal agencies to design cost-effective, evidence-based regulations that are compatible with economic growth, job creation, and competitiveness. The President's plan recognizes that these principles should not only guide the Federal government's approach to new regulations, but to existing ones as well. To that end, Executive Order 13563 requires agencies to review existing significant rules to determine if they are outmoded, ineffective, insufficient, or excessively burdensome.

Accordingly, the Maritime Administration is soliciting public comment concerning amendment of its administrative claims governing seaman's administrative actions and claim litigation. 46 CFR part 327 prescribes rules and regulations pertaining to the filing of admiralty claims and the administrative allowance or disallowance (actual or presumed) of such claims, in whole or in part. The existing Part 327 addresses only Seamen's Claims. This NPRM divides Part 327 into three sections, all of which are related to admiralty claims. Subpart I addresses Seamen's Claims governed by the Clarification Act, 50 U.S.C. 1291(a). Subpart II addresses claims filed under the Admiralty Extension Act, 46 U.S.C. 30101, a statutory provision which extends the admiralty and maritime jurisdiction of the United States to cases of injury or damage to a person or property caused by a vessel on navigable waters, even though the injury or damage is done or consummated on land. Subpart III establishes a procedure for filing administrative claims for all admiralty claims not covered by Subparts A or B, or the Contracts Disputes Act (41 U.S.C. 601 *et seq.*).

The filing of proper administrative claims under Sections I and II must take place before filing suit against the United States. For example, under the Clarification Act, before suit can be filed against the United States, there must be a denial of an administrative claim filed by officers and members of crews injured aboard MarAd vessels. Before suit can be filed against the United States under the Admiralty Extension Act, there must be an administrative denial of a claim filed under that Act. The new Subpart C establishes an optional procedure whereby anyone having an admiralty claim not covered by either Subparts A, B or under the Contracts Disputes Act can file an administrative claim with MarAd.

Subpart A of Part 327 has also been updated to include technical changes such as MarAd's new address at 1200 New Jersey Avenue and to include corrections to statutory references, some of which were made obsolete as the result of the codification of the Appendix to title 46 of the United States Code. In addition to these technical changes, MarAd proposes to modernize the regulation by allowing the use of pictures and video recordings as evidence in administrative actions and litigation. The current regulations do not provide for the use of such evidence. The new regulation also requires that the seamen filing claims sign the claims and verify that they are correct.

Subpart B sets out specific details concerning compliance with the administrative claim requirement of the Admiralty Extension Act, 46 U.S.C. 30301(c)(2), with respect to filing suit against the United States. Under this provision, no civil suit can be filed against the United States ''until the expiration of the 6-month period after the claim has been presented in writing to the agency owning or operating the vessel causing the injury or damage.''

Subpart C provides a means whereby an administrative claim can be filed with respect to any other admiralty matters not addressed in Subparts A and B or in the Contracts Disputes Act (41 U.S.C. 601 *et seq.*). This will provide a means to address administratively admiralty claims made by other persons or legal entities such as longshoremen and harbor workers, contractors, invitees injured aboard vessels, and the owners of damaged vessels filing claims governed by the Suits in Admiralty Act (46 U.S.C. 30901 *et seq.*) and the Public Vessels Act (46 U.S.C.A. 31101 *et seq.*).

As Executive Order 13563 reaffirms, the regulatory process must be transparent and provide opportunities for public participation. MarAd particularly believes that the review of its administrative claims regulations will be more meaningful if there is input from those affected by those regulations. It is suggested that comments address how MarAd can better provide for the efficient and appropriate administration and resolution of administrative claims arising under the Clarification Act, the Admiralty Extension Act, the Suits in Admiralty Act and the Public Vessels Act.

Public Participation

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments. MarAd encourages you to provide concise comments. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments. Please submit your comments, including the attachments, to addresses given above under **ADDRESSES**.

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, Maritime Administration, at the address given above under **FOR FURTHER INFORMATION CONTACT**. When you send comments containing information claimed to be confidential information, you should include a cover letter setting forth with specificity the basis for any such claim.

MarAd will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, MarAd will also consider comments received after that date. If a comment is received too late for MarAd to consider in developing a final rule (assuming that one is issued), MarAd will consider that comment as an informal suggestion for future rulemaking action.

For access to the docket to read background documents, including those referenced in this document, or to submit or read comments received, go to the DOT Docket Center located on the ground floor, room W12–140, U.S. Department of Transportation's Building, 1200 New Jersey Avenue SE., Washington, DC 20590–0001 between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To review documents, read comments or to submit comments, the docket is also available online at *http://www.regulations.gov.,* keyword search MARAD 2011–XXXX.

Please note that even after the comment period has closed, MarAd will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, MarAd recommends that you periodically check the Docket for new material.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review the DOT Privacy Act system of records notice for the Federal Docket Management System (FDMS) in the **Federal Register** published on January 17, 2008, (73 FR 3316) at *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

Rulemaking Analysis and Notices

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review) and DOT Regulatory Policies and Procedures

Under E.O. 12866 (58 FR 51735, October 4, 1993), supplemented by E.O.13563 (76 FR 3821, January 18, 2011) and DOT policies and procedures, MarAd must determine whether a regulatory action is ''significant,'' and therefore subject to OMB review and the requirements of the E.O. The Order defines ''significant regulatory action'' as one likely to result in a rule that may: (1) 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 government or communities. (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency. (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

MarAd has determined that this final rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, it was not reviewed by the Office of Management and Budget. This final rule will not result in an annual effect on the economy of $100 million or more. It also is not considered a major rule for purposes of Congressional review under Public Law 104–121. The rule is also not significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034, February 26, 1979). The costs and overall economic impact of this rulemaking do not require further analysis.

Executive Order 13132 (Federalism)

We analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism'') and have determined that it does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement. This rule has no substantial effect on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. Nothing in this document preempts any State law or regulation. Therefore, MarAd did not consult with State and local officials because it was not necessary.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

MarAd does not believe that this final rule will significantly or uniquely affect the communities of Indian tribal governments when analyzed under the principles and criteria contained in Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments). Therefore, the funding and consultation requirements of this Executive Order do not apply.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rule.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires MarAd to assess whether this rule would have a significant economic impact on a substantial number of small entities and to minimize any adverse impact. MarAd certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Environmental Assessment

We have analyzed this final rule for purposes of compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and have concluded that under the categorical exclusions provision in section 4.05 of Maritime Administrative Order (MAO) 600–1, ''Procedures for Considering Environmental Impacts,'' 50 FR 11606 (March 22, 1985), neither the preparation of an Environmental Assessment, an Environmental Impact Statement, nor a Finding of No Significant Impact for this rulemaking is required. This rulemaking has no environmental impact.

Executive Order 13211 (Energy Supply, Distribution, or Use)

MarAd has determined that the proposed rule would not significantly affect energy supply, distribution, or use. Therefore, no Statement of Energy Effects is required.

Executive Order 13045 (Protection of Children)

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, requires agencies issuing ''economically significant'' rules that involve an environmental health or safety risk that may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. As discussed previously, this proposed rule is not economically significant, and it would cause no environmental or health risk that disproportionately affects children.

Executive Order 12988 (Civil Justice Reform)

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

Executive Order 12630 (Taking of Private Property)

This rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and

Interference with Constitutionally Protected Property Rights.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) requires Federal agencies proposing to adopt Government technical standards to consider whether voluntary consensus standards are available. If the Agency chooses to adopt its own standards in place of existing voluntary consensus standards, it must explain its decision in a separate statement to OMB. MarAd determined that there are no voluntary national consensus standards related to the filing of the seamen's claims, administrative actions and Admiralty Extension Act claims addressed by this regulation.

International Trade Impact Assessment

This rule is not expected to contain standards-related activities that create unnecessary obstacles to the foreign commerce of the United States.

Privacy Impact Assessment

Section 522(a)(5) of the Transportation, Treasury, Independent Agencies, and General Government Appropriations Act, 2005 (Pub. L. 108–447, div. H, 118 Stat. 2809 at 3268) requires the Department of Transportation and certain other Federal agencies to conduct a privacy impact assessment of each proposed rule that will affect the privacy of individuals. Claims submitted under this rule will be treated the same as all legal claims received by MarAd. The processing and treatment of any claim within the scope of this rulemaking by MarAd shall comply with all legal, regulatory and policy requirements regarding privacy.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. This NPRM proposes regulatory clarification to seamen's claims, administrative action procedures and Admiralty Extension Claim procedures. This rulemaking contains no new or amended information collection or recordkeeping requirements that have been approved or require approval by the Office of Management and Budget.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 requires Agencies to evaluate whether an Agency action would result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $141.3 million or more (as adjusted for inflation) in any 1 year, and if so, to take steps to minimize these unfunded mandates. This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $141.3 million or more to either State, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objectives of the rule.

Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 46 CFR Part 327

Administrative practice and procedures, Claims, Seaman.

Accordingly, the Maritime Administration proposes to revise part 327 of 46 CFR, to read as follows:

PART 327—SEAMEN'S CLAIMS; ADMINISTRATIVE ACTION AND LITIGATION

Sec.

Subpart A—Seamen's Claims; Administrative Action and Litigation

327.1 Purpose.
327.2 Statutory provisions.
327.3 Required claims submission.
327.4 Claim requirements.
327.5 Filing claims.
327.6 Notice of allowance or disallowance.
327.7 Administrative disallowance presumption.
327.8 Court action.

Subpart B—Admiralty Extension Act Claims Administrative Action and Litigation

327.20 Admiralty Jurisdiction Extension Claims: Required claims.
327.21 Definitions.
327.22 Who may present claims.
327.23 Insurance and other subrogated claims.
327.24 Actions by claimant.
327.25 Contents of a claim.
327.26 Evidence supporting a claim.
327.27 Proof of amount claimed for personal injury.
327.28 Proof of amount claimed for loss of, or damage to, property.
327.29 Effect of other payments to claimant.
327.30 Statute of limitations for AEA and claim requirements.
327.31 Statute of limitations not tolled by administrative consideration of claims.
327.32 Notice of claim acceptance or denial.
327.33 Claim denial presumption.
327.34 Court action.

Subpart C—Other Admiralty Claims

327.40 Other Admiralty Claims.
327.41 Definitions.
327.42 Who may present claims.
327.43 Insurance and other subrogated claims.
327.44 Actions by claimant.
327.45 Contents of a claim.
327.46 Evidence supporting a claim.
327.47 Proof of amount claimed for personal injury.
327.48 Proof of amount claimed for loss of, or damage to, property.
327.49 Effect of other payments to claimant.
327.50 Statute of limitations for other admiralty claims and claim requirements.
327.51 Statute of limitations not tolled by administrative consideration of claims.
327.52 Notice of claim acceptance or denial.

Authority: 46 U.S.C. Chapters 301–309.

Subpart A—Clarification Act Claims: Seamen's Claims; Administrative Action and Litigation

§ 327.1 Purpose.

This part prescribes rules and regulations pertaining to the filing of claims designated in § 327.3 of this part and the administrative allowance, or disallowance (actual and presumed), of such claims, in whole or in part, filed by officers and members of crews (hereafter referred to as ''seamen'') employed on vessels as employees of the United States through the National Shipping Authority (NSA), Maritime Administration (MarAd), or successor.

§ 327.2 Statutory provisions.

(a) These regulations are enacted to implement the administrative claims procedures set forth in 50 U.S.C. App. 1291(a).

§ 327.3 Required claims submission.

All claims specified in 50 U.S.C. App. 1291(a) (2) and (3), quoted in § 327.2(b) of this part, shall be submitted for administrative consideration, as provided in §§ 327.4 and 327.5 of this part, prior to institution of court action thereon.

§ 327.4 Claim requirements.

(a) Form. The claim may be in any form and shall be

(1) In writing,

(2) Designated as a claim,

(3) Disclose that the object sought is the administrative allowance of the claim,

(4) Comply with the requirements of this part, and

(5) Filed as provided in § 327.5 of this part.

(6) The claim must be signed or attested to by the claimant. The statements made in the claim should be made to the best of the knowledge of the claimant and are subject to the provision of 18 U.S.C. §§ 287 and 1001 and all other penalty provisions for making false, fictitious, or fraudulent claims, statements or entries, or falsifying, concealing, or covering up a material fact in any matter within the jurisdiction of any department or agency of the United States. Any lawsuits filed contrary to the provisions of section 5 of the Suits in Admiralty Act, as amended by Public Law 877, 81st Congress (64 Stat. 1112; 46 U.S.C. § 30901 *et seq.*), shall not be in compliance with the requirements of this part.

(b) Contents. Each claim shall include the following information:

(1) With respect to the seaman:

(i) Name;

(ii) Mailing address;

(iii) Date of birth;

(iv) Legal residence address;

(v) Place of birth; and

(vi) Merchant mariner license or document number and social security number.

(2) With respect to the basis for the claim:

(i) Name of vessel on which the seaman was serving when the incident occurred that is the basis for the claim;

(ii) Place where the incident occurred;

(iii) Time of incident—year, month and day, and the precise time of day, to the minute, where possible;

(iv) Narrative of the facts and circumstances surrounding the incident, including a statement explaining why the United States is liable for this claim;

(v) Pictures, video recordings and other physical evidence related to the case and

(vi) The names, addresses, and telephone numbers, if available, of others who can supply factual information about the incident and its consequences.

(3) A sum certain dollar amount of claim, which includes a total for all amounts sought. The claim shall explain the amounts sought for:

(i) Past loss of earnings or earning capacity;

(ii) Future loss of earnings or earning capacity;

(iii) Medical expenses paid out of pocket;

(iv) Pain and suffering; and

(v) Any other loss arising out of the incident (describe).

(4) All medical and clinical records of physicians and hospitals related to a seaman's claim for injury, illness, or death shall be attached. If the claimant does not have a copy of each record, the claimant shall identify every physician and hospital having records relating to the seaman and shall provide written authorization for MarAd to obtain all such records. The claim shall also include the number of days the seaman worked as a merchant mariner and the earnings received for the current calendar year, as well as for the two preceding calendar years.

(5) If the claim does not involve a seaman's death, the following information shall be submitted with the claim:

(i) Date the seaman signed a reemployment register as a merchant mariner;

(ii) Copy of the medical fit-for-duty certificate issued to the seaman;

(iii) Date and details of next employment as a seaman; and

(iv) Date and details of next employment as other than a seaman.

(6) If the claim is for other than personal injury, illness or death, the claim shall provide all supporting information concerning the nature and dollar amount of the loss.

§ 327.5 Filing claims.

(a) Claims may be filed by or on behalf of seamen or their surviving dependents or beneficiaries, or by their legal representatives. Claims shall be filed either by personal delivery or by registered mail.

(b) The claimant shall send the claim directly to the Chief, Division of Marine Insurance, Maritime Administration, Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590. A copy of each claim shall be filed with the Ship Manager or General Agent of the vessel with respect to which such claim arose.

§ 327.6 Notice of allowance or disallowance.

MarAd shall give prompt notice in writing of the allowance or disallowance of each claim, in whole or in part, by mail to the last known address of, or by personal delivery to, the claimant or the claimant's legal representative. In the case of administrative disallowance, in whole or in part, such notice shall contain a brief statement of the reason for such disallowance.

§ 327.7 Administrative disallowance presumption.

If MarAd fails to give written notice of allowance or disallowance of a claim in accordance with § 327.6 of this part within sixty (60) calendar days following the date of the receipt of such claim by the proper person designated in § 327.5 of this part, such claim shall be presumed to have been ''administratively disallowed,'' within the meaning in section 1(a) of 50 U.S.C. App. § 1291(a), quoted in section 327.2(b) of this part.

§ 327.8 Court action.

No seamen, having a claim specified in subsections (2) and (3) of section 1(a) of 50 U.S.C. App. § 1291(a), their surviving dependents and beneficiaries, or their legal representatives shall institute a court action for the enforcement of such claim unless such claim shall have been prepared and filed in accordance with §§ 327.4 and 327.5 of this part and shall have been administratively disallowed in accordance with § 327.6 or 327.7 of this part.

This part prescribes rules and regulations pertaining to the filing of claims designated in § 327.3 of this part and the administrative allowance, or disallowance (actual and presumed), of such claims, in whole or in part, filed by officers and members of crews (hereafter referred to as ''seamen'') employed on vessels through the National Shipping Authority (NSA), Maritime Administration (MarAd), or successor organization.

Subpart B—Admiralty Extension Act Claims; Administrative Action and Litigation

§ 327.20 Admiralty Jurisdiction Extension Claims: Required claims.

(a) Pursuant to 46 U.S.C. 30101(c) of the Admiralty Extension Act (AEA), administrative claims involving the extension of admiralty jurisdiction to cases of damage or injury on land caused by a Maritime Administration vessel on navigable waters must be presented in writing to the Maritime Administration in accordance with § 327.20–34 of this part prior to institution of a court action thereon.

(b) A civil action against the United States for injury or damage done or consummated on land by a vessel on navigable waters may not be brought until the earlier occurrence of either the denial of the claim by the Maritime Administration or the presumptive denial of the claim which arises 6 months after the claim has been presented in writing to the Maritime Administration. 46 U.S.C. 30101(c)(2). Note that the 6 month period of review will not begin until a valid claim is filed pursuant to § 327.25.

(c) Proceedings against the United States pursuant to the requirements of the AEA and these regulations is the exclusive remedy available against the

United States of America, acting by and through the Maritime Administration, with respect to such injuries and damages.

§ 327.21 Definitions.

(a) Accrual Date. The day on which the alleged wrongful act or omission results in injury or damage for which a claim is made.

(b) Claim. A written notification of an incident, signed by the claimant, describing the incident and explaining why the United States is liable. The claim shall be accompanied by a demand for the payment of a sum certain of money, with a statement as to how that sum certain was calculated and all documents supporting the amount claimed. Where damages for medical injuries are made, the doctor's statement relating the injuries to the accident should be attached as well as medical release forms for each treating physician, hospital, and medical care provider.

§ 327.22 Who may present claims.

(a) General rules:

(1) A claim for property loss or damage may be presented by anyone having an interest in the property, including an insurer or other subrogee.

(2) A claim for personal injury may be presented by the person injured.

(3) A claim based on death may be presented by the executor or administrator of the decedent's estate, or any other person legally entitled to assert such a claim under local law. The claimant's status must be stated in the claim.

(4) A claim for medical, hospital, or burial expenses may be presented by any person who by reason of family relationship has, in fact, incurred the expenses.

(b) A joint claim must be presented in the names of and signed by, the joint claimants, and the settlement will be made payable to the joint claimants.

(c) A claim may be presented by a duly authorized agent, legal representative or survivor, if it is presented in the name of the claimant. If the claim is not signed by the claimant, the agent, legal representative, or survivor shall indicate their title or legal capacity and provide evidence of their authority to present the claim.

(d) Where the same claimant has a claim for damage to or loss of property and a claim for personal injury or a claim based on death arising out of the same incident, they must be combined in one claim.

§ 327.23 Insurance and other subrogated claims.

(a) The claims of an insured (subrogor) and an insurer (subrogee) for damages arising out of the same incident constitute a single claim.

(b) An insured (subrogor) and an insurer (subrogee) may file a claim jointly or separately. If the insurer has fully reimbursed the insured, payment will only be made to the insurer. If separate claims are filed, the settlement will be made payable to each claimant to the extent of that claimant's undisputed interest. If joint claims are filed, the settlement will be sent to the insurer.

(c) Each claimant shall include with a claim, a written disclosure concerning insurance coverage including:

(1) The names and addresses of all insurers;

(2) The kind and amount of insurance;

(3) The policy number;

(4) Whether a claim has been or will be presented to an insurer, and, if so, the amount of that claim; and whether the insurer has paid the claim in whole or in part, or has indicated payment will be made.

(d) Each subrogee shall substantiate an interest or right to file a claim by appropriate documentary evidence and shall support the claim as to liability and measure of damages in the same manner as required of any other claimant. Documentary evidence of payment to a subrogor does not constitute evidence of liability of the United States or conclusive evidence of the amount of damages. The Maritime Administration makes an independent determination on the issues of fact and law based upon the evidence of record.

§ 327.24 Actions by claimant.

(a) Form of claim. The claim must meet the requirements of § 327.24.

(b) Presentation. The claim must be presented in writing to the Office of Chief Counsel, Attn. Chief Counsel, Maritime Administration, Department of Transportation, 1200 New Jersey Ave SE., Washington, DC 20590–0001.

§ 327.25 Contents of a claim.

(a) A valid claim will contain the following:

(1) Identification of the Maritime Administration as the agency whose act or omission gave rise to the claim;

(2) The full name and mailing address of the claimant. If this mailing address is not claimant's residence, the claimant shall also include residence address;

(3) The date, time, and place of the incident giving rise to the claim;

(4) The amount claimed, in a sum certain, supported by independent evidence of property damage or loss, personal injury, or death, as applicable together with supporting medical records and a HIPPA compliant medical waiver for each treating physician or hospital;

(5) A detailed description of the incident giving rise to the claim and the factual basis upon which it is claimed the Maritime Administration is liable for the claim;

(6) A description of any property damage or loss, including the identity of the owner, if other than the claimant, as applicable;

(7) The nature and extent of the injury, as applicable;

(8) The full name, title, if any, and address of any witness to the incident and a brief statement of the witness' knowledge of the incident;

(9) A description of any insurance carried by the claimant or owner of the property and the status of any insurance claim arising from the incident; and

(10) An agreement by the claimant to accept the total amount claimed in full satisfaction and final settlement of the claim, lien or subrogation claim on the claimed amount, or any assignment of the claim.

(b) A claimant or duly authorized agent or legal representative must sign in ink a claim and any amendment to that claim. The claim shall include a statement that the information provided is true and correct to the best of the claimant's knowledge, information, and belief. If the person's signature does not include the first name, middle initial, if any, and surname, that information must be included in the claim. A married woman must sign her claim in her given name, *e.g.,* ''Mary A. Doe,'' rather than ''Mrs. John Doe.''

§ 327.26 Evidence supporting a claim.

(a) The claimant shall present any evidence in the claimant's possession that supports the claim. This evidence shall include, if available, statements of witnesses, accident or casualty reports, photographs and drawings.

(b) Notwithstanding anything in these regulations, the claimant shall provide such additional reasonable documents and evidence as requested by the Maritime Administration with respect to the claim. Failure to respond to reasonable requests for additional information and documentation can result in a determination that a valid claim has not been submitted.

§ 327.27 Proof of amount claimed for personal injury.

The following evidence must be presented when appropriate in claims:

(a) Itemized medical, hospital, and burial bills.

(b) A written report by the attending physician including:

(1) The nature and extent of the injury and the treatment;

(2) The necessity and reasonableness of the various medical expenses incurred;

(3) Duration of time injuries prevented or limited employment;

(4) Past, present, and future limitations on employment;

(5) Duration and extent of pain and suffering and of any disability or physical disfigurement;

(6) A current prognosis;

(7) Any anticipated medical expenses;

(8) Any past medical history of the claimant relevant to the particular injury alleged; and

(9) If required by the Maritime Administration, an examination by an independent medical facility or physician to provide independent medical evidence against which to evaluate the written report of the claimant's physician. The Maritime Administration determines the need for this examination, makes mutually convenient arrangements for such an examination, and bears the costs thereof.

(c) All hospital records or other medical documents from either this injury or any relevant past injury.

(d) If the claimant is employed, a written statement by the claimant's employer certifying the claimant's:

(1) Age;

(2) Occupation;

(3) Hours of employment;

(4) Hourly rate of pay or weekly salary;

(5) Time lost from work as a result of the incident; and

(6) Claimant's actual period of employment, full-time or part-time, and any effect of the injury upon such employment to support claims for lost earnings.

(e) If the claimant is self-employed, written statements, or other evidence showing:

(1) The amount of earnings actually lost; and

(2) The Federal tax return if filed for the three previous years.

(f) If the claim arises out of injuries to a person providing services to the claimant, statement of the cost necessarily incurred to replace the services to which claimant is entitled under law.

§ 327.28 Proof of amount claimed for loss of, or damage to, property.

The following evidence must be presented when appropriate:

(a) For each particular lost item, evidence of its value such as a bill of sale and a written appraisal, or two written appraisals, from separate disinterested dealers or brokers, market quotations, commercial catalogs, or other evidence of the price at which like property can be obtained in the community. The Maritime Administration may waive these requirements when circumstances warrant. The reasonable cost of any appraisal may be included as an element of damage if not deductible from any bill submitted to claimant.

(b) For each particular damaged item which can be economically repaired, evidence of cost of repairs such as a receipted bill and one estimate, or two estimates, from separate disinterested repairmen. The Maritime Administration may waive these requirements when circumstances warrant. The reasonable cost of any estimate may be included as an element of damage if not deductible from any repair bill submitted to claimant.

(c) For any claim for property damage which may result in payment in excess of $20,000.00, a survey or appraisal shall be performed as soon as practicable after the damage accrues, and, unless waived in writing, shall be performed jointly with a government representative.

(d) If the item is so severely damaged that it cannot be economically repaired or used, it shall be treated as a lost item.

(e) If a claim includes loss of earnings or use during repairs to the damaged property, the following must also be furnished and supported by competent evidence:

(1) The date the property was damaged;

(2) The name and location of the repair facility;

(3) The beginning and ending dates of repairs and an explanation of any delay between the date of damage and the beginning date;

(4) A complete description of all repairs performed, segregating any work performed for the owner's account and not attributable to the incident involved, and the costs thereof;

(5) The date and place the property was returned to service after completion of repairs, and an explanation, if applicable, of any delay;

(6) Whether or not a substitute for the damaged property was available. If a substitute was used by the claimant during the time of repair, an explanation of the necessity of using the substitute, how it was used, and for how long, and the costs involved. Any costs incurred that would have been similarly incurred by the claimant in using the damaged property must be identified;

(7) Whether or not during the course of undergoing repairs the property would have been used, and an explanation submitted showing the identity of the person who offered that use, the terms of the offer, time of prospective service, and rate of compensation; and

(8) If at the time of damage the property was under charter or hire, or was otherwise employed, or would have been employed, the claimant shall submit a statement of operating expenses that were, or would have been, incurred. This statement shall include wages and all bonuses which would have been paid, the value of fuel and the value of consumable stores, separately stated, which would have been consumed, and all other costs of operation which would have been incurred including, but not limited to, license and parking fees, personnel expenses, harbor fees, wharfage, dockage, shedding, stevedoring, towage, pilotage, inspection, tolls, lockage, anchorage and moorage, grain elevation, storage, and customs fees.

(f) For each item which is lost, actual or constructive, proof of ownership.

§ 327.29 Effect of other payments to claimant.

The total amount to which the claimant may be entitled is normally computed as follows:

(a) The total amount of the loss, damage, or personal injury suffered for which the United States is liable, less any payment the claimant has received from the following sources:

(1) The military member or civilian employee who caused the incident;

(2) The military member's or civilian employee's insurer; and

(3) Any joint tort-feasor or insurer.

(b) No deduction is generally made for any payment the claimant has received by way of voluntary contributions, such as donations of charitable organizations.

§ 327.30 Statute of limitations for AEA and claim requirements.

A civil suit must be filed within two years of the Accrual Date. No civil suit may be brought until the earlier occurrence of either the denial of a claim or the presumptive denial of the claim after 6 months from the date the claim was properly presented in writing to the Maritime Administration.

§ 327.31 Statute of limitations not tolled by administrative consideration of claims.

The statute of limitations for filing a civil action under 46 U.S.C. § 30101(b) is not tolled by MarAd's administrative consideration of a claim.

§ 327.32 Notice of claim acceptance or denial.

The Maritime Administration shall give prompt notice in writing of the acceptance or denial of each claim in whole or in part, by mail to the last known address of, or by personal delivery to, the claimant or the claimant's legal representative. In the case of denial, such notice shall contain a brief statement of the reason for such a denial.

§ 327.33 Claim denial presumption.

If the Maritime Administration fails to give written notice of acceptance or denial of a claim in accordance with § 327.30 of this part within 6 months following the date of receipt of such a claim by the proper person designated in § 327.24(b) of this part, such claim shall be presumed to have been denied by the Maritime Administration.

§ 327.34 Court action.

No person, surviving dependent or beneficiary, or legal representative, having a claim specified under 46 U.S.C. 30101(a) against the Maritime Administration, shall institute a court action against the Maritime Administration unless an administrative claim has previously been properly presented and filed in accordance with § 327.22, § 327.23, and § 327.24 of this part, and such administrative claim has been subsequently denied in accordance with § 327.32 or § 327.33 of this part.

Subpart C—Other Admiralty Claims.

§ 327.40 Other Admiralty Claims.

(a) Admiralty claims caused by United States owned and operated vessels on navigable waters or otherwise that are not covered under the Clarification Act (50 U.S.C. app. 1291(a)), the Admiralty Extension Act (46 U.S.C. 30101) or the Contracts Disputes Act (41 U.S.C. 601 *et seq.*) may be filed with the Maritime Administration in accordance with § 327.40–52 of this part.

(b) A civil action against the United States for admiralty claims caused by United States owned and operated vessels on navigable waters or otherwise that are not covered under the Clarification Act (50 U.S.C. app. 1291(a)), the Admiralty Extension Act (46 U.S.C. 30101) or the Contracts Disputes Act (41 U.S.C. 601 *et seq.*) may be brought without the filing of an administrative claim. This Part III sets forth the optional procedure for filing such claims with the Maritime Administration in advance of litigation. Once litigation is filed, the authority to handle such claims is vested with the Justice Department, not the agency.

(c) Proceeding against the United States pursuant to the requirements this Part III is not a requirement for filing suit against the United States of America, acting by and through the Maritime Administration, with respect to such admiralty claims.

§ 327.41 Definitions.

(a) Accrual Date. The day on which the alleged wrongful act or omission results in injury or damage for which a claim is made.

(b) Claim. A written notification of an incident, signed by the claimant, describing the incident and explaining why the United States is liable. The claim shall be accompanied by a demand for the payment of a sum certain of money, with a statement as to how that sum certain was calculated and all documents supporting the amount claimed. Where damages for medical injuries are made, the doctor's statement relating the injuries to the accident should be attached as well as medical release forms for each treating physician, hospital, and medical care provider.

§ 327.42 Who may present claims.

(a) General rules:

(1) A claim for property loss or damage may be presented by anyone having an interest in the property, including an insurer or other subrogee.

(2) A claim for personal injury may be presented by the person injured.

(3) A claim based on death may be presented by the executor or administrator of the decedent's estate, or any other person legally entitled to assert such a claim under local law. The claimant's status must be stated in the claim.

(4) A claim for medical, hospital, or burial expenses may be presented by any person who by reason of family relationship has, in fact, incurred the expenses.

(5) A joint claim must be presented in the names of and signed by, the joint claimants, and the settlement must be made payable to the joint claimants.

(b) A claim may be presented by a duly authorized agent, legal representative or survivor, if it is presented in the name of the claimant. If the claim is not signed by the claimant, the agent, legal representative, or survivor shall indicate their title or legal capacity and provide evidence of their authority to present the claim.

(c) Where the same claimant has a claim for damage to or loss of property and a claim for personal injury or a claim based on death arising out of the same incident, they must be combined in one claim.

§ 327.43 Insurance and other subrogated claims.

(a) The claims of an insured (subrogor) and an insurer (subrogee) for damages arising out of the same incident constitute a single claim.

(b) An insured (subrogor) and an insurer (subrogee) may file a claim jointly or separately. If the insurer has fully reimbursed the insured, payment will only be made to the insurer. If separate claims are filed, the settlement will be made payable to each claimant to the extent of that claimant's undisputed interest. If joint claims are filed, the settlement will be sent to the insurer.

(c) Each claimant shall include with a claim, a written disclosure concerning insurance coverage including:

(1) The names and addresses of all insurers;

(2) The kind and amount of insurance;

(3) The policy number; and

(4) Whether a claim has been or will be presented to an insurer, and, if so, the amount of that claim; and whether the insurer has paid the claim in whole or in part, or has indicated payment will be made.

(d) Each subrogee shall substantiate an interest or right to file a claim by appropriate documentary evidence and shall support the claim as to liability and measure of damages in the same manner as required of any other claimant. Documentary evidence of payment to a subrogor does not constitute evidence of liability of the United States or conclusive evidence of the amount of damages. The Maritime Administration makes an independent determination on the issues of fact and law based upon the evidence of record.

§ 327.44 Actions by claimant.

(a) Form of claim. The claim should meet the requirements of § 327.44 of this part.

(b) Presentation. The claim must be presented in writing to the Office of Chief Counsel, Attn: Chief Counsel, Maritime Administration, Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590–0001.

§ 327.45 Contents of a claim.

(a) A properly filed claim shall include the following, however, any of the following requirements may be waived by the Maritime Administration:

(1) Identification of the Maritime Administration as the agency whose act or omission gave rise to the claim;

(2) The full name and mailing address of the claimant. If this mailing address is not claimant's residence, the claimant shall also include residence address;

(3) The date, time, and place of the incident giving rise to the claim;

(4) The amount claimed, in a sum certain, supported by independent evidence of property damage or loss, personal injury, or death, as applicable together with supporting medical records and a HIPPA compliant medical waiver for each treating physician, hospital, or medical provider;

(5) A detailed description of the incident giving rise to the claim and the factual basis upon which it is claimed the United States is liable for the claim;

(6) A description of any property damage or loss, including the identity of the owner, if other than the claimant, as applicable;

(7) The nature and extent of the injury, as applicable;

(8) The full name, title, if any, and address of any witness to the incident and a brief statement of the witness' knowledge of the incident;

(9) A description of any insurance carried by the claimant or owner of the property and the status of any insurance claim arising from the incident; and

(10) An agreement by the claimant to accept the total amount claimed in full satisfaction and final settlement of the claim, lien, or subrogation claim on the claimed amount, or any assignment of the claim.

(b) A claimant or duly authorized agent or legal representative must sign in ink a claim and any amendment to that claim. The claim shall include a statement that the information provided is true and correct to the best of the claimant's knowledge, information, and belief. If the person's signature does not include the first name, middle initial, if any, and surname, that information must be included in the claim. A married woman must sign her claim in her given name, *e.g.,* ''Mary A. Doe,'' rather than ''Mrs. John Doe.''

§ 327.46 Evidence supporting a claim.

(a) The claimant should present any evidence in the claimant's possession that supports the claim. This evidence shall include, if available, statements of witnesses, accident or casualty reports, photographs and drawings.

(b) Notwithstanding anything in these regulations, the claimant shall provide such additional documents and evidence as requested by the Maritime Administration with respect to the claim. Failure to respond to reasonable requests for additional information and documentation can result in a determination that a proper claim has not been submitted.

§ 327.47 Proof of amount claimed for personal injury.

The following evidence must be presented when appropriate in claims:

(a) Itemized medical, hospital, and burial bills.

(b) A written report by the attending physician including:

(1) The nature and extent of the injury and the treatment;

(2) The necessity and reasonableness of the various medical expenses incurred;

(3) Duration of time injuries prevented or limited employment;

(4) Past, present, and future limitations on employment;

(5) Duration and extent of pain and suffering and of any disability or physical disfigurement;

(6) A current prognosis;

(7) Any anticipated medical expenses;

(8) Any past medical history of the claimant relevant to the particular injury alleged; and

(9) At the request of the Maritime Administration, an examination by an independent medical facility or physician may be required to provide independent medical evidence against which to evaluate the written report of the claimant's physician. The Maritime Administration determines the need for this examination, makes mutually convenient arrangements for such an examination, and bears the costs thereof.

(c) All hospital records or other medical documents from either this injury or any relevant past injury.

(d) If the claimant is employed, a written statement by the claimant's employer certifying the claimant's:

(1) Age;

(2) Occupation;

(3) Hours of employment;

(4) Hourly rate of pay or weekly salary;

(5) Time lost from work as a result of the incident; and

(6) Claimant's actual period of employment, full-time or part-time, and any effect of the injury upon such employment to support claims for lost earnings.

(e) If the claimant is self-employed, written statements, or other evidence showing:

(1) The amount of earnings actually lost, and

(2) The Federal tax return if filed for the three previous years.

(f) If the claim arises out of injuries to a person providing services to the claimant, statement of the cost necessarily incurred to replace the services to which claimant is entitled under law.

§ 327.48 Proof of amount claimed for loss of, or damage to, property.

The following evidence should be presented when appropriate:

(a) For each particular lost item, evidence of its value such as a bill of sale and a written appraisal, or two written appraisals, from separate disinterested dealers or brokers, market quotations, commercial catalogs, or other evidence of the price at which like property can be obtained in the community. The Maritime Administration may waive these requirements when circumstances warrant. The reasonable cost of any appraisal may be included as an element of damage if not deductible from any bill submitted to claimant.

(b) For each particular damaged item which can be economically repaired, evidence of cost of repairs such as a receipted bill and one estimate, or two estimates, from separate disinterested repairmen. The Maritime Administration may waive these requirements when circumstances warrant. The reasonable cost of any estimate may be included as an element of damage if not deductible from any repair bill submitted to claimant.

(c) For any claim which may result in payment in excess of $20,000.00, a survey or appraisal shall be performed as soon as practicable after the damage accrues, and, unless waived in writing, shall be performed jointly with a government representative.

(d) If the item is so severely damaged that it cannot be economically repaired or used, it shall be treated as a lost item.

(e) If a claim includes loss of earnings or use during repairs to the damaged property, the following must also be furnished and supported by competent evidence:

(1) The date the property was damaged;

(2) The name and location of the repair facility;

(3) The beginning and ending dates of repairs and an explanation of any delay between the date of damage and the beginning date;

(4) A complete description of all repairs performed, segregating any work performed for the owner's account and not attributable to the incident involved, and the costs thereof;

(5) The date and place the property was returned to service after completion of repairs, and an explanation, if applicable, of any delay;

(6) Whether or not a substitute for the damaged property was available. If a substitute was used by the claimant during the time of repair, an explanation of the necessity of using the substitute, how it was used, and for how long, and the costs involved. Any costs incurred that would have been similarly incurred by the claimant in using the damaged property must be identified;

(7) Whether or not during the course of undergoing repairs the property would have been used, and an explanation submitted showing the identity of the person who offered that use, the terms of the offer, time of prospective service, and rate of compensation; and

(8) If at the time of damage the property was under charter or hire, or was otherwise employed, or would have been employed, the claimant shall submit a statement of operating expenses that were, or would have been, incurred. This statement shall include wages and all bonuses which would have been paid, the value of fuel and the value of consumable stores, separately stated, which would have been consumed, and all other costs of operation which would have been incurred including, but not limited to, license and parking fees, personnel expenses, harbor fees, wharfage, dockage, shedding, stevedoring, towage, pilotage, inspection, tolls, lockage, anchorage and moorage, grain elevation, storage, and customs fees.

(f) For each item which is lost, actual or constructive, proof of ownership.

§ 327.49 Effect of other payments to claimant.

The total amount to which the claimant may be entitled is normally computed as follows:

(a) The total amount of the loss, damage, or personal injury suffered for which the United States is liable, less any payment the claimant has received from the following sources:

(1) The military member or civilian employee who caused the incident;

(2) The military member's or civilian employee's insurer; and

(3) Any joint tort-feasor or insurer.

(b) No deduction is generally made for any payment the claimant has received by way of voluntary contributions, such as donations of charitable organizations.

§ 327.50 Statute of limitations for other admiralty claims and claim requirements.

A civil suit must be filed within the statute of limitations of the specific admiralty claim. The start date for such statute of limitations determinations shall be the Accrual Date.

§ 327.51 Statute of limitations not tolled by administrative consideration of claims.

The statute of limitations for filing a civil action under 46 U.S.C. 30101(b) is not tolled by the Maritime Administration's administrative consideration of a claim.

§ 327.52 Notice of claim acceptance or denial.

The Maritime Administration shall give prompt notice in writing of the acceptance or denial of each claim in whole or in part, by mail to the last known address of, or by personal delivery to, the claimant or the claimant's legal representative. In the case of denial, such notice shall contain a brief statement of the reason for such a denial.

Dated: January 27, 2012.

By Order of the Maritime Administrator.

Julie Agarwal,

Secretary, Maritime Administration.

[FR Doc. 2012–2253 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–81–P

Notices

Federal Register
Vol. 77, No. 22
Thursday, February 2, 2012

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

Farm Service Agency

Commodity Credit Corporation

Information Collection Request; Debt Settlement Policies and Procedures

AGENCY: Farm Service Agency and Commodity Credit Corporation, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) and the Commodity Credit Corporation (CCC) are requesting comments from all interested individuals and organizations on an extension of a currently approved information collection that supports the FSA and CCC Debt Settlement Policies and Procedures regulations.

DATES: We will consider comments that we receive April 2, 2012.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, OMB control number, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Thomas F. Harris II, Claims Program Specialist, Financial Management Division, Office of Budget and Finance, Farm Service Agency, USDA, STOP 0581, 355 E Street SW., Suite 11–181B, Washington, DC 20024.

Comments also should be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be obtained from Thomas F. Harris II at the above address.

FOR FURTHER INFORMATION CONTACT: Thomas F. Harris II, Claims Program Specialist, telephone (202) 772–6014.

SUPPLEMENTARY INFORMATION:

Title: Debt Settlement Policies and Procedures.

OMB Control Number: 0560–0146.

Expiration Date of Approval: July 31, 2012.

Type of Request: Extension with no revision.

Abstract: This information collection is needed to enable FSA and CCC to effectively administer the regulations at 7 CFR 792 (FSA) and 7 CFR 1403 (CCC) on debt settlement policies and procedures and on the identification of and settlement of outstanding claims. Collection of outstanding debts owed to FSA or to CCC can be effected by installment payments if a debtor furnishes satisfactory evidence of inability to pay a claim in full, and if the debtor specifically requests an installment agreement. Part of the requirement is that the debtor furnishes this request in writing and with a financial statement or other information that would disclose a debtor's assets and liabilities. This information is required in order to evaluate any proposed plan. Such requests for documentation furnished by the debtor are also used in the other collection tools employed by both FSA and CCC in managing debt settlement policies and procedures. If an installment agreement is approved, then a Promissory Note (CCC–279), or an approved alternative promissory note format, must be executed between the debtor and the FSA/CCC representative(s).

During the past two years, over $22,425,803.74 in debt collection for Farm Programs and for the Commodity Office were facilitated by the use of this requested information and 149 Promissory Notes were established between debtors and FSA and CCC from 10/01/2009 to 10/01/2011. Total active Note amount for the past two years is presently 228 total Promissory Notes (includes beginning outstanding notes (227); total notes established (149); notes defaulted (3), notes paid off in full (50); notes paid, small balance loans (41); notes written off (45) and notes discharged in Bankruptcy (09) with a beginning outstanding amount in 2009 of $31,131,509.78, and an ending outstanding amount of $22,425,803.74).

The Debt Collection Improvement Act of 1996 requires the head of an agency to take all appropriate steps to collect delinquent debts before discharging such debts. The current information collection forms and formats have been successfully used for the past several years and have become familiar tools for both the agency employees and for the producer. Thus, adequate forms and formats already exist and are in use. Developing new forms and formats could be costly and is not required to meet the demands of the Debt Collection Improvement Act of 1996. Nonetheless, comment is requested on how the forms and process may be improved, as specified below.

Estimate of burden: Public reporting burden for this information collection is estimated to average 1 hour per response. The average travel time, which is included in the total burden, is estimated to be 1 hour per respondent.

Respondents: Producers participating in FSA and CCC programs.

Estimated number of Annual Respondents: 300.

Estimated number of Responses per Respondent: 1.

Estimated Total Annual Responses: 300.

Estimated Total Annual Burden on Respondents: 200 hours.

We are requesting comments on all aspects of this information collection and to help us to:

(1) Determine whether the continued collection of information is still necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Assess the accuracy of the FSA's estimate of burden including the validity of the methodology and assumptions used;

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

(4) 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.

All responses to this notice, including name and addresses when provided, will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Signed on January 27, 2012.

James Monahan,

Acting Administrator Farm Service Agency, and Executive Vice President, Commodity Credit Corporation.

[FR Doc. 2012–2259 Filed 2–1–12; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Summer Food Service Program; 2012 Reimbursement Rates

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the annual adjustments to the reimbursement rates for meals served in the Summer Food Service Program for Children. These adjustments address changes in the Consumer Price Index, as required under the Richard B. Russell National School Lunch Act. The 2012 reimbursement rates are presented as a combined set of rates to highlight simplified cost accounting procedures. The 2012 rates are also presented individually, as separate operating and administrative rates of reimbursement, to show the effect of the Consumer Price Index adjustment on each rate.

DATES: *Effective Date:* January 1, 2012.

FOR FURTHER INFORMATION CONTACT: Tina Namian, Head, CACFP and SFSP Section, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, United States Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302, (703) 305–2590.

SUPPLEMENTARY INFORMATION: This Program is listed in the Catalog of Federal Domestic Assistance under No. 10.559 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials (7 CFR part 3015, Subpart V, and final rule-related notice published at 48 FR 29114, June 24, 1983).

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This notice is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. Additionally, this notice has been determined to be exempt from formal review by the Office of Management and Budget under Executive Order 12866.

Definitions

The terms used in this notice have the meaning ascribed to them under 7 CFR part 225 of the Summer Food Service Program regulations.

Background

This notice informs the public of the annual adjustments to the reimbursement rates for meals served in the Summer Food Service Program (SFSP). In accordance with sections 12(f) (42 U.S.C. 1760(f)) and 13 (42 U.S.C. 1761) of the Richard B. Russell National School Lunch Act (NSLA), and SFSP regulations in 7 CFR part 225, the United States Department of Agriculture (USDA) announces the adjustments in SFSP payments for meals served to participating children during calendar year 2012.

The 2012 reimbursement rates are presented as a combined set of rates to highlight simplified cost accounting procedures. Reimbursement is based solely on a ''meals times rates'' calculation, without comparison to actual or budgeted costs.

Sponsors receive reimbursement that is determined by the number of reimbursable meals served multiplied by the combined rates for food service operations and administration. However, the combined rate is based on separate operating and administrative rates of reimbursement, each of which is adjusted differently for inflation.

Calculation of Rates

The combined rates are constructed from individually authorized operating and administrative reimbursements. Simplified procedures provide flexibility, enabling sponsors to manage their reimbursements to pay for any allowable cost, regardless of the cost category. Program sponsors remain responsible, however, for ensuring proper administration of the Program, while providing the best possible nutrition benefit to children.

The operating and administrative rates are calculated separately. However, the calculations of adjustments for both are based on the same set of changes in the *Food Away From Home* series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the United States Department of Labor. They represent a 2.87 percent increase in this series for the 12 month period, from November 2010 through November 2011 (from 227.512 in November 2010 to 234.046 in November 2011).

Table of 2012 Reimbursement Rates

Presentation of the 2012 maximum per meal rates for meals served to children in SFSP combines the results from the calculations of operational and administrative payments, which are further explained in this notice. The total amount of payments to State agencies for disbursement to SFSP sponsors will be based upon these adjusted combined rates and the number of meals of each type served. These adjusted rates will be in effect from January 1, 2012 through December 31, 2012.

SUMMER FOOD SERVICE PROGRAM

[2012 Reimbursement rates (combined)]

Per meal rates in whole or fractions of U.S. dollars	All states except Alaska and Hawaii		Alaska		Hawaii	
	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites
Breakfast	1.9350	1.8975	3.1325	3.0725	2.2650	2.2225
Lunch or Supper	3.3800	3.3250	5.4900	5.4000	3.9650	3.9000
Snack	0.7975	0.7800	1.3000	1.2725	0.9325	0.9100

Operating Rates

The portion of the SFSP rates for operating costs is based on payment amounts set in section 13(b)(1) of the NSLA (42 U.S.C. 1761(b)(1)). They are rounded down to the nearest whole cent, as required by section 11(a)(3)(B) of the NSLA (42 U.S.C. 1759a(a)(3)(B)).

SUMMER FOOD SERVICE PROGRAM

[Operating component of 2012 reimbursement rates]

Operating rates in U.S. dollars, rounded down to the nearest whole cent	All states except Alaska and Hawaii	Alaska	Hawaii
Breakfast	1.76	2.85	2.06
Lunch or Supper	3.06	4.97	3.59
Snack	0.71	1.16	0.83

Administrative Rates

The administrative cost component of the reimbursement is authorized under section 13(b)(3) of the NSLA (42 U.S.C. 1761(b)(3)). Rates are higher for sponsors of sites located in rural areas and for ''self-prep'' sponsors that prepare their own meals, at the SFSP site or at a central facility, instead of purchasing them from vendors. The administrative portion of SFSP rates are adjusted, either up or down, to the nearest quarter-cent.

SUMMER FOOD SERVICE PROGRAM

[Administrative component of 2012 reimbursement rates]

Administrative rates in U.S. dollars, adjusted, up or down, to the nearest quarter-cent	All states except Alaska and Hawaii		Alaska		Hawaii	
	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites	Rural or self-prep sites	All other types of sites
Breakfast	0.1750	0.1375	0.2825	0.2225	0.2050	0.1625
Lunch or Supper	0.3200	0.2650	0.5200	0.4300	0.3750	0.3100
Snack	0.0875	0.0700	0.1400	0.1125	0.1025	0.0800

Authority: Sections 9, 13, and 14, Richard B. Russell National School Lunch Act (42 U.S.C. 1758, 1761, and 1762a, respectively).

Dated: January 24, 2012.

Audrey Rowe,

Administrator.

[FR Doc. 2012–2358 Filed 2–1–12; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Utilities Service

Notice of Contract Proposals (NOCP) for Payments to Eligible Advanced Biofuel Producers

AGENCY: Rural Business-Cooperative Service and Rural Utilities Service, USDA.

ACTION: Notice.

SUMMARY: The Notice of Contract Proposals announces the availability of up to $25 million to make payments to advanced biofuel producers for the production of eligible advanced biofuels in Fiscal Year 2012. The 2008 Farm Bill provided $105 million in mandatory funding to support payments for advanced biofuels. The fiscal year 2012 Appropriations Act imposes a limitation of $65 million that can be used for these activities in 2012. Approximately $40 million will be used to pay producers for Fiscal Year 2011 fourth quarter and incremental payments.

DATES: Applications for participating in the Advanced Biofuel Payment Program for Fiscal Year 2012 were accepted from October 1, 2011, through October 31, 2011 in accordance with 7 CFR part 4288, subpart B, section 4288.120(b). Applications received after October 31, 2011, regardless of their postmark, will not be considered for Fiscal Year 2012 funds.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** for addresses concerning applications for the Advanced Biofuel Payment Program for Fiscal Year 2012 funds.

FOR FURTHER INFORMATION CONTACT: For information about the Fiscal Year 2012 applications and for Advanced Biofuel Payment Program assistance, please contact a USDA Rural Development Energy Coordinator, as provided in the **SUPPLEMENTARY INFORMATION** section of this Notice, or Diane Berger, USDA Rural Development, 1400 Independence Avenue SW., Room 6865, STOP 3225, Washington, DC 20250. Telephone: (202) 260–1508. Fax: (202) 720–2213. Email: *diane.berger@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Fiscal Year 2012 Applications for the Advanced Biofuel Payment Program

An applicant (unless the applicant is an individual) must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number, which can be obtained at no cost via a toll-free request line at 1–(866) 705–5711 or online at *http://fedgov.dnb.com/webform.* Complete applications were submitted to the Rural Development State Office in the State in which the applicant's principal place of business is located.

Universal Identifier and Central Contract Registration (CCR)

Unless exempt under 2 CFR 25.110, the applicant must:

(a) Be registered in the CCR prior to submitting an application or plan;

(b) Maintain an active CCR registration with current information at all times during which it has an active Federal award or an application or plan under consideration by the Agency; and

(c) Provide its DUNS number in each application or plan it submits to the Agency.

Rural Development Energy Coordinators

Note: Telephone numbers listed are not toll-free.

Alabama

Marcia Johnson, USDA Rural Development, Suite 601, Sterling Centre, 4121 Carmichael Road, Montgomery, AL 36106–3683, (334) 279–33453, *marcia.johnson@al.usda.gov*

Alaska

Chad Stovall, USDA Rural Development, 800 West Evergreen, Suite 201, Palmer, AK 99645–6539, (907) 761–7718, *chad.stovall@ak.usda.gov*

American Samoa (See Hawaii)

Arizona

Gary Mack, USDA Rural Development, 230 North First Avenue, Suite 206, Phoenix, AZ 85003–1706, (602) 280–8700, *gary.mack@az.usda.gov*

Arkansas

Laura Tucker, USDA Rural Development, 700 West Capitol Avenue, Room 3416, Little Rock, AR 72201–3225, (501) 301–3280, *Laura.Tucker@ar.usda.gov*

California

Philip Brown, USDA Rural Development, 430 G Street, #4169, Davis, CA 95616, (530) 792–5811, *Phil.brown@ca.usda.gov*

Colorado

Janice Pond, USDA Rural Development, Denver Federal Center, Building 56, Room 2300, P.O. Box 25426, Denver, CO 80225–0426, (720) 544–2907, *janice.pond@co.usda.gov*

Commonwealth of the Northern Marianas Islands–CNMI (see Hawaii)

Connecticut (see Massachusetts)

Delaware/Maryland

Bruce Weaver, USDA Rural Development, 1221 College Park Drive, Suite 200, Dover, DE 19904, (302) 857–3629, *Bruce.Weaver@de.usda.gov*

Federated States of Micronesia (See Hawaii)

Florida/Virgin Islands

Angela Prioleau, USDA Rural Development, 4440 NW. 25th Place, Gainesville, FL 32606, (352) 338–3412, *Angela.Prioleau@fl.usda.gov*

Georgia

J. Craig Scroggs, USDA Rural Development, 111 E. Spring St., Suite B, Monroe, GA 30655, Phone (770) 267–1413 ext. 113, *craig.scroggs@ga.usda.gov*

Guam (See Hawaii)

Hawaii/Guam/Republic of Palau/Federated States of Micronesia/Republic of the Marshall Islands/American Samoa/Commonwealth of the Northern Marianas Islands—CNMI

Tim O'Connell, USDA Rural Development, Federal Building, Room 311, 154 Waianuenue Avenue, Hilo, HI 96720, (808) 933–8313, *Tim.Oconnell@hi.usda.gov*

Idaho

Brian Buch, USDA Rural Development, 9173 W. Barnes Drive, Suite A1, Boise, ID 83709, (208) 378–5623, *Brian.Buch@id.usda.gov*

Illinois

Mary Warren, USDA Rural Development, 2118 West Park Court, Suite A, Champaign, IL 61821, (217) 403–6218, *Mary.Warren@il.usda.gov*

Indiana

Jerry Hay, USDA Rural Development, 5975 Lakeside Boulevard, Indianapolis, IN 46278, (812) 346–3411, Ext. 126, *Jerry.Hay@in.usda.gov*

Iowa

Kate Sand, USDA Rural Development, 909 E. 2nd Avenue, Suite C, Indianola, IA 50125, (515) 961–5365 Ext. 13060, *kate.sand@ia.usda.gov*

Kansas

David Kramer, USDA Rural Development, 1303 SW. First American Place, Suite 100, Topeka, KS 66604–4040, (785) 271–2730, *david.kramer@ks.usda.gov*

Kentucky

Scott Maas, USDA Rural Development, 771 Corporate Drive, Suite 200, Lexington, KY 40503, (859) 224–7435, *scott.maas@ky.usda.gov*

Louisiana

Kevin Boone, USDA Rural Development, 905 Jefferson Street, Suite 320, Lafayette, LA 70501, (337) 262–6601, Ext. 133, *Kevin.Boone@la.usda.gov*

Maine

Beverly Stone, USDA Rural Development, 967 Illinois Avenue, Suite 4, P.O. Box 405, Bangor, ME 04402–0405, (207) 990–9125, *beverly.stone@me.usda.gov*

Maryland (see Delaware)

Massachusetts/Rhode Island/Connecticut

Charles W. Dubuc, USDA Rural Development, 60 Quaker Lane, Suite 44, Warwick, RI 02886, (401) 822–8867, *Charles.Dubuc@ma.usda.gov*

Michigan

Rick Vanderbeek, USDA Rural Development, 3001 Coolidge Road, Suite 200, East Lansing, MI 48823, (517) 324–5218, *rick.vanderbeek@mi.usda.gov*

Minnesota

Ron Omann, USDA Rural Development, 375 Jackson St., Suite 410, St. Paul, MN 55101, (651) 602–7796, *Ron.Omann@mn.usda.gov*

Mississippi

G. Gary Jones, USDA Rural Development, 100 W. Capital Street, Suite 831, Jackson, MS 39269, (601) 965–5457, *george.jones@ms.usda.gov*

Missouri

Matt Moore, USDA Rural Development, 601 Business Loop 70 West, Parkade Center, Suite 235, Columbia, MO 65203, (573) 876–9321, *matt.moore@mo.usda.gov*

Montana

John Guthmiller, USDA Rural Development, 2229 Boot Hill Court, P.O. Box 850, Bozeman, MT 59771, (406) 585–2550, *john.guthmiller@mt.usda.gov*

Nebraska

Debra Yocum, USDA Rural Development, 100 Centennial Mall North, Room 152, Federal Building, Lincoln, NE 68508, (402) 437–5554, *Debra.Yocum@ne.usda.gov*

Nevada

Mark Williams, USDA Rural Development, 1390 South Curry Street, Carson City, NV 89703, (775) 887–1222, Ext 116, *mark.williams@nv.usda.gov*

New Hampshire (See Vermont)

New Jersey

Victoria Fekete, USDA Rural Development, 8000 Midlantic Drive, Suite 500N, Mt. Laurel, NJ 08054, (856) 787–7752, *Victoria.Fekete@nj.usda.gov*

New Mexico

Jesse Monfort Bopp, USDA Rural Development, 6200 Jefferson Street NE., Room 255, Albuquerque, NM 87109, (505) 761–4952, *Jesse.bopp@nm.usda.gov*

New York

Scott Collins, USDA Rural Development, 9025 River Road, Marcy, NY 13403, (315) 736–3316 Ext. 127, *scott.collins@ny.usda.gov*

North Carolina

David Thigpen, USDA Rural Development, 4405 Bland Rd., Suite 260, Raleigh, NC, 27609, (919) 873–2065, *David.Thigpen@nc.usda.gov*

North Dakota

Dennis Rodin, USDA Rural Development, Federal Building, Room 208, 220 East Rosser Avenue, P.O. Box 1737, Bismarck, ND 58502–1737, (701) 530–2068, *Dennis.Rodin@nd.usda.gov*

Ohio

Randy Monhemius, USDA Rural Development, Federal Building, Room 507, 200 North High Street, Columbus, OH 43215–2418, (614) 255–2424, *Randy.Monhemius@oh.usda.gov*

Oklahoma

Jody Harris, USDA Rural Development, 100 USDA, Suite 108, Stillwater, OK 74074–2654, (405) 742–1036, *Jody.harris@ok.usda.gov*

Oregon

Don Hollis, USDA Rural Development, 200 SE. Hailey Ave, Suite 105, Pendleton, OR 97801, (541) 278–8049, Ext. 129, *Don.Hollis@or.usda.gov*

Pennsylvania

Amanda Krugh, USDA Rural Development, 1 Credit Union Place, Suite 330, Harrisburg, PA 17110–2996, (717) 237–2289, *Amanda.Krugh@pa.usda.gov*

Puerto Rico

Luis Garcia, USDA Rural Development, IBM Building, 654 Munoz Rivera Avenue, Suite 601, Hato Rey, PR 00918–6106, (787) 766–5091, Ext. 151, *Luis.Garcia@pr.usda.gov*

Republic of Palau (See Hawaii)

Republic of the Marshall Islands (See Hawaii)

Rhode Island (see Massachusetts)

South Carolina

Shannon Legree, USDA Rural Development, Strom Thurmond Federal Building, 1835 Assembly Street, Room 1007, Columbia, SC 29201, (803) 253–3150, *Shannon.Legree@sc.usda.gov*

South Dakota

Kenneth Lynch, USDA Rural Development, Federal Building, Room 210, 200 4th Street SW., Huron, SD 57350, (605) 352–1120, *ken.lynch@sd.usda.gov*

Tennessee

Will Dodson, USDA Rural Development, 3322 West End Avenue, Suite 300, Nashville, TN 37203–1084, (615) 783–1350, *will.dodson@tn.usda.gov*

Texas

Billy Curb, USDA Rural Development, Federal Building, Suite 102, 101 South Main Street, Temple, TX 76501, (254) 742–9775, *billy.curb@tx.usda.gov*

Utah

Roger Koon, USDA Rural Development, Wallace F. Bennett Federal Building, 125 South State Street, Room 4311, Salt Lake City, UT 84138, (801) 524–4301, *Roger.Koon@ut.usda.gov*

Vermont/New Hampshire

Cheryl Ducharme, USDA Rural Development, 89 Main Street, 3rd Floor, Montpelier, VT 05602, (802) 828–6083, *cheryl.ducharme@vt.usda.gov*

Virginia

Laurette Tucker, USDA Rural Development, 1606 Santa Rosa Road, Suite 238, Richmond, VA 23229, (434) 392–4906, Ext. 126 or (804) 287–1606, *Laurette.Tucker@va.usda.gov*

Virgin Islands (see Florida)

Washington

Mary Traxler, USDA Rural Development, 1835 Black Lake Blvd. SW., Suite B, Olympia, WA 98512, (360) 704–7762, *Mary.Traxler@wa.usda.gov*

West Virginia

Lisa Sharp, USDA Rural Development, 1550 Earl Core Road, Suite 101, Morgantown, WV 26505, (304) 284–4871, *lisa.sharp@wv.usda.gov*

Wisconsin

Brenda Heinen, USDA Rural Development, 4949 Kirschling Court, Stevens Point, WI 54481, (715) 345–7615, Ext. 139, *Brenda.Heinen@wi.usda.gov*

Wyoming

Jon Crabtree, USDA Rural Development, Dick Cheney Federal Building, 100 East B Street, Room 1005, P.O. Box 11005, Casper, WY 82602, (307) 233–6719, *Jon.Crabtree@wy.usda.gov*

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements associated with the Advanced Biofuel Payments Program, as covered in this Notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0057.

Overview

Federal Agency Name: Rural Business-Cooperative Service (an agency of the United States Department of Agriculture in the Rural Development mission area).

Contract Proposal Title: Advanced Biofuel Payment Program.

Announcement Type: Annual announcement.

Catalog of Federal Domestic Assistance Number. The CFDA number for this Notice is 10.867.

Dates: The Advanced Biofuels Program sign-up period for Fiscal Year 2012 was October 1 to October 31, 2011.

Availability of Notice and Rule. This Notice and the interim rule for the Advanced Biofuel Payment Program are available on the USDA Rural Development Web site at *http://www.rurdev.usda.gov/BCP_Biofuels.html.*

I. Funding Opportunity Description

A. *Purpose of the Program.* The purpose of this program is to support and ensure an expanding production of advanced biofuels by providing payments to eligible advanced biofuel producers. Implementing this program not only promotes the Agency's mission of promoting sustainable economic development in rural America, but is an important part of achieving the Administration's goals for increased biofuel production and use by providing economic incentives for the production of advanced biofuels.

B. *Statutory Authority.* This program is authorized under 7 U.S.C 8105.

C. *Definition of Terms.* The definitions applicable to this Notice are published at 7 CFR 4288.102.

II. Award Information

A. *Available funds.* The Agency is authorizing up to $25 million for this program in Fiscal Year 2012. The 2008 Farm Bill provided $105 million in mandatory funding to support payments for advanced biofuels. The fiscal year 2012 Appropriations Act imposes a limitation of $65 million that can be used for these activities in 2012. Approximately $40 million will be used to pay producers for Fiscal Year 2011 fourth quarter and incremental payments.

B. *Approximate number of awards.* The number of awards will depend on the number of participating advanced biofuel producers.

C. *Range of amounts of each payment.* There is no minimum or maximum payment amount that an individual producer can receive. The amount that each producer receives will depend on the number of eligible advanced biofuel producers participating in the program for Fiscal Year 2012, the amount of advanced biofuels being produced by such advanced biofuel producers, and the amount of funds available.

D. *Contract.* For producers participating in this program for the first time in Fiscal Year 2012, a contract will need to be entered into with the Agency and the contract period will continue indefinitely until terminated as provided for in 7 CFR 4288.121(d). For producers that participated in this program in Fiscal Year 2011, the contract period continues indefinitely until terminated as provided for in 7 CFR 4288.121(d).

E. *Production period.* Payments to participating advanced biofuel producers under this Notice will be made on actual eligible advanced biofuels produced from October 1, 2011 through September 30, 2012.

F. *Type of instrument.* Payment.

III. Eligibility Information

A. *Eligible applicants.* To be eligible for this program, an applicant must meet the eligibility requirements specified in 7 CFR 4288.110.

B. *Biofuel eligibility.* To be eligible for payment, an advanced biofuel must meet the eligibility requirements specified in 7 CFR 4288.111.

C. *Payment eligibility.* To be eligible for program payments, an advanced biofuel producer must maintain the records specified in 7 CFR 4288.113.

IV. Fiscal Year 2012 Application and Submission Information

A. *Address to request applications.* Annual Application, Contract, and Payment Request forms are available from the USDA, Rural Development State Office, Rural Development Energy Coordinator. The list of Rural Development Energy Coordinators is provided in the **SUPPLEMENTARY INFORMATION** section of this Notice.

B. *Content and form of submission.* The enrollment provisions, including application content and form of submission, are specified in 7 CFR 4288.120 and 4288.121.

C. *Submission dates and times.*

(1) *Enrollment.* Advanced biofuel producers who expect to produce eligible advanced biofuel at any time during Fiscal Year 2012 must have enrolled in the program by October 31, 2011, even if the producer has an existing contract with the Agency. Applications received after this date, regardless of their postmark, will not be considered by the Agency for Fiscal Year 2012 funds. Producers who participated in this Program in Fiscal Year 2009, Fiscal Year 2010, and/or Fiscal Year 2011 must have submitted a new application under this Notice to be considered for Fiscal Year 2012 funds.

(2) *Payment applications.* Advanced biofuel producers must submit Form RD 4288–3, ''Advanced Biofuel Payment Program—Payment Request,'' for each of the four Federal fiscal quarters of Fiscal Year 2012. Each form must be submitted by 4:30 p.m. on January 31, 2012, for the first quarter; April 30, 2012, for the second quarter; July 31, 2012, for the third quarter; and October 31, 2012, for the fourth quarter. Neither complete nor incomplete payment applications received after such dates and times will be considered, regardless of the postmark on the application.

D. *Funding restrictions.* For Fiscal Year 2012, not more than 5 percent of the funds will be made available to eligible producers with a refining capacity (as determined for the prior fiscal year) exceeding 150,000,000 gallons of a liquid advanced biofuel per year or exceeding 15,900,000 million British Thermal Units of biogas and solid advanced biofuel per year. (In calculating whether a producer meets either of these capacities, production of all advanced biofuel facilities in which the producer has 50 percent or more ownership will be totaled.) The remaining funds will be made available to all other producers.

E. *Payment provisions.* Fiscal Year 2012 payments will be made according to the provisions specified in 7 CFR 4288.130 through 4288.137.

V. Administration Information

A. *Notice of eligibility.* The provisions of 7 CFR 4288.112 apply to this Notice. These provisions include notifying an applicant determined to be eligible for participation and assigning such applicant a Contract number and notifying an applicant determined to be ineligible, including the reason(s) the applicant was rejected and providing such applicant appeal rights as specified in 7 CFR 4288.103.

B. *Administrative and National Policy requirements.*

(1) *Review or appeal rights.* A person may seek a review of an adverse agency decision or appeal to the National Appeals Division as provided in 7 CFR 4288.103.

(2) *Compliance with other laws and regulations.* The provisions of 7 CFR 4288.104 apply to this Notice, which includes requiring advanced biofuel producers to be in compliance with other applicable Federal, State, and local laws.

(3) *Oversight and monitoring.* The provisions of 7 CFR 4288.105 apply to this Notice, which includes the right of the Agency to verify all payment applications and subsequent payments and the requirement that each eligible advanced biofuel producer make available at one place at all reasonable times for examination by representatives of USDA, all books, papers, records, contracts, scale tickets, settlement sheets, invoices, written price quotations, and other documents related to the program that are within the control of such advanced biofuel producer for not less than three years from each Program payment date.

(4) *Exception authority.* The provisions of 7 CFR 4288.107 apply to this Notice.

C. *Environmental review.* Rural Development's compliance with the National Environmental Policy Act of 1969 (NEPA) is implemented in its regulations at 7 CFR part 1940, subpart G. The Agency has reviewed the circumstances under which financial assistance may be provided under this Program and has determined that proposals that do not involve additional facility construction fall within the categorical exclusion from NEPA reviews provided for in 7 CFR 1940.310(c)(1). Applicants whose proposal involves additional facility construction should provide Form RD 1940–20, ''Request for Environmental Information,'' as part of their application. Rural Development will then determine whether the proposal is categorically excluded under 7 CFR 1940.310(c)(1) or whether additional actions are necessary to comply with 7 CFR part 1940, subpart G.

VI. Agency Contacts

For assistance on this payment program, please contact a USDA Rural Development Energy Coordinator, as provided in the **SUPPLEMENTARY INFORMATION** section of this Notice, or Diane Berger, USDA Rural Development, 1400 Independence Avenue SW., Room 6865, STOP 3225, Washington, DC 20250. Telephone: (202) 260–1508. Fax: (202) 720–2213. Email: *diane.berger@wdc.usda.gov.*

VII. Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

To file a complaint of discrimination write to USDA, Director, Office of Adjudication and Compliance, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call (800) 795–3272 (voice) or (202) 720–6382 (TDD). USDA is an equal opportunity provider, employer, and lender.

Dated: January 27, 2012.

Judith A. Canales,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2012–2240 Filed 2–1–12; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Notice of Funding Availability (NOFA) for Repowering Assistance Payments to Eligible Biorefineries

AGENCY: Rural Business-Cooperative Service and Rural Utilities Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces the acceptance of applications for payments to eligible biorefineries to encourage the

use of renewable biomass as a replacement fuel source for fossil fuels used to provide process heat or power in the operation of these eligible biorefineries. To be eligible for payments, biorefineries must have been in existence on or before June 18, 2008. The Notice announces the availability of approximately $25 million to make payments to eligible biorefineries in Fiscal Year 2012, which includes carry-over funds from Fiscal Year 2011.

DATES: Applications for participating in this program for Fiscal Year 2012 will be accepted from February 2, 2012 through June 1, 2012. Applications received after June 1, 2012, regardless of their postmark, will not be considered for Fiscal Year 2012 payments. If the actual deadline falls on a weekend or a federally-observed holiday, the deadline is the next Federal business day.

ADDRESSES: Application materials may be obtained by contacting USDA, Rural Development-Energy Division, Program Branch, Attention: Repowering Assistance Program, 1400 Independence Avenue SW., Stop 3225, Washington, DC 20250–3225.

Submit applications to USDA, Rural Development-Energy Division, Program Branch, Attention: Repowering Assistance Program, 1400 Independence Avenue SW., Stop 3225, Washington, DC 20250–3225.

FOR FURTHER INFORMATION CONTACT: For further information on this payment program, please contact Fred Petok, USDA, Rural Development, Business Programs Energy Division, 1400 Independence Avenue SW., Room 6870, STOP 3225, Washington, DC 20250–3225. Telephone: (202) 720–1400. Email: *frederick.petok@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection requirements associated with the Section 9004 Repowering Assistance Payments to Eligible Biorefineries program, as covered in this Notice, have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0058.

Overview

Federal Agency Name: Rural Business-Cooperative Service (an agency of the United States Department of Agriculture in the Rural Development mission area).

Payment Proposal Title: Repowering Assistance Program.

Announcement Type: Initial announcement.

Catalog of Federal Domestic Assistance Number. The CFDA number for this Notice is 10.866.

Dates: The Repowering Assistance Program application period for Fiscal Year 2012 is February 2, 2012 to June 1, 2012.

Availability of Notice and Rule. This Notice and the interim rule for the Repowering Assistance Program are available on the USDA Rural Development Web site at *http://www.rurdev.usda.gov/BCP_RepoweringAssistance.html.*

I. Funding Opportunity Description

A. *Purpose of the Program.* The purpose of this program is to provide financial incentives to biorefineries in existence on or before June 18, 2008, the date of the enactment of the Food, Conservation, and Energy Act of 2008 (the 2008 Farm Bill) (Pub. L. 110–246), to replace the use of fossil fuels used to produce heat or power at their facilities by installing new systems that use renewable biomass, or to produce new energy from renewable biomass.

B. *Statutory Authority.* This program is authorized under 7 U.S.C. 8104.

C. *Definition of Terms.* The definitions applicable to this Notice are published at 7 CFR 4288.2.

II. Award Information

A. *Available funds.* The Agency is authorizing approximately $25 million for this program in Fiscal Year 2012, in addition to any carry-over funds from Fiscal Year 2011.

B. *Number of payments.* The number of payments will depend on the number of participating biorefineries.

C. *Amount of payments.* The Agency will determine the amount of payments to be made to a biorefinery by taking into consideration the percentage reduction in fossil fuel used by the biorefinery (including the quantity of fossil fuels a renewable biomass system is replacing) and the cost and cost-effectiveness of the renewable biomass system.

D. *Payment limitations.* There is no minimum payment amount that an individual biorefinery can receive. The maximum amount an individual biorefinery can receive under this Notice is 50 percent of total eligible project costs up to a maximum of $10 million.

E. *Project costs.* Eligible project costs will be only for project related construction costs for repowering improvements associated with the equipment, installation, engineering, design, site plans, associated professional fees, permits and financing fees. Any project costs incurred by the applicant prior to application for payment assistance under this Notice will be ineligible for payment assistance.

F. *Type of instrument.* Payment agreement.

III. Eligibility Information

A. *Eligible applicants.* Program requirements are found in 7 CFR 4288.10 published in the **Federal Register** on February 11, 2011. To be eligible for this program, an applicant must be a biorefinery that has been in existence on or before June 18, 2008, and will utilize renewable biomass for replacement fuel.

B. *Ineligible projects.* A project is not eligible under this Notice if it is using feedstocks for repowering that are feed grain commodities that received benefits under Title I of the Food, Conservation, and Energy Act of 2008.

IV. Multiple Submissions

Corporations and entities with more than one biorefinery can submit an application for only one of their biorefineries. However, if a corporation or entity has multiple biorefineries located at the same location, the entity may submit an application that covers such biorefineries provided the heat and power used in the multiple biorefineries are centrally produced.

V. Scoring Advice

A. Cost Effectiveness. To be credible and meet the minimum scoring criteria, the project must have a simple payback period of no more than 10 years (*i.e.,* must be awarded at least 5 points for cost-effectiveness under 7 CFR 4288.21(b)(1)).

B. *Percentage of reduction of fossil fuel use.* To be credible and meet the minimum scoring criteria, the applicant must demonstrate that the repowering project has an anticipated annual reduction in fossil fuel use of at least 40 percent (*i.e.,* the application must be awarded at least 5 points for percentage of reduction of fossil fuel use under 7 CFR 4288.21(b)(2)).

VI. Project Financing

The applicant must demonstrate that it has sufficient funds or has obtained commitments for sufficient funds to complete the repowering project taking into account the amount of the payment request in the application.

VII. Fiscal Year 2012 Application and Submission Information

A. *To request applications.* Application materials, including application forms, regulations, instructions, and other materials related

to this program, are available from the USDA Rural Development State Office, Renewable Energy Coordinator and the USDA Rural Development Web site at *http://www.rurdev.usda.gov/BCP_RepoweringAssistance.html.*

http://www.rurdev.usda.gov/BCP_ReapLoans.html.

B. *Content and form of submission.* Applicants must submit a signed original and one copy of an application containing all the information specified in 7 CFR 4288.20(b) and (c).

C. *Submission dates and times.* Applications to participate in this program for Fiscal Year 2012 must be submitted between February 2, 2012 and June 1, 2012. Applications received after 4:30 p.m. June 1, 2012, regardless of their postmark, will not be considered by the Agency for Fiscal Year 2012 payments.

D. *Payment provisions.* Fiscal Year 2012 payments will be made according to the provisions specified in 7 CFR 4288.13(b) and (c) and in 7 CFR 4288.24.

VIII. Application Review and Selection Information

The Agency will evaluate projects based on the cost, cost-effectiveness, and capacity of projects to reduce fossil fuels. The cost of the project will be taken into consideration in the context of each project's ability to economically produce energy from renewable biomass to replace its dependence on fossil fuels. Projects with higher costs that are less efficient will not score well. The scoring criteria are designed to evaluate projects on simple payback as well as the percentage of fossil fuel reduction.

A. *Review.* The Agency will review applications submitted under this Notice in accordance with 7 CFR 4288.21(a).

B. *Scoring.* The Agency will score applications submitted under this Notice in accordance with 7 CFR 4288.21(b).

C. *Ranking and selecting applications.* All scored applications will be ranked by the Agency as soon after June 1, 2012 as possible. The Agency will consider the score an application has received compared to the scores of other applications in the priority list, with higher scoring applications receiving first consideration for payments. Using the application scoring criteria point values specified in 7 CFR 4288.21, the Agency will select applications for payments.

D. *Availability of funds.* As applications are funded, if insufficient funds remain to pay the next highest scoring application, the Agency may elect to pay a lower scoring application. Before this occurs, the Agency will provide the applicant of the higher scoring application the opportunity to reduce the amount of its payment request to the amount of funds available. If the applicant agrees to lower its payment request, it must certify that the purposes of the project can be met, and the Agency must determine the project is feasible at the lower amount.

IX. Administration Information

A. *Notice of eligibility.* The provisions of 7 CFR 4288.23 apply to this Notice. These provisions include notifying an applicant determined to be eligible for participation and notifying an applicant determined to be ineligible, including their application score and ranking and the score necessary to qualify for payments.

B. *Administrative and National Policy requirements.*

(1) *Review or appeal rights.* A person may seek a review of an agency adverse decision or appeal to the National Appeals Division as provided in 7 CFR 4288.3.

(2) *Compliance with other laws and regulations.* The provisions of 7 CFR 4288.4 apply to this Notice, which includes requiring participating biorefineries to be in compliance with other applicable Federal, State, and local laws.

(3) *Oversight and monitoring.* The provisions of 7 CFR 4288.5(a) and (b) apply to this Notice, which includes the right of the Agency to verify all payment applications and subsequent payments and the requirement that each biorefinery must make available, at one place at all reasonable times for examination by the Agency, all books, documents, papers, receipts, payroll records, and bills of sale adequate to identify the purposes for which, and the manner in which, funds were expended for all eligible project costs for a period of not less than 3 years from the final payment date.

(4) *Reporting.* Upon completion of the repowering project funded under this Notice, the biorefinery must submit a report, in accordance with 7 CFR 4288.5(c), to the Agency annually for the first 3 years after completion of the project. The reports are to be submitted as of October 1 of each year.

(5) *Exception authority.* The provisions of 7 CFR 4288.7 apply to this Notice.

(6) *Succession and control of facilities and production.* The provisions of 7 CFR 4288.25 apply to this Notice.

C. *Environmental review.* All recipients under this Notice are subject to the requirements of 7 CFR Part 1940, subpart G.

X. Agency Contacts

For further information about this Notice, please contact Fred Petok, USDA, Rural Development, Business Programs Energy Division, 1400 Independence Avenue SW., Room 6870, STOP 3225, Washington, DC 20250–3225. Telephone: (202) 720–1400. Email: *frederick.petok@wdc.usda.gov.*

XI. Nondiscrimination Statement

USDA prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal, or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, *etc.*) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

To file a complaint of discrimination write to USDA, Director, Office of Adjudication and Compliance, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call (800) 795–3272 (voice) or (202) 720–6382 (TDD). USDA is an equal opportunity provider, employer, and lender.

Dated: January 23, 2012.

Judith A. Canales,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2012–2244 Filed 2–1–12; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

[Docket No. 110906558–1551–01]

Privacy Act of 1974; System of Records

AGENCY: Office of Inspector General (OIG), Department of Commerce (DOC).

ACTION: Notice of Proposed Amendment to Privacy Act System of Records, ''Investigative and Inspection Records—COMMERCE/DEPT–12.''

SUMMARY: In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4) and (11), and Office of Management and Budget (OMB) Circular A–130, Appendix I, ''Federal Agency Responsibility for Maintaining Records about Individuals,'' DOC OIG

proposes to amend the system of records entitled ''Investigative and Inspection Records—COMMERCE/DEPT–12,'' to include the new automated Inspector General Complaint Intake Reporting and Tracking System (''IG–CIRTS''); change the system name to ''OIG Investigative Records''; update OIG routine uses; update OIG's practices for electronically storing, retrieving, and safeguarding records in the System, and generally update the systems notice. The new system will enhance efficiency in the complaint intake and case tracking processes, reduce burdens of paper storage, and update protections in access and storage of information within the records system. Accordingly, ''Investigative and Inspection Records—COMMERCE/DEPT—12,'' published in the **Federal Register**, 50 FR 9102–9105 (Mar. 6, 1985), is amended and restated as shown below. DOC OIG invites public comment on the amended system announced in this publication.

DATES: *Comment date:* To be considered, written comments on the proposed amended system must be submitted on or before March 5, 2012.

Effective Date: Unless comments are received, the amended system of records will become effective, as proposed, on the date a subsequent notice is published in the **Federal Register**.

ADDRESSES: Please address comments to Counsel to the Inspector General, Room 7892, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; by email to *IGCounsel@oig.doc.gov;* or by facsimile to (202) 501–7335. For further information, general questions, and privacy-related issues, please contact the Counsel to the Inspector General at (202) 482–5992.

SUPPLEMENTARY INFORMATION: The Inspector General Act of 1978, as amended, 5 U.S.C. App. 3, authorizes DOC OIG to conduct investigations to detect and prevent fraud, waste, mismanagement and abuse, and to promote economy and efficiency, in the DOC's programs and operations. OIG uses records in this system in the course of investigating individuals and entities suspected of criminal, civil, or administrative misconduct, and in supporting related judicial and administrative proceedings. OIG's Office of Investigations (OI) maintains and manages OIG's investigative records. The updates to the system will not involve the collection of additional categories of information, but will provide methods for data tracking and retrieval previously unavailable. The new system will enhance efficiency in the complaint intake and case tracking processes, reduce burdens of paper storage, and update protections in access and storage of information within the records system.

SYSTEM NAME:

COMMERCE/DEPT–12, OIG Investigative Records.

SECURITY CLASSIFICATION:

Sensitive but Unclassified (SBU).

SYSTEM LOCATION:

U.S. Department of Commerce, Office of Inspector General, 14th Street and Constitution Avenue NW., Washington, DC 20230; U.S. Department of Commerce, Office of Inspector General, Regional Offices, and investigative site(s) used in the course of OIG investigation(s).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

In connection with its investigative duties, DOC OIG maintains records in its records system on the following categories of individuals insofar as they are relevant to any investigation or preliminary inquiry undertaken to determine whether to commence an investigation: subjects of investigations; complainants; witnesses; confidential and non-confidential informants; contractors; subcontractors; recipients of federal funds and their contractors/subcontractors and employees; individuals interacting with DOC employees or management; current, former, and prospective DOC employees; alleged violators of DOC rules and regulations; union officials; individuals who are investigated and/or interviewed; persons suspected of violations of administrative, civil, and/or criminal provisions; grantees; sub-grantees; lessees; licensees; persons engaged in official business with the DOC; or other persons identified by the OIG or by other agencies, constituent units of the DOC, and members of the general public in connection with the authorized functions of the OIG. The names of individuals and related information may be received by referral or through inquiries initiated at the discretion of the Inspector General in the conduct of assigned duties.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains investigative reports and materials gathered or created with regard to investigations of administrative, civil, and criminal matters by DOC OIG and other Federal, State, local, tribal, territorial, non-governmental, international, foreign regulatory, or foreign law enforcement agencies or entities. Categories of records may include: complaints; requests to investigate; information contained in criminal, civil, or administrative referrals; statements from subjects and/or witnesses; affidavits, transcripts, police reports, photographs, and/or documents relative to a subject's prior criminal record; medical records; accident reports; materials and intelligence information from other governmental investigatory or law enforcement organizations; information relative to the status of a particular complaint or investigation, including any determination relative to criminal prosecution, civil, or administrative action; general case management documentation; subpoenas and evidence obtained in response to subpoenas; evidence logs; pen registers; correspondence; records of investigation; and other data and evidence collected or generated by OIG's Office of Investigations while conducting its official duties.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Inspector General Act of 1978, 5 U.S.C. App. 3, as amended.

PURPOSE:

The records contained in this system are used by DOC OIG to carry out its statutory responsibilities under the Inspector General Act of 1978, 5 U.S.C. App. 3, as amended, to conduct and supervise investigations, prevent and detect fraud, waste, and abuse, and promote economy, efficiency, and effectiveness in DOC programs and operations. The records are used in the course of investigating individuals and entities suspected of criminal, civil, or administrative misconduct and in supporting related judicial and administrative proceedings.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record from this system of records may be disclosed, as a routine use, to a Federal, state or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current license, if necessary to obtain information relevant to a DOC decision concerning the assignment, hiring, or retention of an individual, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular A–19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

5. A record in this system of records may be disclosed, as a routine use, to the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C . 552).

6. A record in this system may be transferred, as a routine use, to the Office of Personnel Management for personnel research purposes; as a data source for management information; for the production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained; or for related manpower studies.

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his or her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose and any other relevant (*i.e.* GSA or DOC) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the appropriate agency or entity, whether Federal, State, local, tribal, territorial, foreign, or international, charged with the responsibility for investigating or prosecuting a violation of any law, rule, regulation or order. Routine use for law enforcement purposes also includes disclosure to individuals or to agencies, whether Federal, State, local, foreign, or international, when necessary to further the ends of an investigation.

9. A record from this system of records may be disclosed, as a routine use, to representatives of the Department of Justice (DOJ) or of any other agency that is responsible for representing DOC interests in connection with judicial, administrative or other proceedings. This includes circumstances in which (1) the DOC or OIG, or any component thereof; (2) any employee of the DOC or OIG in his or her official capacity; (3) any employee of the DOC or OIG in his or her individual capacity, where DOJ has agreed to represent or is considering a request to represent the employee; or (4) the United States or any of its components, is a party to pending or potential litigation or has an interest in such litigation; in which the DOC or OIG is likely to be affected by the litigation, or in which the DOC or OIG determines that the use of such records by the DOJ is relevant and necessary to the litigation; provided, however, that in each case, the DOC or OIG determines that disclosure of records to the DOJ or representative is a use of the information that is compatible with the purpose for which the records were collected. Records may also be disclosed to representatives of DOJ and other U.S. Government entities, to the extent necessary, to obtain their advice on any matter relevant to an OIG investigation.

10. A record from this system of records may be disclosed, as a routine use, to any source from which additional information is requested in order to obtain information relevant to: a decision by either the DOC or OIG concerning the hiring, assignment, or retention of an individual or other personnel action; the issuance, renewal, retention, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance, retention, or revocation of a license, grant, award, contract, or other benefit to the extent the information is relevant and necessary to a decision by the DOC or OIG on the matter.

11. A record from this system of records may be disclosed, as a routine use, to a Federal, State, local, tribal, territorial, foreign, international, or other public authority in response to its request in connection with: the hiring, assignment, or retention of an individual; the issuance, renewal, retention, or revocation of a security clearance; the reporting of an investigation of an individual; the execution of a security or suitability investigation; the letting of a contract; or the issuance, retention, or revocation of a license, grant, award, contract, or other benefit conferred by that entity to the extent that the information is relevant and necessary to the requesting entity's decision on the matter.

12. A record in this system of records may be disclosed, as a routine use, in the event that a record, either by itself or in combination with other information, indicates a violation or a potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto; or a violation or potential violation of a contract provision. In these circumstances, the relevant records in the system may be referred, as a routine use, to the appropriate agency or entity, whether Federal, State, local, tribal, territorial, foreign, or international charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, order, or contract.

13. A record in this system of records may be disclosed, as a routine use, to any source from which additional information is requested, either private or governmental, to the extent necessary to solicit information relevant to any investigation, audit, or evaluation.

14. A record in this system of records may be disclosed, as a routine use, to a foreign government or international organization pursuant to an international treaty, convention, implementing legislation, or executive agreement entered into by the United States.

15. A record in this system of records may be disclosed, as a routine use, to contractors, grantees, consultants, or volunteers performing or working on a contract, service, grant, cooperative agreement, job, or other activity for the DOC or OIG, who have a need to access the information in the performance of their duties or activities. When appropriate, recipients will be required to comply with the requirements of the Privacy Act of 1974 as provided in 5 U.S.C. 552a(m).

16. A record in this system of records may be disclosed, as a routine use, to representatives of the Office of Personnel Management, the Office of Special Counsel, the Merit Systems Protection Board, the Federal Labor Relations Authority, the Equal Employment Opportunity Commission, the Office of Government Ethics, and other Federal agencies in connection with their efforts to carry out their responsibilities to conduct examinations, investigations, and/or settlement efforts, in connection with administrative grievances, complaints, claims, or appeals filed by an employee, and such other functions promulgated in 5 U.S.C. 1205–06.

17. A record in this system of records may be disclosed, as a routine use, to a grand jury agent pursuant to a Federal or State grand jury subpoena or to a

prosecution request that such record be released for the purpose of its introduction to a grand jury.

18. A record in this system of records may be disclosed, as a routine use, to the Departments of the Treasury and Justice in circumstances in which OIG seeks to obtain, or has in fact obtained, an ex parte court order to obtain tax return information from the Internal Revenue Service.

19. A record in this system of records may be disclosed, as a routine use, to any Federal official charged with the responsibility to conduct qualitative assessment reviews of internal safeguards and management procedures employed in investigative operations for purposes of reporting to the President and Congress on the activities of OIG. This disclosure category includes other Federal Offices of Inspectors General and members of the Council of Inspectors General on Integrity and Efficiency, and officials and administrative staff within their investigative chain of command, as well as authorized officials of DOJ and its component, the Federal Bureau of Investigation.

20. A record in this system of records may be disclosed, as a routine use, to appropriate agencies, entities, and persons when (1) it is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) it is determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identify theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by OIG, DOC, or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm.

21. A record in this system of records may be disclosed, as a routine use, to the public or to the media for release to the public, following consultation with the DOC Chief Privacy Officer, when the matter under investigation has become public knowledge or the Inspector General determines that such disclosure is necessary to preserve confidence in the integrity of the Inspector General audit, inspection, review, or investigative process, or is necessary to demonstrate the accountability of DOC employees, officers or individuals covered by the system, unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

22. A record in this system of records may be disclosed, as a routine use, to Congress, congressional committees, or the staffs thereof, in order to fulfill the Inspector General's responsibility, as mandated by the Inspector General Act of 1978, to keep the Congress, in connection with its oversight and legislative functions concerning the administration of programs and operations administered or financed by DOC, fully and currently informed concerning fraud and other serious problems, abuses, and deficiencies concerning the administration of programs and operations administered or financed by DOC.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records and other media (photographs, audio recording, diskettes, CDs, etc.) are stored in GSA-approved security containers with combination locks in a secured area. Electronic records are maintained on two servers, a data server which maintains the IG–CIRTS database, and a file server which maintains case files and related materials. Both servers are maintained in a secured, restricted-area facility.

RETRIEVABILITY:

Paper records are retrieved by alphabetical indices cross referenced to file numbers. Electronic records are retrieved via 'Secure Socket Layer' (SSL) encryption search mechanisms. Electronic searches may be performed by search criteria that include case numbers, names of individuals or organizations, and other key word search variations.

SAFEGUARDS:

Paper records are kept in locked cabinets, secured rooms, in a guarded building, and used only by authorized screened personnel. Electronic records are stored on two servers maintained in a locked facility that is secured at all times by security systems and video cameras. Data in the system are encrypted and password protected. Access to electronic records is restricted to DOC OIG staff individually authorized to access the IG–CIRTS application. Passwords are changed every 90 days. Backup tapes are stored in a locked and controlled room in a secure off-site facility.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the DOC OIG Records Retention Schedules approved by the National Archives and Records Administration.

SYSTEM MANAGER NAME AND ADDRESS:

Deputy Assistant Inspector General for Investigations, Room 7898c, Office of Inspector General, United States Department of Commerce, 1401 Constitution Ave., NW., Washington, DC 20230.

NOTIFICATION PROCEDURE:

The Inspector General has exempted this system from the procedures of the Privacy Act relating to individuals' requests for notification of the existence of records on themselves.

RECORD ACCESS PROCEDURE:

The Inspector General has exempted this system from the access procedures of the Privacy Act.

CONTESTING RECORDS PROCEDURE:

The Inspector General has exempted this system from the contest procedures of the Privacy Act.

RECORD SOURCE CATEGORIES:

DOC OIG collects information from a wide variety of sources, including information from the DOC and other Federal, State, and local agencies, subjects, witnesses, complainants, victims, confidential and non-confidential sources, individuals, and non-governmental entities.

SYSTEM EXEMPTIONS FROM CERTAIN PROVISIONS OF THE ACT:

Under 5 U.S.C. 552a(j)(2), the head of any agency may exempt any system of records within the agency from certain provisions of the Privacy Act of 1974, if the agency or component that maintains the system performs as its principal function any activities pertaining to the enforcement of criminal laws. The Inspector General Act of 1978, 5 U.S.C. App. 3, as amended, mandates the Inspector General to recommend policies for, and to conduct, supervise and coordinate activities in the Department and between the Department and other Federal, State and local government agencies with respect to all matters relating to the prevention and detection of fraud in programs and operations administered or financed by the Department, and to the identification and prosecution of participants in such fraud. Under the

Act, whenever the Inspector General has reasonable grounds to believe there has been a violation of Federal criminal law, the Inspector General must report the matter expeditiously to the Attorney General. In addition to these principal functions pertaining to the enforcement of criminal laws, the Inspector General may receive and investigate complaints on information from various sources concerning the possible existence of activities constituting violations of law, rules or regulations, or mismanagement, gross waste of funds, abuses of authority or substantial and specific danger to the public health and safety. The provisions of the Privacy Act of 1974 from which exemptions are claimed under 5 U.S.C. 552a(j)(2) are as follows: 5 U.S.C. 552a(c)(3) and (4); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1), (2) and (3); 5 U.S.C. 552a(e)(4)(G), (H), and (I); 5 U.S.C. 552a(e)(5) and (8); 5 U.S.C. 552a(f); 5 U.S.C. 552a(g).

To the extent that the exemption under 5 U.S.C. 552a(j)(2) is held to be invalid, then the exemptions under 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5) are claimed for all material which meets the criteria of these three subsections.

Provisions of the Privacy Act of 1974 from which exemptions are claimed under 5 U.S.C. 552a(k)(1), (k)(2) and (k)(5) are as follows: 5 U.S.C. 552a(c)(3); 5 U.S.C. 552a(d); 5 U.S.C. 552a(e)(1); 5 U.S.C. 552a(e)(4)(G), (H), and (I); 5 U.S.C. 552a(f).

Reasons for exemptions: In general, the exemption of this information and material is necessary in order to accomplish the law enforcement function of the Office of Inspector General, to prevent disclosure of classified information as required by Executive Order, to prevent subjects of investigations from frustrating the investigatory process, to prevent the disclosure of investigative techniques, to fulfill commitments made to protect the confidentiality of sources, to maintain access to sources of information, and to avoid endangering these sources and law enforcement personnel. Detailed reasons follow:

Reasons for exemptions under 5 U.S.C. 552a(j)(2) and (k)(2):

(1) 5 U.S.C. 552a(c)(3) requires that upon request, an agency must give an individual named in a record an accounting which reflects the disclosure of the record to other persons or agencies. This accounting must state the date, nature and purpose of each disclosure of the record and the name and address of the recipient. The application of this provision would alert subjects of an investigation to the existence of the investigation and that such persons are subjects of that investigation. Since release of such information to subjects of an investigation would provide the subjects with significant information concerning the nature of the investigation, it could result in the altering or destruction of documentary evidence, improper influencing of witnesses, and other activities that could impede or compromise the investigation.

(2) 5 U.S.C. 552a(c)(4), (d), (e)(4)(G) and (H), (f) and (g) relate to an individual's right to be notified of the existence of records pertaining to such individual; requirements for identifying an individual who requests access to records; the agency procedures relating to access to records and the contest of information contained in such records; and the civil remedies available to the individual in the event of adverse determinations by an agency concerning access to or amendment of information contained in records systems. This system is exempt from the foregoing provisions for the following reasons: To notify an individual at the individual's request of the existence of records in an investigative file pertaining to such individual, or to grant access to an investigative file could interfere with investigative and enforcement proceedings, deprive co-defendants of a right to a fair trial or other impartial adjudication, constitute an unwarranted invasion of personal privacy of others, disclose the identity or confidential sources, reveal confidential information supplied by these sources and disclose investigative techniques and procedures.

(3) 5 U.S.C. 552a(e)(4)(I) requires the publication of the categories of sources of records in each system of records. The application of this provision could disclose investigative techniques and procedures and cause sources to refrain from giving such information because of fear of reprisal, or fear of breach of promises of anonymity and confidentiality. This would compromise the ability to conduct investigations, and to identify, detect, and apprehend violators.

(4) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual that is relevant and necessary to accomplish a purpose of the agency required by statute or Executive Order. An exemption from the foregoing is needed:

a. Because it is not possible to detect relevance or necessity of specific information in the early stages of a criminal or other investigation.

b. Relevance and necessity are questions of judgment and timing. What appears relevant and necessary when collected may ultimately be determined to be unnecessary. It is only after the information is evaluated that the relevance and necessity of such information can be established.

c. In any investigation the Inspector General may obtain information concerning the violations of laws other than those within the scope of his or her jurisdiction. In the interest of effective law enforcement, the Inspector General should retain this information as it may aid in establishing patterns of criminal activity, and provide leads for those law enforcement agencies charged with enforcing other segments of criminal or civil law.

d. In interviewing persons, or obtaining other forms of evidence during an investigation, information may be supplied to the investigator which related to matters incidental to the main purpose of the investigation but which may relate to matters under the investigative jurisdiction of another agency. Such information cannot readily be segregated.

(5) 5 U.S.C. 552a(e)(2) requires an agency to collect information to the greatest extent practicable directly from the subject individual when the information may result in adverse determinations about an individual's rights, benefits, and privilege under Federal programs. The application of the provision would impair investigations of illegal acts, violations of the rules of conduct, merit system and any other misconduct for the following reasons:

a. In certain instances the subject of an investigation cannot be required to supply information to investigators. In those instances, information relating to a subject's illegal acts, violations of rules of conduct, or any other misconduct, etc., must be obtained from other sources.

b. Most information collected about an individual under investigation is obtained from third parties such as witnesses and informers. It is not feasible to rely upon the subject of the investigation as a source for information regarding his or her activities.

c. The subject of an investigation will be alerted to the existence of an investigation if any attempt is made to obtain information from subject. This could afford the individual the opportunity to conceal any criminal activities to avoid apprehension.

d. In any investigation, it is necessary to obtain evidence from a variety of sources other than the subject of the investigation in order to verify the evidence necessary for successful litigation.

(6) 5 U.S.C. 552a(e)(3) requires that an agency must inform the subject of an investigation who is asked to supply information of:

a. The authority under which the information is sought and whether disclosure of the information is mandatory or voluntary,

b. The purposes for which the information is intended to be used,

c. The routine uses which may be made of the information, and

d. The effects on the subject, if any, of not providing the requested information. The reasons for exempting this system of records from the foregoing provision are as follows:

(i) The disclosure to the subject of the investigation as stated in (b) above would provide the subject with substantial information relating to the nature of the investigation and could impede or compromise the investigation.

(ii) If the subject were informed of the information required by this provision, it could seriously interfere with undercover activities requiring disclosure of undercover agents' identity and impairing their safety, as well as impairing the successful conclusion of the investigation.

(iii) Individuals may be contacted during preliminary information-gathering in investigations before any individual is identified as the subject of an investigation. Informing the individual of the matters required by this provision would hinder or adversely affect any present or subsequent investigations.

(7) 5 U.S.C. 552a(e)(5) requires that records be maintained with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in making any determination about an individual. Because the law defines ''maintain'' to include the collection of information, complying with this provision would prevent the collection of any data not shown to be accurate, relevant, timely, and complete at the moment of its collection. In gathering information during the course of an investigation it is not possible to determine this prior to collection of the information. Facts are first gathered and then placed into a logical order which objectively proves or disproves criminal behavior on the part of the suspect. Material which may seem unrelated, irrelevant, incomplete, untimely, etc., may take on added meaning as an investigation progresses. The restrictions in this provision could interfere with the preparation of a complete investigative report.

(8) 5 U.S.C. 552a(e)(8) requires an agency to make reasonable efforts to serve notice on an individual when any record of such individual is made available to any persons; under compulsory legal process when such process becomes a matter of public record. The notice requirements of this provision could prematurely reveal an ongoing criminal investigation to the subject of the investigation.

Reasons for exemptions under 5 U.S.C. 552a(k)(1):

(1) 5 U.S.C. 552a(c)(3) requires that an agency make accountings of disclosures of records available to individuals named in the record at their request. These accountings must state the date, nature and purpose of each disclosure of the record and the name and address of the recipient. The application of this provision would alert subjects of an investigation to the existence of the investigation, and that such persons are subjects of that investigation, information which if known might cause damage to national security.

(2) 5 U.S.C. 552a(d), (e)(4)(G) and (H), and (f) relate to an individual's right to be notified of the existence of records pertaining to such individual; requirements for identifying an individual who requests access to records; and the agency procedures relating to access to records, and the contest of information contained in such records. This system is exempt from the foregoing provisions for the following reasons: To notify an individual at the individual's request of the existence of records in an investigative file pertaining to such individual or to grant access to an investigative file could interfere with investigations undertaken in connection with national security; or could disclose the identity of sources kept secret to protect national security or reveal confidential information supplied by these sources.

(3) 5 U.S.C. 552a(e)(4)(I) requires the publication of the categories of sources of records in each system of records. The application of this provision could disclose the identity of sources kept secret to protect national security.

(4) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual that is relevant and necessary to accomplish a purpose of the agency required by statute or Executive Order. An exemption from the foregoing is needed:

a. Because it is not possible to detect relevance or necessity of specific information in the early stages of an investigation involving national security matters.

b. Relevance and necessity are questions of judgment and timing. What appears relevant and necessary when collected may ultimately be determined to be unnecessary. It is only after the information is evaluated that the relevance and necessity of such information can be established.

c. In any investigation the Inspector General may obtain information concerning the violators of laws other than those within the scope of his or her jurisdiction. In the interests of effective law enforcement, the Inspector General should retain this information as it may aid in establishing patterns of criminal activity, and provide leads for those law enforcement agencies charged with enforcing other segments of criminal or civil law.

d. In interviewing persons, or obtaining forms of evidence during an investigation, information may be supplied to the investigator which relate to matters incidental to the main purpose of the investigation but which may relate to matters under the investigative jurisdiction of another agency. Such information cannot readily be segregated.

Reasons for exemptions under 5 U.S.C. 552a(k)(5):

(1) 5 U.S.C. 552a(c)(3) requires that an agency make accountings of disclosures of records available to individuals named in the records at their request. These accountings must state the date, nature and purpose of each disclosure of the record and the name and address of the recipient. The application of this provision would alert subjects of an investigation to the existence of the investigation and that such persons are subjects of that investigation. Since release of such information to subjects of an investigation would provide the subject with significant information concerning the nature of the investigation, it could result in the altering or destruction of documentary evidence, improper influencing of witnesses, and other activities that could impede or compromise the investigation.

(2) 5 U.S.C. 552a(d), (e)(4)(G) and (H), and (f) relate to an individual's right to be notified of the existence of records pertaining to such individual; requirements for identifying an individual who requests access to records; and the agency procedures relating to access to records and the contest of information contained in such records. This system is exempt from the foregoing provisions for the following reasons: To notify an individual at the individual's request of the existence of records in an investigative file pertaining to such individual or to grant

access to an investigative file could interfere with investigative and enforcement proceedings; co-defendants of a right to a fair trial; constitute an unwarranted invasion of personal privacy of others; disclose the identity of confidential sources and reveal confidential information supplied by these sources; and disclose investigative techniques and procedures.

(3) 5 U.S.C. 552a(e)(4)(I) requires the publication of the categories of sources of records in each system of records. The application of this provision could disclose investigative techniques and procedures and cause sources to refrain from giving such information because of fear of reprisal, or fear of breach of promises of anonymity and confidentiality. This would compromise the ability to conduct investigations, and to make fair and objective decisions on questions of suitability for Federal employment and related issues.

(4) 5 U.S.C. 552a(e)(1) requires each agency to maintain in its records only such information about an individual that is relevant and necessary to accomplish a purpose of the agency required by statute or Executive Order. An exemption from the foregoing is needed:

a. Because it is not possible to detect relevance or necessity of specific information in the early stages of an investigation.

b. Relevance and necessity are questions of judgment and timing. What appears relevant and necessary when collected may ultimately be determined to be unnecessary. It is only after that information is evaluated that the relevance and necessity of such information can be established.

c. In any investigation the Inspector General may obtain information concerning the violations of laws other than those within the scope of his or her jurisdiction. In the interest of effective law enforcement, the Inspector General should retain this information as it may aid in establishing patterns of criminal activity, and provide leads for those law enforcement agencies charged with enforcing other segments of criminal or civil law.

d. In interviewing persons, or obtaining other forms of evidence during an investigation, information may be supplied to the investigator which relate to matters incidental to the main purpose of the investigation but which may relate to matters under investigative jurisdiction of another agency. Such information cannot readily be segregated.

Dated: December 16, 2011.

Jonathan R. Cantor,

Chief Privacy Officer, Department of Commerce.

[FR Doc. 2012–2359 Filed 2–1–12; 8:45 am]

BILLING CODE 3510–55–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–803]

Light-Walled Welded Rectangular Carbon Steel Tubing From Taiwan: Continuation of Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the Department of Commerce (the Department) and the International Trade Commission (ITC) that revocation of the antidumping duty order on light-walled welded rectangular carbon steel tubing from Taiwan would likely lead to a continuation or recurrence of dumping and material injury to an industry in the United States, the Department is publishing a notice of continuation of the antidumping duty order.

DATES: *Effective Date:* February 2, 2012.

FOR FURTHER INFORMATION CONTACT: Jerrold Freeman or Minoo Hatten, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0180 or (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2011, the Department initiated, and the ITC instituted, the sunset review of the antidumping duty order [1] on light-walled welded rectangular carbon steel tubing from Taiwan pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). *See Initiation of Five-Year (''Sunset'') Review,* 76 FR 38613 (July 1, 2011) and *Certain Pipe and Tube From Brazil, India, Korea, Mexico, Taiwan, Thailand, and Turkey,* 76 FR 38691 (July 1, 2011).

As a result of this sunset review, the Department determined that revocation of the antidumping duty order on light-walled welded rectangular carbon steel tubing from Taiwan would be likely to lead to continuation or recurrence of dumping and notified the ITC of the magnitude of the margins likely to prevail should the order be revoked. *See Light-Walled Welded Rectangular Carbon Steel Tubing From Taiwan: Final Results of the Expedited Sunset Review of the Antidumping Duty Order,* 76 FR 64312 (October 18, 2011).

On January 24, 2012, pursuant to section 752(a) of the Act, the ITC published its determination that revocation of the antidumping duty order on light-walled welded rectangular carbon steel tubing from Taiwan would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. *See Light-Walled Rectangular Pipe and Tube From Taiwan,* 77 FR 3497 (January 24, 2012), and ITC Publication 4301 (January 2012) entitled *Light-Walled Rectangular Pipe and Tube From Taiwan (Investigation No. 731–TA–410 (Third Review)).*

Scope of the Order

The product covered by the order is light-walled welded carbon steel pipe and tube of rectangular (including square) cross-section having a wall thickness of less than 0.156 inch. This merchandise is classified under item number 7306.61.5000 of the Harmonized Tariff Schedule (HTS). It was formerly classified under item number 7306.60.5000. The HTS item numbers are provided for convenience and customs purposes only. The written product description remains dispositive.

Continuation of the Order

As a result of the determinations by the Department and the ITC that revocation of this antidumping duty order 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 order on light-walled welded rectangular carbon steel tubing from Taiwan.

U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of continuation of this order will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of this order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

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[1] *Antidumping Duty Order; Light-Walled Welded Rectangular Carbon Steel Tubing From Taiwan,* 54 FR 12467 (March 27, 1989).

This five-year sunset review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: January 25, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2012–2252 Filed 2–1–12; 8:45 am]

BILLING CODE 3510–DS–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

No FEAR Act Notice; Notice of Rights and Protections Available Under the Federal Antidiscrimination and Whistleblower Protection Laws

AGENCY: The Bureau of Consumer Financial Protection. ACTION: Notice.

SUMMARY: The Bureau of Consumer Financial Protection (CFPB or the Bureau) is providing notice to its employees, former employees, and applicants for Federal employment about the rights and remedies available to them under the Federal antidiscrimination, whistleblower protection, and retaliation laws. This notice fulfills CFPB's initial notification obligation under the Notification and Federal Employees Antidiscrimination and Retaliation Act (No FEAR Act), as implemented by Office of Personnel Management (OPM) regulations.

FOR FURTHER INFORMATION CONTACT: Liza Strong, Office of Human Capital, 1700 G Street, NW Washington, DC 20037, (202) 435–7655. Additional information can be found on CFPB's Web site at *http://www.consumerfinance.gov.*

SUPPLEMENTARY INFORMATION: On May 15, 2002, Congress enacted the Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002 (No FEAR Act), Public Law 107–174, 116 Stat. 566 (5 U.S.C. 2301 note). The Act is intended to hold Federal agencies accountable for violations of antidiscrimination and whistleblower protection laws. In support of this purpose, Congress found that ''agencies cannot be run effectively if those agencies practice or tolerate discrimination.'' Sec. 101(1), Public Law 107–174, 116 Stat. 566. The Act requires CFPB to inform its employees, former employees, and applicants for employment of the rights and protections available under Federal antidiscrimination, whistleblower protection, and retaliation laws. OPM requires agencies to publish the initial notice required by the No FEAR Act in the **Federal Register**. 5 CFR 724.202.

Antidiscrimination Laws

A Federal agency may not discriminate against an employee or applicant with respect to the terms, conditions, or privileges of employment on the basis of race, color, religion, national origin, sex, (including pregnancy and gender identity), age (40 and above), disability, genetic information, marital status, parental status, sexual orientation, political affiliation, military service, or any other non-merit factor. Discrimination on these bases is prohibited by Federal statutes and Executive Orders. 5 U.S.C. 2302(b)(1); 29 U.S.C. 206(d); 29 U.S.C. 631; 29 U.S.C. 633a; 29 U.S.C. 791; 38 U.S.C. 4301–35; 42 U.S.C. 2000e-16; 42 U.S.C. 2000ff-1; E.O. 13087; E.O. 13145; E.O. 13152.

If you believe that you have been the victim of unlawful discrimination on the basis of race, color, religion, sex, national origin, disability, or genetic information, you must contact an Equal Employment Opportunity (EEO) counselor within 45 calendar days of the alleged discriminatory action, or, in the case of a personnel action, within 45 calendar days of the effective date of the action, before you may file a formal complaint of discrimination with your agency. *See, e.g.,* 29 CFR part 1614.

If you believe that you have been the victim of unlawful discrimination on the basis of age, you must either contact an EEO counselor or give notice of your intent to sue to the Equal Employment Opportunity Commission (EEOC) within 180 calendar days of the alleged discriminatory action.

If you are alleging discrimination based on sexual orientation, marital status, parental status, political affiliation, or any other non-merit factor you may file a written complaint with the U.S. Office of Special Counsel (OSC).

If you are alleging discrimination based on military service, you may request assistance from the Veterans' Employment and Training Service (VETS) at the Department of Labor (DOL), the Merit Systems Protection Board (MSPB), or OSC, depending on the circumstances.

Whistleblower Protection Laws

A Federal employee with authority to take, direct others to take, recommend, or approve a personnel action must not use that authority to take or fail to take, or threaten to take or fail to take, a personnel action against an employee or applicant because of disclosure of information by that individual that is reasonably believed to be evidence of violations of law, rule or regulation; gross mismanagement; gross waste of funds; abuse of authority; or substantial and specific danger to public health or safety, unless disclosure of such information is specifically prohibited by law or such information is specifically required by Executive Order to be kept secret in the interest of national defense or the conduct of foreign affairs.

Retaliation against an employee or applicant for making a protected disclosure is prohibited by 5 U.S.C. 2302(b)(8). If you believe that you have been the victim of whistleblower retaliation, you may file a written complaint (Form OSC–11) with OSC at 1730 M Street NW., Suite 218, Washington, DC 20036–4505 or online through the OSC Web site at *http://www.osc.gov.*

Retaliation for Engaging in Protected Activity

A Federal agency may not retaliate against an employee or applicant because that individual exercises his or her rights under any of the Federal antidiscrimination or whistleblower protection laws listed in this Notice. If you believe that you are the victim of retaliation for engaging in protected activity, you must follow the procedures described in the Antidiscrimination Laws and Whistleblower Protection Laws sections of this Notice in order to pursue a legal remedy.

Disciplinary Actions

Each agency has the right to discipline a Federal employee for conduct that is inconsistent with Federal antidiscrimination and whistleblower protection laws up to and including removal from the federal service. If OSC has initiated an investigation under 5 U.S.C. 1214, however, according to 5 U.S.C. 1214(f), agencies must seek approval from the Special Counsel to discipline employees for, among other activities, engaging in prohibited retaliation. Nothing in the No FEAR Act alters existing laws or permits an agency to take unfounded disciplinary action against a Federal employee or to violate the procedural rights of a Federal employee who has been accused of discrimination.

Additional Information

For further information regarding the No FEAR Act regulations, please see 5 CFR part 724, and contact the Office of Human Capital at CFPB. Additional information regarding Federal antidiscrimination, whistleblower protection, and retaliation laws can be found on the EEOC Web site at *http://www.eeoc.gov,* on the OSC Web site at *http://www.osc.gov,* on the DOL Web

site at *http://www.dol.gov,* and the MSPB Web site at *http://www.mspb.gov.*

Existing Rights Unchanged

Pursuant to section 205 of the No FEAR Act, neither the Act nor this notice creates, expands or reduces any rights otherwise available to any employee, former employee or applicant under the laws of the United States, including the provisions of law specified in 5 U.S.C. 2302(d).

Dated: January 27, 2012.

Meredith Fuchs,

Chief of Staff.

[FR Doc. 2012–2280 Filed 2–1–12; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Extension of Public Scoping Period for the Revised Notice of Intent To Prepare an Environmental Impact Statement for Military Training Activities at the Naval Weapons Systems Training Facility, Boardman, OR

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as implemented by the Council on Environmental Quality Regulations (40 CFR parts 1500–1508), the Department of the Navy (DoN) published a revised notice of intent to prepare an Environmental Impact Statement (EIS) for the Naval Weapons Systems Training Facility (NWSTF), Oregon in the **Federal Register** on December 27, 2011 (76 FR 80910). This notice announces a 32-day extension of the public scoping comment period to end on February 27, 2012.

FOR FURTHER INFORMATION CONTACT: Mrs. Amy Burt, Naval Facilities Engineering Command Northwest, 1101 Tautog Circle, Suite 203, Silverdale, WA 98315–1101, Attn: NWSTF Boardman Project Manager; or *http://www.NWSTFBoardmanEIS.com.*

SUPPLEMENTARY INFORMATION: The public scoping period on the NWSTF Boardman EIS will be extended by 32 days, from January 27, 2012 to February 27, 2012. Comments on the scope of the EIS may be submitted in writing or electronically. Written comments should be mailed to Naval Facilities Engineering Command Northwest, Attention: Mrs. Amy Burt, NWSTF Boardman EIS Project Manager, Naval Facilities Engineering Command Northwest, 1101 Tautog Circle, Suite 203, Silverdale, WA 98315–1101. All written comments must be postmarked by February 27, 2012, to ensure they become part of the official record. Comments submitted electronically at the project Web site at *http://www.NWSTFBoardmanEIS.com* must be submitted before the end of the comment period to ensure they become part of the official record. All scoping comments will be taken into account in the Draft EIS.

Dated: January 25, 2012.

J.M. Beal,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–2304 Filed 2–1–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Government-Owned Invention; Available for Licensing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States Government as represented by the Secretary of the Navy and is available for licensing by the Department of the Navy.

The following patent is available for licensing: Patent application 13/168,459: ACCESSORY INTERFACE SYSTEM (An apparatus for mounting accessories on a weapon mount).

ADDRESSES: Written objections are to be filed with Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001, telephone (812) 854–4100.

Authority: 35 U.S.C. 207, 37 CFR Part 404.

Dated: January 25, 2012.

J. M. Beal,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–2299 Filed 2–1–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive Patent License; Daniel Defense, Inc.

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to Daniel Defense, Inc. a revocable, nonassignable, exclusive license to practice in the United States, the Government-owned invention described below: Patent application 13/168,459 (Navy Case 100,359): filed June 24, 2011, entitled ''Accessory Interface System''.

DATES: Anyone wishing to object to the grant of this license must file objections along with supporting evidence, if any, not later than February 17, 2012.

ADDRESSES: Written objections are to be filed with Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001, telephone (812) 854–4100.

Authority: 35 U.S.C. 207, 37 CFR Part 404.

Dated: January 25, 2012.

J.M. Beal,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–2303 Filed 2–1–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Partially Exclusive Patent License; Jinga-hi, Inc.

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy herby gives notice of its intent to grant to Jinga-hi, Inc., a revocable, nonassignable, partially exclusive license in the United States to practice the Government-owned inventions described in U.S. Patent No. 7528606: Coupled Non-linear Sensor System for Sensing a Time-dependent Target Signal and Method of Assembling the System.//U.S. Patent No. 8049570: Coupled bi-stable microcircuit system for ultra-sensitive electrical and magnetic field sensing,//and U.S. Patent Application No. 12/749338: Coupled Bi-Stable Circuit for Ultra-Sensitive

Electric Field Sensing Utilizing Differential Transistors Pairs.

DATES: Anyone wishing to object to the grant of this license must file written objections along with supporting evidence, if any, not later than February 17, 2012.

ADDRESSES: Written objections are to be filed with the Office of Research and Technology Applications, Space and Naval Warfare Systems Center Pacific, Code 72120, 53560 Hull St, Bldg A33 Room 2531, San Diego, CA 92152–5001.

FOR FURTHER INFORMATION CONTACT: Brian Suh, Office of Research and Technology Applications, Space and Naval Warfare Systems Center Pacific, Code 72120, 53560 Hull St, Bldg A33 Room 2531, San Diego, CA 92152–5001, telephone (619) 553–5118, email: *brian.suh@navy.mil.*

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: January 25, 2012.

J. M. Beal,

Lieutenant Commander, Judge Advocate General's Corps,U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2012–2302 Filed 2–1–12; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Proposed Priority, Requirements, Definitions, and Selection Criteria—Arts in Education National Program (AENP)

AGENCY: Office of Innovation and Improvement, Department of Education.

ACTION: Notice.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.351F.

SUMMARY: The Assistant Deputy Secretary proposes a priority, requirements, definitions, and selection criteria under the Arts in Education National Program (AENP). We may use the priority, requirements, definitions, and selection criteria for competitions in fiscal year (FY) 2012 and later years. We intend to use the priority, requirements, definitions, and selection criteria to award a grant to an eligible applicant to encourage and expand national-level high-quality arts education activities and services for children and youth, with special emphasis on serving children from low-income families and children with disabilities.

DATES: We must receive your comments on or before March 5, 2012.

ADDRESSES: Address all comments about this notice to Edith Harvey, U.S. Department of Education, 400 Maryland Avenue SW., room 4W308, Washington, DC 20202–5970.

If you prefer to send your comments by email, use the following address: *edith.harvey@ed.gov.* You must include the phrase ''Arts in Education National Program—Comments on FY 2012 Proposed Priority'' in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Edith Harvey. Telephone: (202) 260–1393 or by email: *edith.harvey@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–(800) 877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priority, requirements, definitions, and selection criteria, we urge you to identify clearly the proposed priority, requirement, definition, or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from the proposed priority, requirements, definitions, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 4W308, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Purpose of Program: The purpose of the AENP is to support national-level high-quality arts education activities and services for children and youth, with special emphasis on serving children from low-income families and children with disabilities.

Program Authority: 20 U.S.C. 7271.

Proposed Priority: This notice contains one proposed priority.

Model Projects

Background

Arts is a core academic subject. Arts education encourages creativity and analytical thinking and it highlights a student's unique qualities. Accordingly, and because the focus of the AENP is to promote high-quality arts education with special emphasis on serving children from low-income families and children with disabilities, we are seeking to support one or more projects that will develop and implement exemplary national-level arts education activities and services.

Proposed Priority

One or more high-quality projects that are designed to develop and implement, or expand, initiatives in arts education and arts integration (as defined in this notice) on a national level for pre-kindergarten-through-grade-12 children and youth, with special emphasis on serving children from low-income families (as defined in this notice) and children with disabilities. In order to meet this priority, an applicant must demonstrate that the project for which it seeks funding will provide services and develop initiatives in multiple schools and school districts throughout the country, including in at least one urban, at least one rural, and at least one high-need community (as defined in this notice).

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register.** The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an

application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirements

Background

The AENP supports the implementation of high-quality arts education and arts integration activities and services in music, dance, theater, media arts, and visual arts, including folk arts. We are proposing these requirements to ensure that funded projects have the capacity to provide high-quality professional development, programming, and resources in all of these art forms and to expand the reach of services through strong partnerships with schools and communities.

Proposed Eligibility and Application Requirements

The Assistant Deputy Secretary proposes the following eligibility and application requirements for this program. We may use one or more of these requirements in any year in which we award grants for the AENP.

1. To be eligible for an award, an applicant must be a national nonprofit arts education organization (as defined in this notice).

2. An applicant must describe in its application how it would serve children from low-income families and children with disabilities.

3. An applicant must describe in its application how it would implement the following activities and services at the national level:

(i) Professional development based on State or national standards for pre-kindergarten-through-grade-12 arts educators (as defined in this notice).

Note: *National standards* are the arts standards developed by the Consortium of National Arts Education Associations or another, comparable set of national arts standards. The standards developed by the Consortium outline what students should know and be able to do in the arts. These are not Department standards. To view the standards, please go to *www.menc.org/resources/view/the-national-standards-for-arts-education-a-brief-history.*

(ii) Development and dissemination of instructional materials, including online resources, in music, dance, theater, media arts, and visual arts, including folk arts, for arts educators.

(iii) Arts-based educational programming in music, dance, theater, media arts, and visual arts, including folk arts, for pre-kindergarten-through-grade-12 students and arts educators.

(iv) Community and national outreach activities and services that strengthen and expand partnerships among schools, school districts, and communities throughout the country.

Proposed Definitions

Background

Several terms associated with this program are not defined in section 9101 of the ESEA. Therefore, we are proposing the following definitions for these terms.

Proposed Definitions

The Assistant Deputy Secretary proposes the following definitions for this program. We may use one or more of these definitions in any year in which we award grants for the AENP.

Arts means music, dance, theater, media arts, and visual arts, including folk arts.

Arts educator means a teacher or other instructional staffer who works in music, dance, theater, media arts, or visual arts, including folk arts.

Arts integration means (i) using high-quality arts instruction within other academic content areas, and (ii) strengthening the arts as a core academic subject in the school curriculum.

High-need community means (i) a political subdivision of a State or portion of a political subdivision of a State, in which at least 50 percent of the children are from low-income families; or (ii) a political subdivision of a State that is among the 10 percent of political subdivisions of the State having the greatest numbers of such children. For the purposes of determining if a community meets this definition, the term ''low-income families'' means families with incomes below the poverty line for the most recent fiscal year for which satisfactory data are available.

National non-profit arts education organization means an organization of national scope that is supported by staff or affiliates at the State and local levels and that has a demonstrated history of advancing high-quality arts education and arts integration for arts educators, education leaders, artists, and students through professional development, partnerships, educational programming, and supporting systemic school reform.

Child from low-income family means a child who is determined by a State educational agency or local educational agency to be a child, in pre-kindergarten through grade 12, from a low-income family, on the basis of (a) the family having an income that meets the poverty criteria established by the U.S Department of Commerce, (b) the child's eligibility for free or reduced-price lunches under the Richard B. Russell National School Lunch Act, (c) the family's receipt of assistance under Part A of title IV of the Social Security Act, or (d) the child's eligibility for medical assistance under the Medicaid program under title XIX of the Social Security Act.

Proposed Selection Criteria

Background

The AENP is intended to support high-quality arts education and arts integration on a national level. To ensure that we award the grant to entities that have demonstrated capacity to meet the purposes of the program, we have developed program-specific selection criteria. We propose to award a grant to an eligible entity on the basis of the quality of applications submitted, after taking into consideration one or more of the following proposed selection criteria as well as the requirements of the program.

Proposed Selection Criteria

The Assistant Deputy Secretary proposes the following selection criteria for evaluating an application under this program. We may apply one or more of these criteria, as well as criteria from the Education Department General Administrative Regulations in 34.CFR 75.210, in any year in which this program is in effect. In the notice inviting applications or the application package or both we will announce the maximum possible points assigned to each criterion.

(1) *Significance.* The Secretary reviews each application to determine the extent to which—

(a) The proposed project is likely to build State and local capacity to provide, improve, or expand arts education and arts integration that address the needs of children and youth, with special emphasis on serving children from low-income families and children with disabilities; and

(b) The applicant has a history of three or more years of demonstrated excellence in the areas of arts education and arts integration on a national scale.

(2) *Quality of the project design.* The Secretary reviews each application to determine the extent to which—

(a) The design of the proposed project is appropriate to, and will successfully address, the arts education needs of pre-kindergarten-through-grade-12 children and youth, with special emphasis on children from low-income families and children with disabilities;

(b) The proposed project will provide high-quality professional development for pre-kindergarten-through-grade-12 arts educators who provide instruction

in music, dance, drama, media arts, or visual arts, including folk arts;

(c) The proposed project will develop and disseminate instructional materials, including online resources, in multiple arts disciplines for arts educators and other instructional staff;

(d) The proposed project will support arts-based educational programming; and

(e) The proposed project will provide community and national outreach that strengthens and expands partnerships among schools, school districts, and communities throughout the country.

(3) *Quality of project services.* In determining the quality of the services to be provided by the proposed project, the Secretary considers the extent to which—

(a) The services to be provided by the proposed project involve the collaboration of appropriate partners in order to maximize the effectiveness of project services; and

(b) The proposed project will provide services and initiatives that will reach students and arts educators in multiple schools and school districts in urban, rural, and high-need communities throughout the country.

Final Priority, Requirements, Definitions, and Selection Criteria

We will announce the final priority, requirements, definitions, and selection criteria in a notice in the **Federal Register.** We will determine the final priority, requirements, definitions, and selection criteria after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use this priority, requirements, definitions, and selection criteria, we invite applications through a notice in the **Federal Register.**

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this proposed priority, requirements, definitions, and selection criteria only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this proposed regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register.** Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.*

Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: January 27, 2012.

James H. Shelton, III.,

Assistant Deputy Secretary for Innovation and Improvement.

[FR Doc. 2012–2309 Filed 2–1–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Ultra-Deepwater Advisory Committee

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Ultra-Deepwater Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, March 1, 2012, 8 a.m.–5 p.m. (CST).

ADDRESSES: Houston Airport Marriott, 18700 John F. Kennedy Boulevard, Houston, Texas 77032.

FOR FURTHER INFORMATION CONTACT: Elena Melchert, U.S. Department of Energy, Office of Oil and Natural Gas, Washington, DC 20585. Telephone: (202) 586–5600.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of the Ultra-Deepwater Advisory Committee is to provide advice on development and implementation of programs related to ultra-deepwater architecture and technology to the Secretary of Energy and to provide recommendations and priorities for the Department of Energy Annual Plan per requirements of the Energy Policy Act of 2005, Title IX, Subtitle J, Section 999D.

Tentative Agenda

March 1, 2012

7:30 a.m.—Registration.
8 a.m.—Welcome & Introductions, Opening Remarks, Discussion of Subcommittee Reports, and Findings regarding the *Draft 2012 Annual Plan.*
Noon—Working Lunch.
1 p.m.—Discussion of Recommendations regarding the *Draft 2012 Annual Plan.*
4:45 p.m.—Public Comments, if any.
5 p.m.—Adjourn.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Elena Melchert at the telephone number listed above. You must make your request for an oral statement at least three business days prior to the meeting, and reasonable provisions will be made to include all who wish to speak. The Designated Federal Officer and the Chairman of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the three-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 60 days at the following Web site: *http://www.fossil.energy.gov/programs/oilgas/advisorycommittees/UltraDeepwater.html.*

Issued at Washington, DC on January 27, 2012.

LaTanya Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–2314 Filed 2–1–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Unconventional Resources Technology Advisory Committee

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Unconventional Resources Technology Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, February 28, 2012, 8 a.m.–5 p.m. (CST) and Wednesday, February 29, 2012, 8 a.m.–12 p.m. (CST).

ADDRESSES: Houston Airport Marriott, 18700 John F. Kennedy Boulevard, Houston, Texas 77032.

FOR FURTHER INFORMATION CONTACT: Elena Melchert, U.S. Department of Energy, Office of Oil and Natural Gas, Washington, DC 20585. Phone: (202) 586–5600.

SUPPLEMENTARY INFORMATION: *Purpose of the Committee:* The purpose of the Unconventional Resources Technology Advisory Committee is to provide advice on development and implementation of programs related to onshore unconventional natural gas and other petroleum resources to the Secretary of Energy; and provide comments and recommendations and priorities for the Department of Energy Annual Plan per requirements of the Energy Policy Act of 2005, Title IX, Subtitle J, Section 999D.

Tentative Agenda

February 28, 2012

7:30 a.m. Registration
8 a.m. Welcome & Introductions, Opening Remarks, Discussion of Subcommittee Reports
Noon Working Lunch
1 p.m. Findings regarding the *Draft 2012 Annual Plan*
4:45 p.m. Public Comments, if any
5 p.m. Adjourn

February 29, 2012

7:30 a.m. Registration
8 a.m. Discussion of Recommendations regarding the *Draft 2012 Annual Plan*
12 p.m. Adjourn

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Elena Melchert at the telephone number listed above. You must make your request for an oral statement at least three business days prior to the meeting, and reasonable provisions will be made to include all who wish to speak. The Designated Federal Officer and the Chairman of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the three-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 60 days at the following Web site: *http://www.fossil.energy.gov/programs/oilgas/advisorycommittees/UnconventionalResources.html.*

Issued at Washington, DC, on January 27, 2012.

LaTanya Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–2316 Filed 2–1–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Basic Energy Sciences Advisory Committee (BESAC). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register.**

DATES: Thursday, February 23, 2012, 8:30 a.m.–5 p.m. and Friday, February 24, 2012, 9 a.m.–12 p.m.

ADDRESSES: Bethesda North Hotel and Conference Center, 5701 Marinelli Road, Bethesda, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Katie Perine; Office of Basic Energy Sciences; U.S. Department of Energy; Germantown Building, 1000 Independence Avenue SW., Washington, DC 20585; Telephone: (301) 903–6529.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of this meeting is to provide advice and guidance with respect to the basic energy sciences research program.

Tentative Agenda: Agenda will include discussions of the following:

- News from Office of Science/DOE.
- News from the Office of Basic Energy Sciences.
- Basic Research Directions for User Science at the National Ignition Facility.
- Materials Sciences and Engineering Division Committee of Visitors.
- Mesoscale Discussion.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Katie Perine by telephone at (301) 903–6594 (fax) or by email at: *katie.perine@science.doe.gov.* Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of this meeting will be available by contacting Ms. Katie Perine at the address or by email listed above.

Issued in Washington, DC on January 27, 2012.

LaTanya R. Butler,

Acting Deputy Committee Management Officer.

[FR Doc. 2012–2315 Filed 2–1–12; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF12–1–000]

Southwestern Power Administration; Notice of Filing

Take notice that on January 9, 2012, the Deputy Secretary of the Department of Energy, pursuant to the authority vested by sections 301(b), 302(a), 402(e), 641, 642, 643, and 644, and by Delegation Order Nos. 00–037.00 (December 6, 2001) and 00–001.00C (January 31, 2007), confirmed, approved, and placed in effect on an interim basis in Rate Order SWPA–63, Southwestern Power Administration Integrated System Rates, Rate Schedule P–11, Wholesale Rates for Hydro Peaking Power, Rate Schedule NFTS–11, Wholesale Rates for Non-Federal Transmission/Interconnection Facilities Service, and Rate Schedule EE–11, Wholesale Rate for Excess Energy, for period January 1, 2012 through September 30, 2015.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on February 8, 2012.

Dated: January 27, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–2355 Filed 2–1–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9626–1; EPA–HQ–ORD–2011–0051]

Draft Integrated Science Assessment for Lead

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: EPA is announcing the availability of a document titled, ''*Second External Review Draft Integrated Science Assessment for Lead''* (EPA/600/R–10/075B). The document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development as part of the review of the national ambient air quality standards (NAAQS) for lead (Pb).

EPA is releasing this draft document to seek review by the Clean Air Scientific Advisory Committee (CASAC) and the public (meeting date and location to be specified in a separate **Federal Register** Notice). The draft document does not represent and should not be construed to represent any final EPA policy, viewpoint, or determination. EPA will consider any public comments submitted in response to this notice when revising the document.

DATES: The public comment period begins February 2, 2012, and ends April 2, 2012. Comments must be received on or before April 2, 2012.

ADDRESSES: The ''*Second External Review Draft Integrated Science Assessment for Lead''* will be available primarily via the Internet on the National Center for Environmental Assessment's home page under the Recent Additions and Publications menus at *http://www.epa.gov/ncea.* A limited number of CD–ROM or paper copies will be available. Contact Ms. Marieka Boyd by phone (919–541–0031), fax (919–541–5078), or email (*boyd.marieka@epa.gov*) to request either of these, and please provide your name, your mailing address, and the document title, ''*Second External*

Review Draft Integrated Science Assessment for Lead'' (EPA/600/R–10/075B) to facilitate processing of your request.

FOR FURTHER INFORMATION CONTACT: For technical information, contact Dr. Ellen Kirrane, NCEA; telephone: 919–541–1340; facsimile: 919–541–2985; or email: *Kirrane.Ellen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About the Document

Section 108(a) of the Clean Air Act directs the Administrator to identify certain pollutants, which among other things, ''cause or contribute to air pollution, which may reasonably be anticipated to endanger public health or welfare'' and to issue air quality criteria for them. These air quality criteria are to ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare, which may be expected from the presence of [a] pollutant in the ambient air. * * *'' Under section 109 of the Act, EPA is to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d) of the Act requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health or welfare. EPA is also required to periodically review and revises the NAAQS, if appropriate, based on the revised air quality criteria.

Pb is one of six principal (or ''criteria'') pollutants for which EPA has established NAAQS. Periodically, EPA reviews the scientific basis for these standards by preparing an Integrated Science Assessment (ISA) (formerly called an Air Quality Criteria Document). The ISA and its supplementary materials provide a comprehensive assessment of the current scientific literature pertaining to known and anticipated effects on public health and welfare associated with the presence of the pollutant in the ambient air, emphasizing information that has become available since the last air quality criteria review in order to reflect the current state of knowledge. As such, the ISA forms the scientific foundation for each NAAQS review and is intended to provide information useful in forming EPA judgments about the different elements of the NAAQS. The CASAC, an independent scientific advisory committee whose review and advisory functions are mandated by Section 109(d)(2) of the Clean Air Act, is charged (among other things) with independent scientific review of EPA's air quality criteria.

On February 26, 2010 (75 FR 8934), EPA formally initiated its current review of the air quality criteria for Pb, requesting the submission of recent scientific information on specified topics. Soon after, a science policy workshop was held to identify key policy issues and questions to frame the review of the Pb NAAQS (75 FR 20843). Drawing from the workshop discussions, a draft ''*Integrated Review Plan for the National Ambient Air Quality Standards for Lead''* (EPA–452/D–11–001) (IRP) was developed and made available in late March 2011 for public comment and consultation with CASAC and was discussed by the CASAC via a publicly accessible teleconference consultation on May 5, 2011 (76 FR 20347, 76 FR 21346). The final IRP was released in December 2011 (76 FR 76972) and is available at *http://www.epa.gov/ttn/naaqs/standards/pb/s_pb_2010_pd.html.*

As part of the science assessment phase of the review, EPA held a workshop in December 2010 (75 FR 69078) to discuss, with invited scientific experts, preliminary draft materials prepared during the ongoing development of the Pb ISA. The first external review draft ISA for Pb was released on May 6, 2011, and is available at *http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=226323.* The CASAC Pb Review Panel met at a public meeting on July 20, 2011, to review the draft ISA (76 FR 36120). Subsequently, on December 9, 2011, the CASAC panel provided a consensus letter for their review to the Administrator of the EPA *http://yosemite.epa.gov/sab/sabproduct.nsf/WebCASAC/D3E2E8488025344D852579610068A8A1/$File/EPA-CASAC-12-002-unsigned.pdf*). The second external review draft ISA for Pb will be discussed at a public meeting of the CASAC Pb Review Panel, and public comments received will be provided to the CASAC panel. A future **Federal Register** notice will inform the public of the exact date and time of that CASAC meeting.

II. How To Submit Technical Comments to the Docket at *www.regulations.gov*

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2011–0051, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: ORD.Docket@epa.gov.*
- *Fax:* 202–566–1753.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460. The phone number is 202–566–1752.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, Room 3334, EPA West Building, 1301 Constitution Avenue NW., Washington, DC. The EPA Docket Center 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. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

If you provide comments by mail or hand delivery, please submit three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2011–0051. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information through *www.regulations.gov* or email that you consider to be CBI or otherwise protected. The *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 email comment directly to EPA without going through *www.regulations.gov,* your email 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 *www.epa.gov/epahome/dockets.htm.*

Docket: Documents in the docket are listed in the *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 materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: January 26, 2012.

Darrell A. Winner,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2012–2327 Filed 2–1–12; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

FDIC Advisory Committee on Community Banking; Notice of Meeting

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of open meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a meeting of the FDIC Advisory Committee on Community Banking, which will be held in Washington, DC. The Advisory Committee will provide advice and recommendations on a broad range of policy issues that have particular impact on small community banks throughout the United States and the local communities they serve, with a focus on rural areas.

DATES: Friday, February 17, 2012, from 8:30 a.m. to 3 p.m.

ADDRESSES: The meeting will be held in the FDIC Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC

FOR FURTHER INFORMATION CONTACT: Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Committee Management Officer of the FDIC, at (202) 898–7043.

SUPPLEMENTARY INFORMATION:

Agenda: The agenda will include a discussion of current issues affecting community banking. The agenda is subject to change. Any changes to the agenda will be announced at the beginning of the meeting.

Type of Meeting: The meeting will be open to the public, limited only by the space available on a first-come, first-served basis. For security reasons, members of the public will be subject to security screening procedures and must present a valid photo identification to enter the building. The FDIC will provide attendees with auxiliary aids (*e.g.,* sign language interpretation) required for this meeting. Those attendees needing such assistance should call (703) 562–6067 (Voice or TTY) at least two days before the meeting to make necessary arrangements. Written statements may be filed with the committee before or after the meeting. This Community Banking Advisory Committee meeting will be Webcast live via the Internet at *http://www.vodium.com/goto/fdic/communitybanking.asp.* This service is free and available to anyone with the following systems requirements: *http://www.vodium.com/home/sysreq.html.* Adobe Flash Player is required to view these presentations. The latest version of Adobe Flash Player can be downloaded at *http://www.adobe.com/shockwave/download/download.cgi?P1_Prod_Version=ShockwaveFlash.* Installation questions or troubleshooting help can be found at the same link. For optimal viewing, a high speed internet connection is recommended. The Community Banking meeting videos are made available on-demand approximately two weeks after the event.

Dated: January 30, 2012.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Committee Management Officer.

[FR Doc. 2012–2292 Filed 2–1–12; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notice

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, February 7, 2012 at 10 a.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This Meeting Will Be Closed To The Public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g. Audits conducted pursuant to 2 U.S.C. 437g, § 438(b), and Title 26, U.S.C. Matters concerning participation in civil actions or proceedings or arbitration. Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Submitted: January 31, 2012.

Shelley E. Garr,

Deputy Secretary of the Commission.

[FR Doc. 2012–2461 Filed 1–31–12; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS12–02]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104 (b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: OCC—250 E Street SW., Room 2C, Washington, DC 20219.

Date: February 8, 2012.

Time: Immediately following the ASC open session.

Status: Closed.

Matters To Be Considered

December 14, 2011 minutes—Closed Session;

Preliminary discussion of State Compliance Reviews.

Dated: January 27, 2012.

James R. Park,

Executive Director.

[FR Doc. 2012–2272 Filed 2–1–12; 8:45 am]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS12–01]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as

amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: OCC—250 E Street SW., Room 2C, Washington, DC 20219.

Date: February 8, 2012.

Time: 10:30 a.m.

Status: Open.

Matters To Be Considered

Summary Agenda

November 17, 2011 minutes—Special Meeting;

December 14, 2011 minutes—Open Session.

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda

Appraisal Foundation 2012 Grant Proposal,

ASC Fiscal Year 2012 Revised Budget,

Response to GAO Report,

Alaska Compliance Review,

Indiana Compliance Review,

Maine Compliance Review,

Oklahoma Compliance Review.

How To Attend and Observe an ASC Meeting

Email your name, organization and contact information to *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street NW., Ste 760, Washington, DC 20005. The fax number is (202) 289–4101. Your request must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: January 27, 2012.

James R. Park,

Executive Director.

[FR Doc. 2012–2273 Filed 2–1–12; 8:45 am]

BILLING CODE 6700–01–P

DEPARTMENT OF THE TREASURY

Office of The Comptroller of the Currency

Federal Reserve System

Federal Deposit Insurance Corporation

Agency Information Collection Activities: Submission for OMB Review; Joint Comment Request

AGENCIES: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection to be submitted to OMB for review and approval under the Paperwork Reduction Act of 1995.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the OCC, the Board, and the FDIC (the agencies), may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

On November 23, 2011, the agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), published a notice in the **Federal Register** (76 FR 72497) requesting public comment on the extension, without revision, of the currently approved information collections: the Country Exposure Report (FFIEC 009) and the Country Exposure Information Report (FFIEC 009a). The comment period for this notice expired on January 23, 2012. No comments were received. The agencies are now submitting requests to OMB for approval of the extension, without revision, of the FFIEC 009 and FFIEC 009a reports.

DATES: Comments must be submitted on or before March 5, 2012.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments should refer to the OMB control number(s) and will be shared among the agencies.

OCC: You should direct all written comments to: Communications Division, Office of the Comptroller of the Currency, Mailstop 2–3, Attention: 1557–0100, 250 E Street SW., Washington, DC 20219. In addition, comments may be sent by fax to (202) 874–5274, or by electronic mail to *regs.comments@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 250 E Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 874–4700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Board: You may submit comments, which should refer to FFIEC 009 or FFIEC 009a, by any of the following methods:

- *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include reporting form number in the subject line of the message.
- *Fax:* (202) 452–3819 or 202–452–3102.
- *Mail:* Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets NW.) between 9 a.m. and 5 p.m. on weekdays.

FDIC: You may submit comments, which should refer to ''Country Exposure Reports, 3064–0017,'' 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 FDIC Web site.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''Country Exposure Reports, 3064–0017'' in the subject line of the message.
- *Mail:* Gary A. Kuiper, Counsel, Attn: Comments, Room F–1086, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the 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.

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. Comments may be inspected at the FDIC Public Information Center, Room E–1002, 3501 Fairfax Drive, Arlington, VA 22226, between 9 a.m. and 5 p.m. on business days.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer for the agencies, Shagufta Ahmed, by mail to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235 725 17th Street NW., Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: For further information about the revisions discussed in this notice, please contact any of the agency clearance officers whose names appear below.

OCC: Ira L. Mills or Mary H. Gottlieb, OCC Clearance Officers, (202) 874–6055 or (202) 874–5090, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 250 E Street SW., Washington, DC 20219.

Board: Cynthia Ayouch, Federal Reserve Board Clearance Officer, (202) 452–3829, Division of Research and Statistics, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Gary Kuiper, Counsel, (202) 898–3877, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

Comments are invited on:

a. Whether the proposed collection of information is necessary for the proper performance of the agencies' functions; including whether the information has practical utility;

b. The accuracy of the agencies' estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected; and

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this notice will be shared among the agencies. All comments will become a matter of public record.

Information Collection Proposal

Proposal to extend for three years, without revision, the following currently approved collections of information:

Report Title: Country Exposure Report and Country Exposure Information Report.

Form Number: FFIEC 009 and FFIEC 009a.

Frequency of Response: Quarterly.

Affected Public: U.S. banks, savings associations, and bank holding companies.

OCC

OMB Number: 1557–0100.

Estimated Number of Respondents: 16 (FFIEC 009), 9 (FFIEC 009a).

Estimated Average Time per Response: 70 burden hours (FFIEC 009), 5.25 burden hours (FFIEC 009a).

Estimated Total Annual Burden: 4,480 burden hours (FFIEC 009), 189 burden hours (FFIEC 009a).

Board

OMB Number: 7100–0035.

Estimated Number of Respondents: 35 (FFIEC 009), 24 (FFIEC 009a).

Estimated Average Time per Response: 70 burden hours (FFIEC 009), 5.25 burden hours (FFIEC 009a).

Estimated Total Annual Burden: 9,800 burden hours (FFIEC 009), 504 burden hours (FFIEC 009a).

FDIC

OMB Number: 3064–0017.

Estimated Number of Respondents: 21 (FFIEC 009), 10 (FFIEC 009a).

Estimated Average Time per Response: 70 burden hours (FFIEC 009), 5.25 burden hours (FFIEC 009a).

Estimated Total Annual Burden: 5,880 burden hours (FFIEC 009), 210 burden hours (FFIEC 009a).

General Description of Reports

These information collections are mandatory: 12 U.S.C. 161 and 1817 (national banks), 12 U.S.C. 248(a), 1844(c), and 3906 (state member banks and bank holding companies); 12 U.S.C. 1817 and 1820 (insured state nonmember commercial and savings banks); and 12 U.S.C. 1464 (for savings associations). The FFIEC 009 information collection is given confidential treatment (5 U.S.C. 552(b)(4) and (b)(8)). The FFIEC 009a information collection is not given confidential treatment.

Abstract

The Country Exposure Report (FFIEC 009) is filed quarterly with the agencies and provides information on international claims of U.S. banks, savings associations, and bank holding companies that is used for supervisory and analytical purposes. The information is used to monitor country exposure of banks to determine the degree of risk in their portfolios and the possible impact on U.S. banks of adverse developments in particular countries. The Country Exposure Information Report (FFIEC 009a) is a supplement to the FFIEC 009 and provides publicly available information on material foreign country exposures (all exposures to a country in excess of 1 percent of total assets or 20 percent of capital, whichever is less) of U.S. banks, savings associations and bank holding companies that file the FFIEC 009 report. As part of the Country Exposure Information Report, reporting institutions must also furnish a list of countries in which they have lending exposures above 0.75 percent of total assets or 15 percent of total capital, whichever is less.

Current Actions

The agencies are not planning any revisions at this time. However, the agencies expect to propose revisions in the near future, including potential changes to the Country Codes used in the FFIEC 009 report in order to more closely match the Country Codes on the Department of the Treasury's Treasury International Capital (TIC) reports (OMB Nos.: 1505–0016, 0017, 0018, 0019, 0020, and 0024).

Dated: January 26, 2012.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Dated: Board of Governors of the Federal Reserve System, January 27, 2012.

Jennifer J. Johnson,

Secretary of the Board,

Dated at Washington, DC, this 25th day of January, 2012.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2012–2274 Filed 2–1–12; 8:45 am]

BILLING CODE 4810–33–P; 6210–01–P; 6714–01–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 applications will also 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 February 27, 2012.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *NBC Bancshares, LLC,* Lincoln, Nebraska; to retain 76.44 percent of the voting shares of Nebraska Bank of Commerce, Lincoln, Nebraska, upon its conversion from a savings association to a Nebraska state banking corporation.

Board of Governors of the Federal Reserve System, January 30, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012–2329 Filed 2–1–12; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–FAS–2012–01; Docket No: 2012–0002; Sequence 4]

Federal Travel Regulation; GSA E-Gov Travel Service (ETS) Transition to E-Gov Travel Service 2 (ETS2)

AGENCY: Federal Acquisition Service (FAS), General Services Administration (GSA).

ACTION: Notice of a bulletin.

SUMMARY: The attached bulletin announces GSA ETS Transition to ETS2.

DATES: *Effective Date:* This bulletin is effective the date of publication.

FOR FURTHER INFORMATION CONTACT: Contact Mr. Frank Robinson, ETS Program Manager Center for Travel Management (QMCD), Office of Travel and Transportation Services (QMC), at *frank.robinson@gsa.gov* or (703) 605–2151.

SUPPLEMENTARY INFORMATION: The Federal Travel Regulation (FTR) Part 301–73 requires all agencies to deploy and implement an ETS. This requirement extends to ETS2. Agencies should begin making plans to transition from ETS to ETS2 during FY12, and must execute a Memorandum of Understanding (MOU) for full deployment of ETS2 with the GSA no later than March 30, 2012.

Dated: January 25, 2012.

Steven Kempf,

Commissioner, Federal Acquisition Service, U.S. General Services Administration.

January 25, 2012

General Services Administration

Washington, DC 22202

E-GOV TRAVEL SERVICE

GSA Bulletin ETS 12–01

TO: Heads of Federal Agencies

SUBJECT: GSA E-Gov Travel Service (ETS) Transition to ETS2

1. What is the purpose of this bulletin?

The Federal Travel Regulation (FTR) Part 301–73 requires all agencies to deploy and implement an E-Gov Travel Service (ETS). ETS is a Governmentwide, web-based, end-to-end travel management service administered by General Services Administration (GSA), Federal Acquisition Service (FAS). This requirement extends to E-Gov Travel Service 2 (ETS2) when it becomes available in Fiscal Year 2012 (FY12). The Department of Defense (DoD) is not subject to this FTR requirement but may choose to participate in ETS2.

2. What is the background of this bulletin?

The ETS Master Contracts expire on November 11, 2013, and GSA plans to award the next generation ETS2 to build on the investment and benefits achieved with ETS. ETS2 will focus on the Administration's principles of strategic sourcing, data-driven transparency, standardization, consolidation, sustainability, and cost reduction. ETS2 is a 15-year Master Contract (3-year base period and three 4-year option periods), with Task Orders at the agency level. Key transition dates are included below:

Date	Event	Agency impact
April 2012	Anticipated ETS2 award	Begin Task Order process.
November 2013	ETS Master Contracts end; anticipated ETS contract extensions are available in the event transition to ETS2 is not complete.	Under anticipated ETS extensions, transaction fees increase as transaction volumes decrease.
November 2014	Anticipated ETS Extension Base Period ends	Transaction fees increase.
November 2015	Anticipated ETS Extension Option Period ends	ETS is no longer available.

It is important for agencies to begin now to prepare for transition from ETS to ETS2.

3. How should agencies prepare?

Agencies should begin making plans to transition from ETS to ETS2 during FY12, and must execute a Memorandum of Understanding (MOU) for full deployment of ETS2 with the GSA no later than March 30, 2012. The MOU will identify key points of contact, including the agency's senior level official responsible for developing and implementing policies and controls to ensure efficient spending on travel, the ETS2 transition manager and transition team members. The MOU will also outline the agency's ETS2 transition plan that provides resources to achieve the following milestone dates:

A. Task Order awarded, negotiated and executed.

B. ETS2 Configuration, Data Loading and Systems Integration completed.

C. Initial Launch/Roll-out begins.

D. ETS2 is fully deployed; ETS task order closed.

An MOU template will be available within 15 business days of the date of this Bulletin.

Agencies are urged to aggressively pursue transition to ETS2, as anticipated contract extensions will have significantly higher transaction fees for agencies that use them. The GSA Center for Travel Management will assist agencies as they transition to ETS2.

4. Whom should I call for further information?

For further information, please contact Mr. Frank Robinson, ETS Program Manager Center for Travel Management (QMCD), Office of Travel and Transportation Services (QMC), Federal Acquisition Service, U. S. General Services Administration at *frank.robinson@gsa.gov* or (703) 605–2151.

Steven Kempf,
Commissioner, Federal Acquisition Service, U.S. General Services Administration.

[FR Doc. 2012–2325 Filed 2–1–12; 8:45 am]

BILLING CODE 6820–89–P

GENERAL SERVICES ADMINISTRATION

[Notice-MV–2012–01; Docket 2012–0002; Sequence 3]

Public Availability of General Services Administration FY 2011 Service Contract Inventory

AGENCY: Office of Acquisition Policy (MV); General Services Administration (GSA).

ACTION: Notice of public availability of FY 2011 Service Contract Inventories.

SUMMARY: GSA is announcing the availability of the FY 2011 Service Contract Inventory.

DATES: *Effective date:* February 2, 2012.

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Mr. Paul F. Boyle in the Office of Acquisition Policy at (202) 501–0324 or via email to *paul.boyle@gsa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Section 743 of Division C of Fiscal Year (FY) 2010 Consolidated Appropriations Act Public Law 111–117, GSA is publishing this notice to advise the public of the availability of the FY 2011 Service Contract Inventory. This inventory provides information on service contract actions over $25,000 that were made in FY 2011. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available on the *http://www.whitehouse.gov/omb/*. The GSA has posted its inventory and summaries of the inventory on the GSA Web site at the following link: *http://www.gsa.gov/gsasci.*

Dated: January 27, 2012.

Joseph A. Neurauter,

Deputy Chief Acquisition Officer, Senior Procurement Executive, Office of Acquisition Policy.

[FR Doc. 2012–2354 Filed 2–1–12; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New; 60-day Notice]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days.

Proposed Project: The Children's Health Insurance Program Reauthorization Act (CHIPRA) Express Lane Eligibility (ELE) Evaluation—OMB No. 0990–NEW—Assistant Secretary Planning and Evaluation (ASPE).

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting the Office of Management and Budget (OMB) approval on a new collection to evaluate the implementation of a new policy known as Express Lane Eligibility (ELE). With ELE, a state's Medicaid and/or Children's Health Insurance Program (CHIP) can rely on another agency's eligibility findings to qualify children for health coverage, despite their different methods of assessing income or otherwise determining eligibility.

CHIPRA authorized an extensive, rigorous evaluation of ELE, creating an exceptional opportunity to document ELE implementation across states and to assess the changes to coverage or administrative costs that may have resulted. The evaluation also provides an opportunity to understand other methods of simplified enrollment that states have been pursuing and to assess the benefits and potential costs of these methods compared to those of ELE. To answer key research questions, ASPE will draw on 5 primary data collections including (1) collecting administrative cost data from ELE and non-ELE states, (2) collecting enrollment data from ELE and non-ELE states, (3) conducting case studies in ELE and non-ELE states, including key informant interviews and focus groups, (4) conducting a 51-state (50 states and the District of Columbia) survey, and (5) holding quarterly monitoring calls with 30 states. This request seeks clearance on all data collections except the collection of administrative cost and enrollment data for ELE states. The administrative cost data, enrollment data, case studies, and 51-state survey will take place only once over the course of the two year evaluation. The quarterly monitoring calls will take place take place 5 times over the course of the 13 months and will include an initial call of up to an hour in length and 4 shorter follow-up calls of about 15 minutes in length each. The administrative cost and enrollment data collection includes contact with key informants and state-level computer programmers and will be collected using Microsoft document templates. The qualitative case studies will include site visit interviews with state and local-level key informants in 8 ELE states and 6 non-ELE states, plus focus groups with

parents of children whose eligibility was established or renewed through ELE methods and parents of children enrolled or renewed through non-ELE routes. The survey component will be conducted using a Dataweb program as well as a paper and pencil option and will involve Medicaid and CHIP program directors from the 50 states and the District of Columbia. Finally, the quarterly monitoring calls will be conducted with a sample of 30 states drawn from both ELE and non-ELE states.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Type of respondent	Number of respondents	Number of responses per respondent	Average burden (in hours) per response	Total burden hours
Administrative Cost Discussion Guide (Attachment B).	Key informants	18	1	1.5	27
Enrollment Extraction Form (Attachment C).	State-level computer programmers	6	1	40	240
ELE Case Study Protocol (Attachment D1).	Key informants (ELE states—state—and local—levels).	120	1	1	120
Non-ELE Case Study Protocol (Attachment D2).	Key informants (non-ELE states—state—and local—levels).	90	1	1	90
Moderator's Guide (Attachments E1 and E2).	Focus group participants (2 focus groups in 8 ELE states and 2 focus groups in 4 non-ELE states = 24 focus groups).	240	1	1.5	360
51-State Survey (Attachment F)	Medicaid and CHIP officials	51	1	45/60	38
Quarterly Interview Protocol (Attachment G).	Key informants (quarterly monitoring calls).	30	5	30/60	75
Total					950

Keith A.Tucker,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2012–2275 Filed 2–1–12; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute for Occupational Safety and Health

Final Effect of Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice concerning the final effect of the HHS decision to designate a class of employees from the Pantex Plant in Amarillo, Texas, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On December 21, 2011, as provided for under 42 U.S.C. 7384q(b), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Pantex Plant in Amarillo, Texas, during the period from January 1, 1958 through December 31, 1983, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the SEC.

This designation became effective on January 20, 2012, as provided for under 42 U.S.C. 7384*l*(14)(C). Hence, beginning on January 20, 2012, members of this class of employees, defined as reported in this notice, became members of the SEC.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone (877) 222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012–2249 Filed 2–1–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Calleen S. Zach, Creighton University: Based on evidence obtained from Creighton University (CU) and additional evidence gathered by the Office of Research Integrity (ORI) during its oversight review, ORI found that Ms. Calleen S. Zach, former Research Assistant and Data Base Manager, CU, engaged in research misconduct in research funded by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant R01 HD046991.

Specifically, ORI found that the Respondent provided falsified subject enrollment numbers in an application to NIH for continued funding of R01 HD046991 in 2008, a no-cost, one-year extension request for R01 HD046991 (April 8, 2009, letter to NICHD, NIH), and an application for additional funding of R01 HD046991 (June 30, 2009, to NICHD, NIH). In addition, she knowingly and intentionally provided falsified subject enrollment numbers in reports to the CU Institutional Review Board (IRB) in 2008 and 2009.

ORI concluded that Respondent's knowing and intentional falsification of data constitutes research misconduct as defined by 42 CFR 93.103. In addition, ORI found that Respondent's intentionally deceptive behavior, including false statements made to the CU institutional officials, forgery of petty cash receipts, and theft of NIH

research grant funds establish a lack of trustworthiness and present responsibility to be a steward of Federal funds. 2 CFR 180.125, 180.800(d), 376.10.

The following administrative actions have been implemented for a period of five (5) years, beginning on January 23, 2012:

(1) Ms. Zach is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government, referred to as ''covered transactions'' as defined in 2 CFR 180.200, 376.10; and

(2) Ms. Zach is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2012–2276 Filed 2–1–12; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Assessing the Feasibility of Disseminating EHC Products through Educational Activities.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on November 23rd, 2011 and allowed 60 days for public comment. No substantive comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by March 5, 2012.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Assessing the Feasibility of Disseminating EHC Products through Educational Activities

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve under the Paperwork Reduction Act of 1995 this collection of information from users of products provided by the John M. Eisenberg Clinical Decisions and Communications Science Center (Eisenberg Center). Information collected consists of feedback from managers, instructors, and learners about these health care guides and other products presented as part of Continuing Medical Education activities.

AHRQ is the lead agency charged with supporting research designed to improve the quality of healthcare, reduce its cost, improve patient safety, decrease medical errors, and broaden access to essential services. AHRQ's Eisenberg Center's mission is improving communication of research findings to a variety of audiences (''customers''), including consumers, clinicians, and health care policy makers. The Eisenberg Center compiles research results into useful formats for customer stakeholders. The Eisenberg Center also conducts investigations into effective communication of research findings in order to improve the usability and rapid incorporation of findings into medical practice. The Eisenberg Center is one of three components of AHRQ's Effective Health Care (EHC) Program.

A primary goal of the Eisenberg Center is to translate results from systematic reviews of evidence comparing the effectiveness of two or more clinical care processes into information that can be used to support clinical decision-making. The major products of such efforts are brief guides designed for clinicians, patients, and policy makers that summarize the evidence concerning the effectiveness of various diagnostic and treatment processes. All of the guides and other products are designed to help decision makers, including clinicians and health care consumers, use research evidence to maximize the benefits of health care, minimize harm, and optimize the use of health care resources.

The collections proposed under this project include activities to assess the feasibility of disseminating EHC products through Continuing Medical Education (CME) activities, specifically those planned and implemented by member organizations of the Society of Academic Continuing Medical Education (SACME). SACME is an organization with members in both the U.S. and Canada formed in 1976 to ''promote the research, scholarship, evaluation and development of CME and Continuing Professional Development (CPD) that helps to enhance the performance of physicians and other healthcare professionals practicing in the United States, Canada, and elsewhere for purposes of improving individual and population health.''

For this project, the Eisenberg Center will work with six organizations selected from applications submitted by SACME members that had been invited to compete for funding. The Eisenberg Center selected sites based on the size of each organization's CME audience, the project's ability to inform the CME community, its degree of generalizability and replicability, and overall quality. Organizations selected for participation in the feasibility study have committed to specific activities designed to disseminate EHC Program summary guides to physicians, other clinicians, instructional faculty, and clinical researchers who participate in CME activities. Another partner in these efforts is the Association of American Medical Colleges (AAMC), which is assisting the project through access to MedEdPORTAL and CME4docs, two recently launched initiatives that are designed to encourage use of high quality CME resources by medical school faculty and others involved in development and delivery of CME.

This research has the following goals:

(1) Identify critical factors that enhance or impede integration of EHC products into CME activities;

(2) Assess strategies to remove, overcome, or work around barriers to

integration of EHC products into CME programming with selected audiences;

(3) Confirm approaches that can be used in whole or in part to create and deliver effective CME instruction about EHC products (e.g., clinician guides, consumer guides, faculty slide sets); and,

(4) Review early educational program outcomes associated with integration of EHC products into CME activities.

This study is being conducted by AHRQ through its contractor, the Eisenberg Center—Baylor College of Medicine (EC–BMC), pursuant to AHRQ's statutory authority to conduct and support research, and disseminate information, on healthcare and on systems for the delivery of such care, including activities with respect to both the quality, effectiveness, efficiency, appropriateness and value of healthcare services and clinical practice. 42 U.S.C. 299a(a)(1) and (4).

Method of Collection

To achieve the goals of this project the following activities and data collections will be implemented:

(1) Interviews with CME Project Directors—Semi-structured interviews will be conducted with the representative of each participating CME institution leading the development and implementation of the educational activities associated with the study. The director is typically, but not always, an expert physician. The interviews will be designed to: (a) Assess perceived feasibility and obtain feedback on strategies used to integrate EHC products into their planned CME activities involving varied content, instructional methods, and delivery formats; and, (b) characterize barriers and facilitators to the integration of EHC products into specific CME activities.

(2) Focus Group with CME Project Directors—A focus group will also be convened with the CME Project Directors described above near the midpoint of the project to: (a) Obtain feedback on the perceived usefulness, currency and quality of the EHC products; and, (b) explore the overall implications concerning CME activities as an avenue for disseminating EHC products.

(3) Interviews with Faculty Members—Semi-structured interviews will be conducted with clinicians who served as faculty in the CME activities associated with this study to: (a) Obtain perspectives on the quality, relevance, and utility of the resources that they accessed and integrated into their CME activities; (b) identify obstacles to the integration of EHC products into specific CME activities and contexts; and, (c) identify additional tools or resources that could facilitate the integration of EHC content into CME activities.

(4) Initial Survey Assessments of CME Participants—Learner questionnaires will be administered to each clinician participating in a CME activity to determine the degree to which the learning activities with integrated EHC products affected educational outcomes such as levels of knowledge about specific clinical treatment issues and incorporation of new knowledge into clinical practice. The initial questionnaire will be distributed by paper or electronically at the immediate conclusion of participation in the CME activity.

(5) Follow-up Survey Assessments of CME Participants—A second questionnaire will be distributed electronically two months after each activity to each clinician learner and will be accessible through the Eisenberg Center Web site. An email message will be sent to invite participation and will include a link to the questionnaire. Gathering such data will provide a view of current awareness of EHC products and learners' intentions to use the products in practice as well as perceptions of barriers to implementation.

The collected data will be used to determine the feasibility of: (a) Including EHC products (*i.e.,* clinician guides, consumer guides, faculty slide sets) in CME activities that employ varied delivery modalities; and, (b) initiating additional studies to identify factors that promote effective integration of evidence-based content into educational activities. The data gathered from physicians and other clinical professionals who are participating in CME activities will foster understanding of the current state of awareness of and willingness to learn about results from comparative effectiveness research studies. The planned assessment approaches will promote better understanding of strategies that are most appropriate for use in incorporating comparativeness effectiveness research findings into CME activities, as well as understanding which strategies produce desired educational outcomes and are most acceptable to targeted learners in this case clinical professionals. The information generated will be used in designing learning programs for delivery through the Eisenberg Center for Clinical Decisions and Communications Science and will be shared with others in the CME community through journal articles, Web-based publications, and scientific presentations.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in this research. Interviews will be conducted with each CME Project Director and will last about 30 minutes, while the focus group will last about 90 minutes. A maximum of 30 interviews will be conducted with CME faculty members. These are estimated to take 30 minutes to complete. The initial survey assessment of CME participant learners will take about 5 minutes to complete per questionnaire, as will the follow-up survey assessment. These questionnaires will be administered to the approximately 4,500 clinicians who will complete one of the study's CME activities. Each learner will be asked to complete both the initial and follow-up surveys.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Type of data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Interviews with CME Project Directors	10	1	30/60	5
Focus Group with CME Project Directors	10	1	1.5	15
Interviews with Faculty Members	30	1	30/60	15
Initial Survey Assessment of CME Participants	4,500	1	5/60	375
Follow up Survey Assessment of CME Participants	4,500	1	5/60	375
Total	9,050	na	na	785

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this research. The total annual cost burden is estimated to be $65,233.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Type of data collection	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Interviews with CME Project Directors	10	5	$64.31+	$322
Focus Group with CME Project Directors	10	15	64.31+	965
Interviews with Faculty Members	30	15	83.59++	1,254
Initial Survey Assessment of CME Participants	4,500	375	83.59++	31,346
Follow up Survey Assessment of CME Participants	4,500	375	83.59++	31,346
Total	9,050	785	na	65,233

+Based upon the mean wages for clinicians (29–1062 family and general practitioners), National Compensation Survey: Occupational wages in the United States May 2010, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm.*

++Based upon the mean wages for clinicians (29–1062 family and general practitioners) and medical and health services managers (11–9111), National Compensation Survey: Occupational wages in the United States May 2010, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm.*

Estimated Annual Cost to the Government

Exhibit 3 shows the total and annualized cost by the major cost components. The maximum cost to the Federal Government is estimated to be $166,417 annually.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$110,846	$55,423
Data Collection Activities	47,563	23,781
Data Processing and Analysis	38,250	19,125
Project Management	73,675	36,838
Overhead	62,500	31,250
Total	332,834	166,417

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and, (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: January 20, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–2130 Filed 2–1–12; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Detecting Emerging Vector Borne Zoonotic Pathogens in Indonesia, Funding Opportunity Announcement (FOA), CK12–002, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 1 p.m.–5 p.m., March 26, 2012 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Detecting Emerging Vector Borne Zoonotic Pathogens in Indonesia, FOA CK12–002, initial review.''

Contact Person for More Information: Greg Anderson, M.P.H., M.S., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 26, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–2298 Filed 2–1–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

World Trade Center Health Program Scientific/Technical Advisory Committee (WTCHP STAC or Advisory Committee), National Institute for Occupational Safety and Health (NIOSH)

Notice of Cancellation: This notice was published in the **Federal Register** on December 29, 2011, Volume 76, Number 250, page 81947. This meeting, scheduled to convene on January 24, 2012 was canceled due to lack of access to the telephone number published to provide public access to the meeting. Notice will be provided when the next meeting is scheduled in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463).

Contact Person for More Information: Paul J. Middendorf, Ph.D., Designated Federal Officer, NIOSH, CDC, 4676 Columbia Parkway, Mailstop R–45, Cincinnati, OH 45226, Telephone: 1–(888) 982–4748, Email: *wtc-stac@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 26, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–2296 Filed 2–1–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10161]

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:* Extension of a currently approved collection; *Title of Information Collection:* New Freedom Initiative—Web-based Reporting System for Grantees; *Use:* CMS awards competitive grants to States and other eligible entities for the purpose of designing and implementing effective and enduring improvements in community-based long-term services and support systems. CMS requires that grantees report on a quarterly, semi-annual, and/or annual basis depending upon the grant type. CMS requires the information obtained through web-based grantee reporting for two reasons: (1) In order to effectively monitor the grants; and, (2) To report to Congress and other interested stakeholders the progress and obstacles experienced by the grantees. The grantees are the respondents to the web-based reporting system. *Form Number:* CMS–10161 (OCN 0938–0979); *Frequency:* Annually, Semi-annually, and Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 171; *Total Annual Responses:* 428; *Total Annual Hours:* 3,764. (For policy questions regarding this collection contact Effie George at (410) 786–8639. 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 address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (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 *April 2, 2012:*

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 CMS–10161 (OCN 0938–0979), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 25, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–2286 Filed 2–1–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Welfare Demonstration Projects Information Collection.

OMB No.: New.

Description: Per section 1130 of the Social Security Act as amended by Public Law 112–34, the Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF), Children's Bureau (CB) is planning to announce an opportunity for title IV–E agencies to submit proposals for new child welfare waiver demonstration projects. CB is able to approve up to ten child welfare

waiver demonstration projects in each of Fiscal Years 2012, 2013 and 2014. These demonstration waiver projects involve the waiver of certain requirements of title IV–E and IV–B. These projects do not provide additional funding to carry out new services; rather they allow more flexible uses of Federal funds in order to test new approaches to service delivery or financing structures in an effort to improve outcomes for children and families involved in the child welfare system. We encourage title IV–E agencies wishing to apply for approval of a waiver demonstration project to submit a letter of intent followed by a full proposal at a later date. For title IV–E agencies that choose to submit a letter of intent, the letter of intent should indicate the title IV–E agency's intent to submit a proposal, and briefly describe the demonstration project, including the nature of the intervention the agency wishes to implement, the target population the agency wishes to serve, the reasons for selecting the proposed project and the evaluation design that the agency is considering. The full proposal must describe the project in extensive detail including the goals identified in statute that the project is intended to accomplish, the geographic areas in which the proposed project will be conducted, the service interventions to be implemented, the impact intervention is expected to have on outcomes related to safety, permanency, well-being, how service provision will change for children and families under the waiver demonstration, a statement of program requirements for waivers needed to conduct the project, an estimate of the projected costs or savings of the proposed project, a description of the proposed evaluation design and an accounting of any other sources of funding that have been used to provide the services that the agency now proposes to address under a waiver demonstration.

Respondents: States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter of intent	10	1	5	50
Full proposal	10	1	40	400

Estimated Total Annual Burden Hours: 450.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed 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 proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (e) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–2320 Filed 2–1–12; 8:45 am]

BILLING CODE 4184–01–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: Cardiac Electrophysiology, Arrhythmia and Sleep Apnea.

Date: February 15, 2012.

Time: 2 p.m. to 5 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: Olga A. Tjurmina, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 451–1375, *ot3d@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics: Topics in Bacterial Pathogenesis.

Date: March 1–2, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Rolf Menzel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, MSC 7808, Bethesda, MD 20892, (301) 435–0952, *menzelro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Non-HIV Diagnostics, Food Safety, Sterilization/Disinfection and Bioremediation.

Date: March 1–2, 2012.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Regis Hotel, 923 16th and K Streets NW., Washington, DC 20006.

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, (301) 435–1167, *pandyaga@mai.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD11–003: Specialized Centers of Research (SCOR) on Sex Differences.
Date: March 1–2, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Robert Garofalo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6156, MSC 7892, Bethesda, MD 20892, (301) 435–1043, *garofalors@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders.
Date: March 1, 2012.
Time: 8 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Delfina, 530 Pico Boulevard, Santa Monica, CA 90405.
Contact Person: Dan D Gerendasy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7843, Bethesda, MD 20892, (301) 408–9164, *gerendad@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.
Date: March 1–2, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda North Marriott & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.
Contact Person: J Scott Osborne, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435–1782, *osbornes@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Virology.
Date: March 1–2, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692, (301) 435–1149, *elzaataf@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Sensory Technologies.
Date: March 1–2, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Fairmont San Francisco, 950 Mason Street, San Francisco, CA 94108.
Contact Person: Paek-Gyu Lee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4201, MSC 7812, Bethesda, MD 20892, (301) 613–2064, *leepg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Non-HIV Anti-Infective Therapeutics.
Date: March 1–2, 2012.
Time: 8:30 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Marina del Rey Hotel, 13534 Bali Way, Waterfront Conference Room, Marina del Rey, CA 90292.
Contact Person: Kenneth M Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 3204, MSC 7808, Bethesda, MD 20892, (301) 496–6980, *izumikm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Microbial Pathogens.
Date: March 1–2, 2012.
Time: 9 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, (301) 996–5819, *zhengli@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–11–304: Development of Appropriate Pediatric Formulations and Drug Delivery Systems.
Date: March 2, 2012.
Time: 8 a.m. to 10 a.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Delfina, 530 Pico Boulevard, Santa Monica, CA 90405.
Contact Person: Dan D Gerendasy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7843, Bethesda, MD 20892, (301) 408–9164, *gerendad@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biostatistical Methods and Research Design Study Section.
Date: March 2, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Hotel Kabuki, 1625 Post Street, San Francisco, CA 94115.
Contact Person: Tomas Drgon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, (301) 435–1017, *tdrgon@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–09–259 and PAR–09–260: Optimization of Small Molecule Probes for the Nervous System.
Date: March 2, 2012.
Time: 10 a.m. to 1 p.m.
Agenda: To review and evaluate grant applications.
Place: Sheraton Delfina, 530 Pico Boulevard, Santa Monica, CA 90405.
Contact Person: Dan D Gerendasy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7843, Bethesda, MD 20892, (301) 408–9164, *gerendad@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: January 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–2324 Filed 2–1–12; 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 Conflicts: Immunobiology.
Date: February 23–24, 2012.
Time: 9 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).
Contact Person: Stephen M. Nigida, Ph.D., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4212, MSC 7812, Bethesda, MD 20892, (301) 435–1222, *nigidas@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Overflow: Cancer Therapeutics.
Date: February 27, 2012.
Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Careen K Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Integrative and Functional Neuroscience.

Date: February 28–29, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7844, Bethesda, MD 20892, (301) 435–1033, *hoshawb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR: Cancer Health Disparities/Diversity in Basic Cancer Research.

Date: March 2, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Cathleen L Cooper, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, (301) 443–4512, *cooperc@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: January 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–2322 Filed 2–1–12; 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; SBIR Topic 68: Multi-Layer Coated Gratings for CT (Contract Review).

Date: February 24, 2012.

Time: 11 a.m. to 4 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: Chang Sook Kim, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7179, Bethesda, MD 20892–7924, (301) 435–0287, *carolko@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Haptoglobin for Sickle Cell Disease.

Date: February 24, 2012.

Time: 12 p.m. to 1 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: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892, (301) 435–0287, *Pintuccig@nhlbi.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: January 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–2318 Filed 2–1–12; 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 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 of Environmental Health Sciences Special Emphasis Panel; Expedited Review of Exposure Assessment Applications.

Date: February 21, 2012.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Key Stone Building 4401, East Campus, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, 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: January 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–2317 Filed 2–1–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4050–DR; Docket ID FEMA–2011–0001]

Alaska; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Alaska (FEMA–4050–DR), dated December 22, 2011, and related determinations.

DATES: *Effective Date:* January 24, 2012.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this declared disaster is now November 8, 2011, through and including November 13, 2011.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–2352 Filed 2–1–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2012–0009]

Notice of Adjustment of Statewide Per Capita Indicator for Recommending a Cost Share Adjustment

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: FEMA gives notice that the statewide per capita indicator for recommending cost share adjustments for major disasters declared on or after January 1, 2012, through December 31, 2012, is $131.

DATES: This notice applies to major disasters declared on or after January 1, 2012.

FOR FURTHER INFORMATION CONTACT: William Roche, Recovery Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3834.

SUPPLEMENTARY INFORMATION: Pursuant to 44 CFR 206.47, the statewide per capita indicator that is used to recommend an increase of the Federal cost share from seventy-five percent (75%) to not more than ninety percent (90%) of the eligible cost of permanent work under section 406 and emergency work under section 403 and section 407 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act is adjusted annually. The adjustment to the indicator is based on the Consumer Price Index for All Urban Consumers published annually by the U.S. Department of Labor. For disasters declared on January 1, 2012, through December 31, 2012, the qualifying indicator is $131 per capita of State population.

This adjustment is based on an increase of 3.0 percent in the Consumer Price Index for All Urban Consumers for the 12-month period that ended December 2011. The Bureau of Labor Statistics of the U.S. Department of Labor released the information on January 19, 2012.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.)

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2012–2353 Filed 2–1–12; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5511–N–07]

Credit Watch Termination Initiative Termination of Direct Endorsement (DE) Approval

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice advises of the cause and effect of termination of Direct Endorsement (DE) Approval taken by HUD's Federal Housing Administration (FHA) against HUD-approved mortgagees through the FHA Credit Watch Termination Initiative. This notice includes a list of mortgagees which have had their DE Approval terminated.

FOR FURTHER INFORMATION CONTACT: The Quality Assurance Division, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000; telephone (202) 708–2830 (this is not a toll-free number). Persons with hearing or speech impairments may access that number through TTY by calling the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: HUD has the authority to address deficiencies in the performance of lenders' loans as provided in HUD's mortgagee approval regulations at 24 CFR 202.3. On May 17, 1999, HUD published a notice (64 FR 26769), on its procedures for terminating Origination Approval Agreements with FHA lenders and placement of FHA lenders on Credit Watch status (an evaluation period). In the May 17, 1999 notice, HUD advised that it would publish in the **Federal Register** a list of mortgagees that have had their Approval Agreements terminated. On January 21, 2010, HUD issued Mortgagee Letter 2010–03, which advised mortgagees of the extended procedures for terminating Underwriting Authority of Direct Endorsement (DE) mortgagees.

Termination of Direct Endorsement Approval (DE Approval): Approval of a DE mortgagee by HUD/FHA authorizes the mortgagee to underwrite single family mortgage loans and submit them to FHA for insurance endorsement. The DE Approval may be terminated on the basis of poor performance of FHA-insured mortgage loans underwritten by the mortgagee. The termination of a mortgagee's DE Approval is separate and apart from any action taken by HUD's Mortgagee Review Board under HUD's regulations at 24 CFR part 25.

Cause: HUD's regulations permit HUD to terminate the DE Approval with any mortgagee having a default and claim rate for loans endorsed within the preceding 24 months that exceeds 200 percent of the default and claim rate within the geographic area served by a HUD field office, and also exceeds the national default and claim rate. For the quarterly review period ending June 30, 2011, HUD is terminating the DE Approval of mortgagees whose default and claim rate exceeds both the national rate and 200 percent of the field office rate.

Effect: Termination of the DE Approval precludes the mortgagee from

underwriting FHA-insured single-family mortgages within the area of the HUD field office(s) listed in this notice. Mortgagees authorized to purchase, hold, or service FHA-insured mortgages may continue to do so.

Loans that closed or were approved before the Termination became effective may be submitted for insurance endorsement. Approved loans are those already underwritten and approved by a DE underwriter, and cases covered by a firm commitment issued by HUD. Cases at earlier stages of processing cannot be submitted for insurance by the terminated mortgagee; however, the cases may be transferred for completion of processing and underwriting to another mortgagee with DE Approval in that area. Mortgagees are obligated to continue to pay existing insurance premiums and meet all other obligations associated with insured mortgages.

A terminated mortgagee may apply for reinstatement of the DE Approval if the DE Approval for the affected area or areas has been terminated for at least six months and the mortgagee continues to be an approved mortgagee meeting the requirements of §§ 202.5, 202.6, 202.7, 202.10 and 202.12. The mortgagee's application for reinstatement must be in a format prescribed by the Secretary and signed by the mortgagee. In addition, the application must be accompanied by an independent analysis of the terminated office's operations as well as its mortgage production, specifically including the FHA-insured mortgages cited in its termination notice. This independent analysis shall identify the underlying cause for the mortgagee's high default and claim rate. The analysis must be prepared by an independent Certified Public Accountant (CPA) qualified to perform audits under Government Auditing Standards as provided by the Government Accountability Office. The mortgagee must also submit a written corrective action plan to address each of the issues identified in the CPA's report, along with evidence that the plan has been implemented. The application for a new Agreement should be in the form of a letter, accompanied by the CPA's report and corrective action plan. The request should be sent to the Director, Office of Lender Activities and Program Compliance, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000 or by courier to 490 L'Enfant Plaza East SW., Suite 3214, Washington, DC 20024–8000.

Action: The following mortgagee has had its DE Approval terminated by HUD:

Mortgagee name	Mortgagee home office address	HUD office jurisdiction	Termination effective date	Homeownership center
Mortgage Source LLC	600 Old Country Rd., Room 210 Garden City, NY 11530–2011 ..	New York	11/1/11	Philadelphia.

Dated: December 20, 2011.

Carol Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–2344 Filed 2–1–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5511–N–06]

Credit Watch Termination Initiative Termination of Origination Approval Agreements

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice advises of the cause and effect of termination of Origination Approval Agreements taken by HUD's Federal Housing Administration (FHA) against HUD-approved mortgagees through the FHA Credit Watch Termination Initiative. This notice includes a list of mortgagees which have had their Origination Approval Agreements terminated.

FOR FURTHER INFORMATION CONTACT: The Quality Assurance Division, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000; telephone 202–708–2830 (this is not a toll-free number). Persons with hearing or speech impairments may access that number through TTY by calling the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: HUD has the authority to address deficiencies in the performance of lenders' loans as provided in HUD's mortgagee approval regulations at 24 CFR 202.3. On May 17, 1999, HUD published a notice (64 FR 26769), on its procedures for terminating Origination Approval Agreements with FHA lenders and placement of FHA lenders on Credit Watch status (an evaluation period). In the May 17, 1999, notice, HUD advised that it would publish in the **Federal Register** a list of mortgagees, which have had their Origination Approval Agreements terminated.

Termination of Origination Approval Agreement: Approval of a mortgagee by HUD/FHA to participate in FHA mortgage insurance programs includes an Origination Approval Agreement (Agreement) between HUD and the mortgagee. Under the Agreement, the mortgagee is authorized to originate single-family mortgage loans and submit them to FHA for insurance endorsement. The Agreement may be terminated on the basis of poor performance of FHA-insured mortgage loans originated by the mortgagee. The termination of a mortgagee's Agreement is separate and apart from any action taken by HUD's Mortgagee Review Board under HUD's regulations at 24 CFR part 25.

Cause: HUD's regulations permit HUD to terminate the Agreement with any mortgagee having a default and claim rate for loans endorsed within the preceding 24 months that exceeds 200 percent of the default and claim rate within the geographic area served by a HUD field office, and also exceeds the national default and claim rate. For the quarterly review period ending June 30, 2011, HUD is terminating the Agreements of mortgagees whose default and claim rate exceeds both the national rate and 200 percent of the field office rate.

Effect: Termination of the Agreement precludes branch(es) of the mortgagee from originating FHA-insured single-family mortgages within the area of the HUD field office(s) listed in this notice and from establishing a new branch in the location(s) covered by the termination. Mortgagees authorized to purchase, hold, or service FHA-insured mortgages may continue to do so.

Loans that closed or were approved before the termination became effective may be submitted for insurance endorsement. Approved loans are those already underwritten and approved by a Direct Endorsement underwriter, and cases covered by a firm commitment issued by HUD. Cases at earlier stages of processing cannot be submitted for insurance by the terminated branch; however, they may be transferred for completion of processing and underwriting to another FHA-insured mortgagee with direct endorsement

approval for the area covered by the termination. Mortgagees are obligated to continue to pay existing insurance premiums and meet all other obligations associated with insured mortgages.

A terminated mortgagee may apply for reinstatement of the Origination Approval Agreement if the approval for the affected branch or branches has been terminated for at least six months and the mortgagee continues to be an approved mortgagee meeting the requirements of §§ 202.5, 202.6, 202.7, 202.8 and 202.12. The mortgagee's application for reinstatement must be in a format prescribed by the Secretary and signed by the mortgagee. In addition, the application must be accompanied by an independent analysis of the terminated office's operations as well as its mortgage production, specifically including the FHA-insured mortgages cited in its termination notice. This independent analysis shall identify the underlying cause for the mortgagee's high default and claim rate. The analysis must be prepared by an independent Certified Public Accountant (CPA) qualified to perform audits under Government Auditing Standards as provided by the Government Accountability Office. The mortgagee must also submit a written corrective action plan to address each of the issues identified in the CPA's report, along with evidence that the plan has been implemented. The application for a new Agreement should be in the form of a letter, accompanied by the CPA's report and corrective action plan. The request should be sent to the Director, Office of Lender Activities and Program Compliance, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410–8000 or by courier to 490 L'Enfant Plaza, East SW., Suite 3214, Washington, DC 20024–8000.

Action:The following mortgagee has had its Origination Agreement terminated by HUD:

Mortgagee name	Mortgagee branch office address	HUD Office jurisdiction	Termination effective date	Homeownership center
Mortgage Source LLC	600 Old Country Rd., Room 210 Garden City, NY 11530–2011	New York	11/1/11	Philadelphia.

Dated: December 20, 2011.

Carol Galante,

Acting Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2012–2345 Filed 2–1–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R9–MB–2011–N016; 91100–3740–GRNT 7C]

Meeting Announcements: North American Wetlands Conservation Council; Neotropical Migratory Bird Conservation Advisory Group

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meetings.

SUMMARY: The North American Wetlands Conservation Council (Council) will meet to select North American Wetlands Conservation Act (NAWCA) grant proposals for recommendation to the Migratory Bird Conservation Commission (Commission). This meeting is open to the public. The Advisory Group for the Neotropical Migratory Bird Conservation Act (NMBCA) grants program (Advisory Group) will also meet. This meeting is also open to the public, and interested persons may present oral or written statements.

DATES: *Council:* Meeting is March 6, 2012, 9:00 a.m. through 4 p.m. If you are interested in presenting information at this public meeting, contact the Council Coordinator no later than March 1, 2012.

Advisory Group: Meeting is March 7, 2012, 10:30 a.m. through 4 p.m. If you are interested in presenting information at this public meeting, contact the Council Coordinator no later than March 1, 2012.

ADDRESSES: The Council meeting will be held at 1150 Connecticut Avenue NW., Suite 600, Washington, DC 20036. The Advisory Group meeting will be held at the Department of the Interior, 1849 C Street NW., North Penthouse, Room 7000 A and B, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Michael Kreger, Acting Council Coordinator, by phone at (703) 358–2489; by email at *dbhc@fws.gov;* or by U.S. mail at U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Mail Stop MBSP 4075, Arlington, VA 22203.

SUPPLEMENTARY INFORMATION:

Background

In accordance with NAWCA (Pub. L. 101–233, 103 Stat. 1968, December 13, 1989, as amended), the State-private-Federal Council meets to consider wetland acquisition, restoration, enhancement, and management projects for recommendation to, and final funding approval by, the Commission. Project proposal due dates, application instructions, and eligibility requirements are available on the NAWCA Web site at *http://www.fws.gov/birdhabitat/Grants/NAWCA/Standard/US/Overview.shtm.* Proposals require a minimum of 50 percent non-Federal matching funds. The Council will consider Canadian and U.S. small grant proposals at the meeting. The Commission will consider the Council's recommendations at its meeting tentatively scheduled for June 13, 2012.

The Advisory Group, named by the Secretary of the Interior under NMBCA (Pub. L. 106–247, 114 Stat. 593, July 20, 2000), will hold its meeting to discuss the strategic direction and management of the NMBCA program and provide advice to the Director of the Fish and Wildlife Service. If you are interested in presenting information at either of these public meetings, contact the Council Coordinator no later than the date under **DATES**.

Meetings

The Council will consider Canadian and U.S. Small grant proposals at the meeting announced in **DATES**. The Commission will consider the Council's recommendations at its meeting tentatively scheduled for June 6, 2012.

The Advisory Group will discuss the strategic direction and management of the NMBCA program at the meeting announced in **DATES**.

PUBLIC INPUT

If you wish to	You must contact the Council Coordinator (see **FOR FURTHER INFORMATION CONTACT**) no later than
Attend the Council meeting	March 1, 2012.
Attend the Advisory Group meeting	March 1, 2012.
Submit written information or questions before the Council meeting for consideration during the meeting	March 1, 2012.
Submit written information or questions before the Advisory Group meeting for consideration during the meeting	March 1, 2012.
Give an oral presentation during the Council meeting	March 1, 2012.
Give an oral presentation during the Advisory Group meeting	March 1, 2012.

Submitting Written Information or Questions

Interested members of the public may submit relevant information or questions for the Council and/or Advisory Group to consider during the public meetings. If you wish to submit a written statement, so that the information may be made available to the Council or Advisory Group for their consideration prior to this meeting, you must contact the Council Coordinator by the date above. Written statements must be supplied to the Council Coordinator in both of the following formats: One hard copy with original signature, and one electronic copy via email (acceptable file formats are Adobe Acrobat PDF, MS Word, MS PowerPoint, or rich text file).

Giving an Oral Presentation

Individuals or groups requesting to make an oral presentation at either the Council or Advisory Group meeting will be limited to 2 minutes per speaker, with no more than a total of 30 minutes for all speakers. Interested parties should contact the Council Coordinator by the date above, in writing (preferably via email; see **FOR FURTHER INFORMATION CONTACT**), to be placed on the public speaker list for either of these meetings. Nonregistered public speakers will not be considered during the Council or Advisory Group meetings. Registered speakers who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, are invited to submit written statements to the Council or Advisory Group within 30 days following the meeting.

Meeting Minutes

Summary minutes of the Council and the Advisory Group meetings will be maintained by the Council Coordinator at the address under **FOR FURTHER INFORMATION CONTACT**. Council meeting minutes will be posted at *http://www.fws.gov/birdhabitat/Grants/NAWCA/CouncilAct.shtm#CouncilMeet* within 30 days following the meeting. Personal copies may be purchased for the cost of duplication. Advisory Group meeting minutes will be posted at *http://www.fws.gov/birdhabitat/Grants/NMBCA/AdGroupAct.shtm*. Personal copies may be purchased for the cost of duplication.

Jerome Ford,

Assistant Director, Migratory Birds.

[FR Doc. 2012–2293 Filed 2–1–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Eastern Band of Cherokee Indians—Cherokee Code Chapter 18B, Regulation of Alcoholic Beverages

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the Amendment to the Eastern Band of Cherokee Indians—Cherokee Code Chapter 18B, Regulation of Alcoholic Beverages. This Ordinance regulates and controls the possession, sale and consumption of liquor within the Eastern Band of Cherokee Indians' Reservation. This Ordinance will increase the ability of the tribal government to control the community's liquor distribution and possession, and at the same time will provide an important source of revenue for the continued operation and strengthening of the tribal government and the delivery of tribal services.

DATES: *Effective Date:* This Amendment is effective 30 days after publication February 2, 2012.

FOR FURTHER INFORMATION CONTACT: Chanda Joseph, Tribal Relations Specialist, Eastern Regional Office, Bureau of Indian Affairs, 545 Marriott Drive, Suite 700, Nashville, Tennessee 37214, Telephone: (615) 564–6750; Fax: (615) 564–6701; or, De Springer, Office of Indian Services, Bureau of Indian Affairs, 1849 C Street NW., MS–4513–MIB, Washington, DC 20240; Telephone: (202) 513–7626.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor ordinances for the purpose of regulating liquor transactions in Indian country. The purpose of this Ordinance is to govern the sale, possession and distribution of alcohol within the Eastern Band of Cherokee Indians' Reservation. On September 8, 2011, the Tribal Council of the Eastern Band of Cherokee Indians duly adopted Ordinance No. 768 (2011) which amended Cherokee Code Chapter 18B. This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs. I certify that the Tribal Council of the Eastern Band of Cherokee Indians duly adopted Ordinance No. 768 (2011) on September 8, 2011.

Dated: January 26, 2012.

Larry Echo Hawk,

Assistant Secretary—Indian Affairs.

The amended sections of Cherokee Code Chapter 18B, Regulation of Alcoholic Beverages read as follows:

Ordinance No. 768 (2011)

Whereas, the Tribal Council established Cherokee Code Chapter 18B to govern the regulation of alcoholic beverages (Chapter 18B is attached); and

Whereas, the North Carolina Legislature has enacted changes to its ABC laws to allow the Tribe to self regulate the purchase, possession, consumption, sale and delivery of alcoholic beverages at retail that require changes to Cherokee Code Chapter 18B.

Now, therefore, be it ordained by the Tribal Council of the Eastern Band of Cherokee Indians in Council assembled, at which a quorum is present, that Chapter 18B of the Cherokee Code is

amended in the nature of a substitute to read as follows:

A new § 18B–109 shall be added as follows:

§ 18B–109. No person shall have malt beverages or unfortified wine shipped directly from a point outside this State to the Eastern Band of Cherokee Indians for resale on Indian country lands, within this State under the jurisdiction of the Eastern Band of Cherokee Indians if those alcoholic beverages are for resale.

A new § 18B–112 shall be added as follows:

§ 18B–112. Tribal alcoholic beverage control.

(a) Chapter 18B of the North Carolina General Statutes has been amended to provide that the Eastern Band of Cherokee Indians, a federally recognized Indian tribe and sovereign nation, shall be exempt from the provisions of Chapter 18B of the North Carolina General Statutes, except for those made applicable by section 18B–112 of the North Carolina General Statutes and enacted as tribal law herein. The Eastern Band of Cherokee Indians shall hold lawful tribal elections as set out in tribal law and in a manner consistent with North Carolina General Statute 18B–600(a), and if the result of such election authorizes the activity upon which a vote was held, the activity shall be deemed authorized by this section. For the purposes of this section, the Tribal Alcoholic Beverage Control Commission shall possess the same powers and authority conveyed upon the North Carolina Alcoholic Beverage Control Commission by any section of Chapter 18B of the North Carolina General Statutes made applicable to the tribe by this section as enacted herein.

(b) Compliance Required. The Eastern Band of Cherokee Indians shall comply with the following provisions of Chapter 18B of the North Carolina General Statutes to the extent they apply to or can be made applicable to the tribe:

(1) The following provisions of Article 1. General Provisions.

a. G.S. 18B–101(4), (7), 7(c), (9), (10), (11), (12), (12a), (13), (14), (14a), (14b) and (15).

b. G.S. 18B–102.1.

c. G.S. 18B–104.

d. G.S. 18B–105 except that this section shall not apply to any establishment where gaming is permitted under a state compact and pursuant to federal law.

e. G.S. 18B–109(b).

f. G.S. 18B–110.

g. G.S. 18B–111.

h. G.S. 18B–112.

(2) Article 1A. Compensation for Injury Caused by Sales to Underage Persons to the extent it applies to retail establishments or the Tribal Alcoholic Beverage Control Commission if it operates ABC stores, or any other permitted establishment, at retail pursuant to the provisions of this section.

(3) Article 3. Sale, Possession, and Consumption, except for G.S. 18B–308 and 18B–309.

(4) Article 4. Transportation.

(5) Article 5. Enforcement, except for G.S. 18B–500 and G.S. 18–501.

(7) Article 9. Issuance of Permits, except for G.S. 18B–902(g) and (h) and G.S. 18B–906.

(8) Article 10. Retail Activity, except for G.S. 18B–1001.1, G.S. 18B–1001.2, and G.S. 18B–1001.3.

Any provision of this Chapter which has not been made applicable to the Eastern Band of Cherokee Indians by this section shall act as a bar to engaging in activity authorized by that Article or section.

(c) Alcoholic Beverages Which May Be Sold. No alcoholic beverage may be sold on Indian Country lands under the jurisdiction of the Eastern Band of Cherokee Indians pursuant to this section which has not been approved for sale in this State by the North Carolina Alcoholic Beverage Control Commission.

(d) Establishment of a Tribal Commission. Chapter 18B of the North Carolina General Statutes has been amended to recognize that the Eastern Band of Cherokee Indians, is authorized to establish a Tribal Alcoholic Beverage Control Commission to regulate the purchase, possession, consumption, sale, and delivery of alcoholic beverages at retail on any land designated as Indian Country pursuant to 18 U.S.C. 1151 under the jurisdiction of the Eastern Band of Cherokee Indians. The tribal commission shall have exclusive authority to issue retail permits to retail establishments, located wholly on Indian Country lands under the jurisdiction of the Eastern Band of Cherokee Indians, and to regulate the purchase, possession, consumption, sale, and delivery of alcoholic beverages at retail outlets and premises. Permits issued by the Tribal Commission pursuant to this section shall be deemed issued by the state for the purposes of sales and delivery of beer and wine by wholesalers to the retail outlets located on Indian Country lands. The fees generated by the Tribal Alcoholic Beverage Control Commission for the issuance of retail permits may be retained by the Eastern Band of Cherokee Indians to offset costs of operating the Tribal Alcoholic Beverage Control Commission.

(e) Establishment of Rules. The Tribal Alcoholic Beverage Control Commission shall adopt the rules of the North Carolina Alcoholic Beverage Commission regulating retail outlet activity.

(f) Authority of the North Carolina Alcoholic Beverage Control Commission. The Tribe recognizes the authority of the North Carolina Alcoholic Beverage Control Commission to enter into agreements with the Tribal Alcoholic Beverage Control Commission to provide for the sale, delivery, and distribution of spirituous liquor to the Tribal Alcoholic Beverage Control Commission. The Tribal Alcoholic Beverage Control Commission shall purchase spirituous liquor for resale by the Tribal Alcoholic Beverage Control Commission exclusively from the North Carolina Alcoholic Beverage Control Commission at the same price and on the same basis that such spirits are purchased by local boards. To the extent there is a conflict of between the Tribal Alcoholic Beverage Control Commission's authority or purpose and the North Carolina Alcoholic Beverage Control Commission's authority or purpose, the North Carolina Alcoholic Beverage Control Commission shall prevail, to the extent there is no conflict of law as provided in Subsection (j) below.

(g) Discrimination. The Tribal Alcoholic Beverage Control Commission shall not discriminate against non-Indians in the application of the Tribal ABC law. Non-Indians shall be entitled to apply for and receive ABC permits in the same manner as an Indian on Indian Country lands under the jurisdiction of the Eastern Band of Cherokee Indians.

(h) Resolution of Contested Cases. If the Tribal Alcoholic Beverage Control Commission levies a fine, or suspends or revokes a permit pursuant to the provisions of G.S. 18B–104 for a violation of the provisions applicable to the Eastern Band of Cherokee Indians in this Section, the permittee shall have the right of appeal of an agency final decision of the Tribal Commission to the tribal courts. Any further appeal shall be to the appellate courts of the tribe. All fines paid to the tribal commission in satisfaction of any penalty assessed by the Tribal Commission may be retained by the Eastern Band of Cherokee Indians to offset costs of operating the Tribal Alcoholic Beverage Control Commission.

(i) Failure to Comply With Laws of the State of North Carolina. The Tribe shall conform to future amendments to Chapter 18B of the North Carolina

General Statutes as required by 18 U.S.C. 1161.

(j) Conflict of Laws. If any provision of North Carolina General Statutes Section 18B–112 or its application conflicts with federal law, the conflict of laws shall be resolved in favor of the federal law unless compliance with the federal law abrogates a right reserved to the State under the Constitution of the United States.

§ 18B–200(e) shall be amended to read as follows:

(e) Employees. The chairman is authorized to employ, discharge, and otherwise supervise subordinate personnel of the Commission.

A new § 18B–200(j) shall be added to read as follows:

(j) All Commissioners are subject to the same criminal background checks as TCGE and TGC employees. Each Commissioner is required to update their information.

§ 18B–203. Powers and duties of the Commission shall be amended to read as follows:

§ 18B–203. Powers and duties of the Commission

(a) Powers.—The Commission shall have authority to:

(1) Administer the Tribal ABC laws;

(2) Provide for enforcement of the Tribal ABC laws, in conjunction with the ALE Division;

(3) Issue ABC permits as allowed under this Ordinance;

(4) Adopt rules and procedures for the issuance and enforcement of ABC permits;

(5) Administer an annual budget with said budget to be approved annually by the Tribal Council;

(6) Act as the distributor of all alcohol on tribal trust lands. Spirituous liquor and fortified wine shall be purchased by the TABCC directly from North Carolina Warehouse, or as needed from a Local ABC Store. Malt beverages and unfortified wine shall be purchased from North Carolina authorized distributors and may be redistributed from a TABCC warehouse or authorized to be delivered directly to a TABCC authorized permitee; and

(7) Issue any Retail ABC license or permit issued by the North Carolina Alcoholic Beverage Control Commission, including a temporary license or permit. Negotiate and enter into contract with North Carolina ABC Commission for purchase of spirituous liquor and fortified wine; and

(8) Adopt fiscal control rules concerning the borrowing of money, maintenance of working capital, investments, appointment of a financial officer, the daily deposit of funds and any other rules necessary to assure the proper accountability of public funds.

§ 18B–600. Alcoholic beverage elections shall be amended to read as follows:

§ 18B–600. Alcoholic beverage elections

(a) All alcohol referendum questions shall be conducted in accordance with Tribal law and its election procedures as set forth in Section 161–9 of the Cherokee Code.

(b) As authorized in NC 18B–600, the following kinds of alcoholic beverage elections shall be allowed as authorized by Tribal Council:

(1) Malt beverage;

(2) Unfortified Wine;

(3) ABC store; and

(4) Mixed beverage

A new § 18B–603 shall be added to read as follows:

§ 18B–603. Effect of alcoholic beverage elections on issuance of permits:

North Carolina 18B–603 language is adopted as Tribal Law (except (e) Mixed Beverages at Airports, (f)(2) Special ABC Areas, and (h) Permits based on existing permits).

§ 18B–700. Retail sale of alcoholic beverages shall be amended to read as follows:

§ 18B–700. Retail sale of alcoholic beverages.

Spirituous liquor, fortified and unfortified wine and malt beverages may be offered for retail sale only under the provisions of a permit issued by the TABCC as authorized by the provisions of this ordinance. The TABCC shall operate any retail spirituous and fortified wine store that may in the future be authorized by Tribal election. The TABCC shall also be authorized to operate a retail malt beverage and unfortified wine store should that facility be authorized by a Tribal election.

§ 18B–800 shall be amended to read as follows:

§ 18B–800. All alcoholic beverages authorized to be sold shall be purchased by the permittee from TABCC or as directed by TABCC.

A New § 18B–804 Alcoholic beverage Pricing shall read as follows:

§ 18B–804. Alcoholic beverage Pricing

The uniform pricing of Spirits sold to permittees and the public shall be the same uniform price as published by North Carolina 18B–804. Where a tax or markup is imposed in this section, the TABCC is authorized to impose the same tax or markup as a Tribal tax or markup, where appropriate, and to utilize such tax or markup in operations of TABCC and profits after operation shall be distributed as determined by Tribal Council.

§ 18B–900 shall be amended to read as follows:

§ 18B–900. The TCGE shall be eligible to receive and to hold a Tribal ABC permit for the retail sale of alcoholic beverages on the premises of Harrah's Cherokee Casino & Hotel as authorized by the special election referendum held on June 4, 2009. At the request of TCGE, TABCC is authorized to issue a permit to a contracted or leased facility providing a service for TCGE on the premises of Harrah's Cherokee Casino and Hotel.

Be it further ordained that this amendment shall be effective upon ratification by the Principal Chief, and all prior ordinances and resolutions that are inconsistent with this ordinance are rescinded.

[FR Doc. 2012–2323 Filed 2–1–12; 8:45 am]

BILLING CODE 4310–4J–P

NATIONAL INDIAN GAMING COMMISSION

Fee Rate

AGENCY: National Indian Gaming Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given, pursuant to 25 CFR 514.1(a)(3), that the National Indian Gaming Commission has adopted preliminary annual fee rates of 0.00% for tier 1 and 0.074% (.00074) for tier 2 for calendar year 2012. These rates shall apply to all assessable gross revenues from each gaming operation under the jurisdiction of the Commission. If a Tribe has a certificate of self-regulation under 25 CFR part 518, the preliminary fee rate on class II revenues for calendar year 2012 shall be one-half of the annual fee rate, which is 0.037% (.00037).

FOR FURTHER INFORMATION CONTACT: Chris White, National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005; telephone (202) 632–7003; fax (202) 632–7066.

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA) established the National Indian Gaming Commission which is charged with, among other things, regulating gaming on Indian lands.

The regulations of the Commission (25 CFR part 514), as amended, provide for a system of fee assessment and payment that is self-administered by gaming operations. Pursuant to those regulations, the Commission is required to adopt and communicate assessment rates; the gaming operations are required to apply those rates to their revenues, compute the fees to be paid, report the revenues, and remit the fees to the Commission.

The preliminary rate being adopted today is effective for calendar year 2012. Therefore, all gaming operations within the jurisdiction of the Commission are required to self administer the provisions of these regulations, and report and pay any fees that are due to the Commission by June 30, 2012.

Dated: January 27, 2012.

Tracie Stevens,

Chairwoman.

Dated: January 27, 2012.

Steffani A. Cochran,

Vice-Chairwoman.

Dated: January 27, 2012.

Daniel Little,

Associate Commissioner.

[FR Doc. 2012–2255 Filed 2–1–12; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0025]

Agency Information Collection Activities: Proposed Collection, Comment Request

AGENCY: Office of Natural Resources Revenue, Interior.

ACTION: Notice of an extension of a currently approved information collection.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Office of Natural Resources Revenue (ONRR) is inviting comments on the renewal of a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The OMB formerly approved this information collection request (ICR) under OMB Control Number 1010–0087. However, OMB approved a new series number and renumbered our ICRs after the Secretary of the U.S. Department of the Interior established ONRR (formerly Minerals Revenue Management, a program under the former Minerals Management Service) by Secretarial Order 3299, effective October 1, 2010. The OMB Control Number for this collection of information now is 1012–0003. In addition, ONRR published a rule, effective October 1, 2010, transferring our regulations from chapter II to chapter XII in title 30 of the Code of Federal Regulations (CFR). This ICR covers the paperwork requirements in the regulations under 30 CFR parts 1227, 1228, and 1229.

DATES: Submit written comments on or before April 2, 2012.

ADDRESSES: You may submit comments on this ICR to ONRR by any of the following methods. Please use ''ICR 1012–0003'' as an identifier in your comment.

- Electronically go to *http://www.regulations.gov.* In the entry titled ''Enter Keyword or ID,'' enter ONRR–2011–0025 and then click search. Follow the instructions to submit public comments. The ONRR will post all comments.
- Mail comments to Hyla Hurst, Regulatory Specialist, Office of Natural Resources Revenue, P.O. Box 25165, MS 64000A, Denver, Colorado 80225. Please reference ICR 1012–0003 in your comments.
- Hand-carry comments or use an overnight courier service. Our courier address is Building 85, Room A–614, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225. Please reference ICR 1012–0003 in your comments.

FOR FURTHER INFORMATION CONTACT: Hyla Hurst, telephone (303) 231–3495, or email *hyla.hurst@onrr.gov.* You may also contact Hyla Hurst to obtain copies, at no cost, of (1) the ICR, (2) any associated forms, and (3) the regulations that require the subject collection of information.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR parts 1227, 1228, and 1229, Delegated and Cooperative Activities with States and Indian Tribes.

OMB Control Number: 1012–0003.

Bureau Form Number: None.

Abstract: The Secretary of the U.S. Department of the Interior is responsible for mineral resource development on Federal and Indian lands and the Outer Continental Shelf (OCS). Under the Mineral Leasing Act of 1920, Outer Continental Shelf Lands Act of 1953, Geothermal Steam Act of 1970, and Indian Mineral Development Act of 1982, the Secretary is responsible for managing the production of minerals from Federal and Indian lands and the OCS, collecting royalties and other mineral revenues from lessees who produce minerals, and distributing the funds collected in accordance with applicable laws. The Secretary also has a trust responsibility to manage Indian lands and seek advice and information from Indian beneficiaries. The ONRR performs the mineral revenue management functions and assists the Secretary in carrying out the Department's trust responsibility for Indian lands. Public laws pertaining to mineral revenues are located on our Web site at *http://www.onrr.gov/Laws_R_D/PublicLawsAMR.htm.*

When a company or an individual enters into a lease to explore, develop, produce, and dispose of minerals from Federal or Indian lands, that company or individual agrees to pay the lessor a share in an amount or value of production from the leased lands. The regulations require the lessee to report various kinds of information to the lessor relative to the disposition of the leased minerals. Such information is generally available within the records of the lessee or others involved in developing, transporting, processing, purchasing, or selling of such minerals. The information ONRR collects includes data necessary to ensure that the lessee accurately values and appropriately pays all royalties and other mineral revenues due.

The Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA), as amended by the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996, sections 3, 4, and 8 for Federal lands, authorizes the Secretary to develop delegated and cooperative agreements with states (sect. 205) and Indian tribes (sect. 202) to carry out certain inspection, auditing, investigation, or limited enforcement activities for oil and gas leases in their jurisdiction. The states and Indian tribes are working partners and are an integral part of the overall onshore and offshore compliance effort. The Appropriations Act of 1992 also authorizes the states and Indian tribes to perform the same functions for coal and other solid mineral leases.

This collection of information is necessary in order for states and Indian tribes to conduct audits and related investigations of Federal and Indian oil, gas, coal, any other solid minerals, and geothermal royalty revenues from Federal and tribal leased lands. Relevant parts of the regulations include 30 CFR parts 1227, 1228, and 1229, as described below:

Title 30 CFR part 1227—Delegation to States, provides procedures to delegate certain Federal minerals revenue management functions to states for Federal oil and gas leases. The regulations provide only audit and investigation functions to states for Federal geothermal and solid mineral leases, and leases subject to section 8(g) of the OCS Lands Act, within their state boundaries. To be considered for such delegation, states must submit a written proposal to ONRR, which ONRR must approve. States also must provide periodic accounting documentation to ONRR.

Title 30 CFR part 1228—Cooperative Activities with States and Indian Tribes, provides procedures for Indian tribes to

carry out audits and related investigations of their respective leased lands. Indian tribes must submit a written proposal to ONRR in order to enter into a cooperative agreement. The proposal must outline the activities the tribe will undertake and must present evidence that the tribe can meet the standards of the Secretary for the activities to be conducted. The tribes also must submit an annual work plan and budget, as well as quarterly reimbursement vouchers.

Title 30 CFR part 1229—Delegation to States, provides procedures for states to carry out audits and related investigations of leased Indian lands within their respective state boundaries, by permission of the respective Indian tribal councils or individual Indian mineral owners. The state must receive the Secretary's delegation of authority and submit annual audit work plans detailing its audits and related investigations, annual budgets, and quarterly reimbursement vouchers. The state also must maintain records.

The ONRR protects proprietary information the states and tribes submit under this collection. We do not collect items of a sensitive nature. States and tribes must respond in order to obtain the benefit of entering into a cooperative agreement with the Secretary.

Frequency of Response: Varies based on the function performed.

Estimated Number and Description of Respondents: 10 states and 6 Indian tribes.

Estimated Annual Reporting and Recordkeeping ''Hour'' Burden: 5,531 hours.

We have not included in our estimates certain requirements performed in the normal course of business and considered usual and customary. The following chart shows the estimated burden hours by CFR section and paragraph:

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS

30 CFR Section	Reporting and recordkeeping requirements	Hour burden per response	Number of annual responses	Annual burden hours
	Part 1227—Delegation to States **Delegation Proposals**			
1227.103; 107; 109; 110(a–b)(1)); 110(c–e); 111(a–b); 805.	What must a State's delegation proposal contain? ..... If you want ONRR to delegate royalty management functions to you, then you must submit a delegation proposal to the ONRR Deputy Director. The ONRR will provide you with technical assistance and information to help you prepare your delegation proposal.	200	1	200
	Delegation Process			
1227.110(b)(2)	If you want to change the terms of your delegation agreement for the renewal period, you must submit a new delegation proposal under this part.	16	11	176
	Existing Delegations **Compensation**			
1227.112(d, e)	What compensation will a State receive to perform delegated functions? You will receive compensation for your costs to perform each delegated function subject to the following conditions. (d) At a minimum, you must provide vouchers detailing your expenditures quarterly during the fiscal year. However, you may agree to provide vouchers on a monthly basis in your delegation agreement. (e) You must maintain adequate books and records to support your vouchers.	4	64	256

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

30 CFR Section	Reporting and recordkeeping requirements	Hour burden per response	Number of annual responses	Annual burden hours
States' Responsibilities To Perform Delegated Functions				
1227.200(a–d)	What are a State's general responsibilities if it accepts a delegation? For each delegated function you perform, you must: (a) * * * seek information or guidance from ONRR regarding new, complex, or unique issues.. (b)(1) * * * Provide complete disclosure of financial results of activities; (2) Maintain correct and accurate records of all mineral-related transactions and accounts; (3) Maintain effective controls and accountability; (4) Maintain a system of accounts (5) Maintain adequate royalty and production information (c) Assist ONRR in meeting the requirements of the Government Performance and Results Act (GPRA) (d) Maintain all records you obtain or create under your delegated function, such as royalty reports, production reports, and other related information. * * * You must maintain such records for at least 7 years.	200	10	2,000
1227.200(e); 801(a); 804	(e) Provide reports to ONRR about your activities under your delegated functions * * * At a minimum, you must provide periodic statistical reports to ONRR summarizing the activities you carried out.	3	44	132
1227.200(f); 401(e); 601(d)	(f) Assist ONRR in maintaining adequate reference, royalty, and production databases.	1	250	250
1227.200(g); 301(e)	(g) Develop annual work plans	60	10	600
1227.200(h)	(h) Help ONRR respond to requests for information from other Federal agencies, Congress, and the public.	8	10	80
1227.400(a)(4) and (a)(6); 401(d); 501(c).	What functions may a State perform in processing production reports or royalty reports? Production reporters or royalty reporters provide production, sales, and royalty information on mineral production from leases that must be collected, analyzed, and corrected (a) If you request delegation of either production report or royalty report processing functions, you must perform (4) Timely transmitting production report or royalty report data to ONRR and other affected Federal agencies (6) Providing production data or royalty data to ONRR and other affected Federal agencies.	250	1	250
1227.400(c)	(c) You must provide ONRR with a copy of any exceptions from reporting and payment requirements for marginal properties and any alternative royalty and payment requirements for unit agreements and communitization agreements you approve.	12	1	12
1227.601(c)	What are a State's responsibilities if it performs automated verification? To perform automated verification of production reports or royalty reports, you must (c) Maintain all documentation and logging procedures	10	1	10
Performance Review				
Subtotal Burden for 30 CFR part 1227.			403	3,966

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

30 CFR Section	Reporting and recordkeeping requirements	Hour burden per response	Number of annual responses	Annual burden hours
	Part 1228—Cooperative Activities With States and Indian Tribes Subpart C—Oil and Gas, Onshore			
1228.100(a) and (b); 101(c); 107(b).	Entering into an agreement (a) * * * Indian tribe may request the Department to enter into a cooperative agreement by sending a letter from * * * tribal chairman * * * to the Director of ONRR (b) The request for an agreement shall be in a format prescribed by ONRR and should include at a minimum the following information: (1) Type of eligible activities to be undertaken (2) Proposed term of the agreement (3) Evidence that * * * Indian tribe meets, or can meet by the time the agreement is in effect. (4) If the State is proposing to undertake activities on Indian lands located within the State, a resolution from the appropriate tribal council indicating their agreement to delegate to the State responsibilities under the terms of the cooperative agreement for activities to be conducted on tribal or allotted land.	200	1	200
1228.101(a)	Terms of agreement (a) Agreements entered into under this part shall be valid for a period of 3 years and shall be renewable * * * upon request of * * * Indian tribe.	15	6	90
1228.101(d)	(d) * * * Indian tribe will be given 60 days to respond to the notice of deficiencies and to provide a plan for correction of those deficiencies.	80	1	80
1228.103(a) and (b)	Maintenance of records (a) * * * Indian tribe entering into a cooperative agreement under this part must retain all records, reports, working papers, and any backup materials. (b) * * * Indian tribe shall maintain all books and records ...	120	6	720
1228.105(a)(1) and (a)(2)	Funding of cooperative agreements (a)(1) The Department may, under the terms of the cooperative agreement, reimburse * * * Indian tribe up to 100 percent of the costs of eligible activities. Eligible activities will be agreed upon annually upon the submission and approval of a work plan and funding requirement (2) A cooperative agreement may be entered into with * * * Indian tribe, upon request, without a requirement for reimbursement of costs by the Department	60	6	360
1228.105(c)	(c) * * * Indian tribe shall submit a voucher for reimbursement of eligible costs incurred within 30 days of the end of each calendar quarter. * * * Indian tribe must provide the Department a summary of costs incurred, for which * * * Indian tribe is seeking reimbursement, with the voucher.	4	24	96
Subtotal Burden for 30 CFR part 1228.			44	1,546

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

30 CFR Section	Reporting and recordkeeping requirements	Hour burden per response	Number of annual responses	Annual burden hours
	Part 1229—Delegation To States **Subpart C—Oil and Gas, Onshore** **Administration Of Delegations**			
1229.100(a)(1) and (a)(2)	Authorities and responsibilities subject to delegation (a) All or part of the following authorities and responsibilities of the Secretary under the Act may be delegated to a State authority: (1) Conduct of audits related to oil and gas royalty payments made to the ONRR which are attributable to leased * * * Indian lands within the State. Delegations with respect to any Indian lands require the written permission, subject to the review of the ONRR, of the affected Indian tribe or allottee. (2) Conduct of investigation related to oil and gas royalty payments made to the ONRR which are attributable to * * * Indian lands within the State. Delegation with respect to any Indian lands require the written permission, subject to the review of the ONRR, of the affected Indian tribe or allottee. No investigation will be initiated without the specific approval of the ONRR.	1	1	1
1229.101 (a) and (d)	Petition for delegation (a) The governor or other authorized official of any State which contains * * * Indian oil and gas leases where the Indian tribe and allottees have given the State an affirmative indication of their desire for the State to undertake certain royalty management-related activities on their lands, may petition the Secretary to assume responsibilities to conduct audits and related investigations of royalty related matters affecting * * * Indian oil and gas leases within the State. (d) In the event that the Secretary denies the petition, the Secretary must provide the State with the specific reasons for denial of the petition. The State will then have 60 days to either contest or correct specific deficiencies and to reapply for a delegation of authority.	1	1	1
1229.102(c)	Fact-finding and hearings (c) A State petitioning for a delegation of authority shall be given the opportunity to present testimony at a public hearing.	1	1	1
1229.103(c)	Duration of delegations; termination of delegations (c) A State may terminate a delegation of authority by giving a 120-day written notice of intent to terminate.	1	1	1
1229.105	Evidence of Indian agreement to delegation In the case of a State seeking a delegation of authority for Indian lands * * * the State petition to the Secretary must be supported by an appropriate resolution or resolutions of tribal councils joining the State in petitioning for delegation and evidence of the agreement of individual Indian allottees whose lands would be involved in a delegation. Such evidence shall specifically speak to having the State assume delegated responsibility for specific functions related to royalty management activities.	1	1	1
1229.106	Withdrawal of Indian lands from delegated authority. If at any time an Indian tribe or an individual Indian allottee determines that it wishes to withdraw from the State delegation of authority in relation to its lands, it may do so by sending a petition of withdrawal to the State.	1	1	1
1229.109(a)	Reimbursement for costs incurred by a State under the delegation of authority. (a) The Department of the Interior (DOI) shall reimburse the State for 100 percent of the direct cost associated with the activities undertaken under the delegation of authority. The State shall maintain books and records in accordance with the standards established by the DOI and will provide the DOI, on a quarterly basis, a summary of costs incurred.	1	1	1

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

30 CFR Section	Reporting and recordkeeping requirements	Hour burden per response	Number of annual responses	Annual burden hours
1229.109(b)	(b) The State shall submit a voucher for reimbursement of costs incurred within 30 days of the end of each calendar quarter.	1	4	4
	Delegation Requirements			
1229.120	Obtaining regulatory and policy guidance All activities performed by a State under a delegation must be in full accord with all Federal laws, rules and regulations, and Secretarial and agency determinations and orders relating to the calculation, reporting, and payment of oil and gas royalties. In those cases when guidance or interpretations are necessary, the State will direct written requests for such guidance or interpretation to the appropriate ONRR officials.	1	1	1
1229.121(a–d)	Recordkeeping requirements (a) The State shall maintain in a safe and secure manner all records, workpapers, reports, and correspondence gained or developed as a consequence of audit or investigative activities conducted under the delegation. (b) The State must maintain in a confidential manner all data obtained from DOI sources or from payor or company sources under the delegation. (c) All records subject to the requirements of paragraph (a) must be maintained for a 6-year period measured from the end of the calendar year in which the records were created * * * Upon termination of a delegation, the State shall, within 90 days from the date of termination, assemble all records specified in subsection (a), complete all working paper files in accordance with § 229.124, and transfer such records to the ONRR (d) The State shall maintain complete cost records for the delegation in accordance with generally accepted accounting principles.	1	1	1
1229.122(a–c)	Coordination of audit activities (a) Each State with a delegation of authority shall submit annually to the ONRR an audit workplan specifically identifying leases, resources, companies, and payors scheduled for audit * * * A State may request changes to its workplan * * * at the end of each quarter of each fiscal year. All requested changes are subject to approval by the ONRR and must be submitted in writing (b) When a State plans to audit leases of a lessee or royalty payor for which there is an ONRR or OIG resident audit team, all audit activities must be coordinated through the ONRR or OIG resident supervisor. (c) The State shall consult with the ONRR and/or OIG regarding resolution of any coordination problems encountered during the conduct of delegation activities	1	1	1
1229.123 (b)(3)(i)	Standards for audit activities (b)(3) *Standards of reporting.* (i) Written audit reports are to be submitted to the appropriate ONRR officials at the end of each field examination	1	1	1
1229.124	Documentation standards Every audit performed by a State under a delegation of authority must meet certain documentation standards. In particular, detailed workpapers must be developed and maintained	1	1	1

RESPONDENTS' ESTIMATED ANNUAL BURDEN HOURS—Continued

30 CFR Section	Reporting and recordkeeping requirements	Hour burden per response	Number of annual responses	Annual burden hours
1229.125(a) and (b)	Preparation and issuance of enforcement documents (a) Determinations of additional royalties due resulting from audit activities conducted under a delegation of authority must be formally communicated by the State, to the companies or other payors by an issue letter prior to any enforcement action. (b) After evaluating the company or payor's response to the issue letter, the State shall draft a demand letter which will be submitted with supporting workpaper files to the ONRR for appropriate enforcement action. Any substantive revisions to the demand letter will be discussed with the State prior to issuance of the letter.	1	1	1
1229.126(a) and (b)	Appeals (a) * * * The State regulatory authority shall, upon the request of the ONRR, provide competent and knowledgeable staff for testimony, as well as any required documentation and analyses, in support of the lessor's position during the appeal process (b) An affected State, upon the request of the ONRR, shall provide expert witnesses from their audit staff for testimony as well as required documentation and analyses to support the Department's position during the litigation of court cases arising from denied appeals.	1	1	1
1229.127	Reports from States The State, acting under the authority of the Secretarial delegation, shall submit quarterly reports which will summarize activities carried out by the State during the preceding quarter of the year under the provisions of the delegation.	1	1	1
Subtotal Burden for 30 CFR part 229.			19	19
TOTAL BURDEN			466	5,531

Estimated Annual Reporting and Recordkeeping ''Non-hour Cost'' Burden: We have identified no ''non-hour cost'' burden 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, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency to ''* * * provide 60-day notice in the **Federal Register** * * * 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.

The PRA also requires agencies to estimate the total annual reporting ''non-hour cost'' burden to respondents or recordkeepers resulting from the collection of information. 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, sampling, and testing equipment; and record storage facilities. Generally, your estimates should not include 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 ICR submission for OMB approval, including appropriate adjustments to the estimated burden. We will provide a copy of the ICR to you without charge upon request. We also will post the ICR on our Web site at *http://www.onrr.gov/Laws_R_D/FRNotices/ICR0087.htm.*

Public Comment Policy: We will post all comments, including names and addresses of respondents, at *http://www.regulations.gov.* Before including your address, phone number, email address, or other personal identifying information in your comment, be advised 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 from public view your personal identifying

information, we cannot guarantee that we will be able to do so.

Information Collection Clearance Officer: Laura Dorey (202) 208–2654.

Dated: January 26, 2012.

Gregory J. Gould,

Director, Office of Natural Resources Revenue.

[FR Doc. 2012–2297 Filed 2–1–12; 8:45 am]

BILLING CODE 4310–T2–P

INTERNATIONAL TRADE COMMISSION

[DN 2874]

Certain Ink Application Devices and Components Thereof and Methods of Using the Same; Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *In Re Certain Ink Application Devices and Components Thereof and Methods of Using the Same,* DN 2874; the Commission is soliciting comments on any public interest issues raised by the complaint.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, Secretary to the Commission, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint filed on behalf of MT.Derm GmbH and Nouveau Cosmetique USA Inc., on January 30, 2012. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain ink application devices and components thereof and methods of using the same. The complaint names T-Tech Tattoo Device Inc. of Canada; Yiwu Beyond Tattoo Equipments Co., Ltd. of China; and Guangzhou Pengcheng Cosmetology Firm of China, as respondents.

The complainant, proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five pages in length, on any public interest issues raised by the complaint. Comments should address whether issuance of an exclusion order and/or a cease and desist order in this investigation would negatively affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the orders are used in the United States;

(ii) Identify any public health, safety, or welfare concerns in the United States relating to the potential orders;

(iii) Indicate the extent to which like or directly competitive articles are produced in the United States or are otherwise available in the United States, with respect to the articles potentially subject to the orders; and

(iv) Indicate whether Complainant, Complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to an exclusion order and a cease and desist order within a commercially reasonable time.

Written submissions must be filed no later than by close of business, eight business days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document and 12 true copies thereof on or before the deadlines stated above with the Office of the Secretary. Submissions should refer to the docket number (''Docket No. 2874'') in a prominent place on the cover page and/or the first page. The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf.* Persons with questions regarding electronic filing should contact the Secretary ((202) 205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50(a)(4) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50(a)(4)).

By order of the Commission.

Issued: January 30, 2012.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–2321 Filed 2–1–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–528]

Used Electronic Products: An Examination of U.S. Exports; Institution of Investigation and Scheduling of Hearing

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of public hearing.

SUMMARY: Following receipt of a request on January 9, 2012, from the United States Trade Representative (USTR) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (Commission) instituted investigation No. 332–528, *Used Electronic Products: An Examination of U.S. Exports.*

DATES: April 16, 2012: Deadline for filing request to appear at the public hearing.

April 30, 2012: Deadline for filing pre-hearing briefs and statements.

May 15, 2012: Public hearing.

May 22, 2012: Deadline for filing post-hearing briefs and statements.

September 14, 2012: Deadline for filing all other written submissions.

February 8, 2013: Transmittal of Commission report to the USTR.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Project Leader Laura Bloodgood (202) 708–4726 or *laura.bloodgood@usitc.gov* or Deputy Project Leader Andrea Boron (202) 205–3433 or *andrea.boron@usitc.gov* for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202) 205–3091 or *william.gearhart@usitc.gov*. The media should contact Margaret O'Laughlin, Office of External Relations (202) 205–1819 or *margaret.olaughlin@usitc.gov*. Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at (202) 205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000.

SUPPLEMENTARY INFORMATION:

Background

As requested by USTR, the Commission will conduct an investigation and prepare a report that describes U.S. exports of used electronic products, such as audio and visual equipment, computers and peripheral equipment, digital imaging devices, telecommunication equipment, and component parts of these products, and such additional electronic products as the Commission deems relevant. As requested, the report will be based on a review of available data and other information, including primary data collected through a survey of enterprises engaged in exporting used electronic products from the United States. The report will cover 2011, or the latest year for which data are available, and, to the extent practicable, include the following:

- The type, volume, and value of, and foreign markets of significance for, exports of used electronic products from the United States;
- The forms and activities, with respect to used electronic products, of enterprises receiving U.S. exporters' shipments, most common end uses of exports in the foreign market (*i.e.,* further processing, final disposal, *etc.*), and the extent of cross-border, intra-firm shipments by U.S. exporters;
- The characteristics of used electronic products exported from the United States, including product condition (*e.g.,* working, non-working, remanufacturable, refurbishable, repairable), composition of shipments (single product type, multiple product types), and the extent to which exports are processed (broken down or stripped), or remain intact prior to exportation;
- The forms, activities and characteristics of domestic exporting enterprises (*e.g.,* original equipment manufacturers, remanufacturers, refurbishers, brokers, recyclers, non-profits, etc.) including the extent to which the exporter is foreign-invested;
- The relative share of sales by U.S. companies of used electronic products that are (1) exported, (2) sold to firms in the United States, (3) processed by the exporter itself, and (4) disposed of by the exporter itself; and
- The factors affecting trade in used electronic products.

The USTR asked that the Commission provide its report no later than 13 months from the date of receipt of the letter.

Public Hearing

A public hearing in connection with this investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC, beginning at 9:30 am on May 15, 2012. Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m., April 16, 2012, in accordance with the requirements in the ''written submissions'' section below. All pre-hearing briefs and statements should be filed with the Secretary no later than 5:15 p.m. on April 30, 2012; and all post-hearing briefs and statements should be filed with the Secretary no later than 5:15 p.m., May 22, 2012. In the event that, as of the close of business on April 16, 2012, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at (202) 205–2000 after April 16, 2012, for information concerning whether the hearing will be held.

Written Submissions

In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received no later than 5:15 p.m., September 14, 2012. All written submissions must conform to the provisions of section 201.8 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 requires that a signed original (or a copy so designated) and fourteen (14) copies of each document be filed. In the event that confidential treatment of a document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules authorize filing submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook on Electronic Filing Procedures, *http://www.usitc.gov/docket_services/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202) 205–2000.

Any submissions that contain confidential business information (CBI) must also conform to the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

In his request letter the USTR said that he anticipates that the Commission's report will be made available to the public in its entirety, and asked that the Commission not include any confidential business or national security information in the report it sends him. Accordingly, any confidential business information received by the Commission in this investigation and used in preparing this report will not be included in the report

that the Commission sends to the USTR and will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.

Issued: January 30, 2012.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2012–2349 Filed 2–1–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Shipyard Employment Standards

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Shipyard Employment Standard'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before March 5, 2012.

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 email 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, Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: (202) 395–6929/Fax: (202) 395–6881 (these are not toll-free numbers), email: *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 email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The information collection requirements of the Standard are directed towards reducing workers' risk of death or serious injury by ensuring that equipment has been tested and is in safe operating condition. The standard for shackles and hooks, 29 CFR 1915.113(b)(1), requires that all hooks for which no applicable manufacturer's recommendations are available be tested and that the employer retain a certification record. The standard on portable air receivers, 29 CFR 1915.172(d), requires that portable, unfired pressure vessels be examined quarterly and subjected to a yearly hydrostatic pressure test and that a certification record be maintained.

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 1218–0220. The current OMB approval is scheduled to expire on January 31, 2012; however, it should be noted that existing information collection requirements 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 October 12, 2011 (76 FR 63327).

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 help ensure appropriate consideration, comments should reference OMB Control Number 1218–0220. 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: Occupational Safety and Health Administration (OSHA).

Title of Collection: Standard on Shipyard Employment (29 CFR part 1915).

OMB Control Number: 1218–0220.

Affected Public: Private Sector—Business or other for-profits.

Total Estimated Number of Respondents: 635.

Total Estimated Number of Responses: 13,051.

Total Estimated Annual Burden Hours: 3,162.

Total Estimated Annual Other Costs Burden: $0.

Dated: January 26, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–2268 Filed 2–1–12; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Occupational Exposure to Hazardous Chemicals in Laboratories Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Occupational Exposure to Hazardous Chemicals in Laboratories Standard'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before March 5, 2012.

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 email 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, Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: (202) 395–6929/Fax: (202) 395–6881 (these are not toll-free numbers), email: *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 email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Occupational Exposure to Hazardous Chemicals in Laboratories Standard applies to laboratories that use hazardous chemicals in accordance with the Standard's definitions for ''laboratory use of hazardous chemicals'' and ''laboratory scale.'' The Standard requires that these laboratories maintain worker exposures at or below the permissible exposure limits specified for the hazardous chemicals in 29 CFR part 1910, subpart Z. They do so by developing a written Chemical Hygiene Plan (CHP) that describes standard operating procedures for using hazardous chemicals; hazard-control techniques; equipment-reliability measures; worker information-and-training programs; conditions under which the employer must approve operations, procedures, and activities before implementation; and medical consultations and examinations. The CHP also designates personnel responsible for implementing the CHP and specifies the procedures used to provide additional protection to workers exposed to particularly hazardous chemicals.

Other information collection requirements of the Standard include documenting exposure monitoring results; notifying workers in writing of these results; presenting specified information and training to workers; establishing a medical surveillance program for overexposed workers; providing required information to the physician; obtaining the physician's written opinion on using proper respiratory equipment; and establishing, maintaining, transferring, and disclosing exposure monitoring and medical records. These collection of information requirements, including the CHP, control worker overexposure to hazardous laboratory chemicals thereby preventing serious illnesses and death among workers exposed to such chemicals.

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 1218–0131. The current OMB approval is scheduled to expire on January 31, 2012; however, it should be noted that existing information collection requirements 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 November 22, 2011 (76 FR 72216).

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 help ensure appropriate consideration, comments should reference OMB Control Number 1218–0131. 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: Occupational Safety and Health Administration (OSHA).

Title of Collection: Occupational Exposure to Hazardous Chemicals in Laboratories Standard.

OMB Control Number: 1218–0131.

Affected Public: Private Sector—Business or other for-profits.

Total Estimated Number of Respondents: 48,461.

Total Estimated Number of Responses: 911,113.

Total Estimated Annual Burden Hours: 293,373.

Total Estimated Annual Other Costs Burden: $41,271,276.

Dated: January 26, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–2269 Filed 2–1–12; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Commercial Diving Operations Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Commercial Diving Operations Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*).

DATES: Submit comments on or before March 5, 2012.

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 email 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, Occupational Safety and Health Administration (OSHA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: (202) 395–6929/Fax: (202) 395–6881

(these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at (202) 693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Commercial Diving Operations Standard information collection requirements are directed toward assuring the safety and health of divers exposed to hyperbaric conditions during and after undersea activities. In addition, the required recordkeeping is intended to bring about a safe workplace and assure the safety of divers. The Standard applies to diving and related support operations conducted by employers involved in general industry, construction, ship repairing, shipbuilding, shipbreaking, and longshoring, and specifies equipment and procedures that prevent injury and death among workers exposed to hazards associated with diving and diving support operations. The Standard contains a number of paperwork requirements codified in regulations 29 CFR 1910.401(b), 1910.410(a)(3) and (a)(4), 1910.420(a), 1910.421(b), 1910.421(f), 1910.421(h), 1910.422(e), 1910.423(b)(1)(ii) through (b)(2), 1910.423(d), 1910.423(e), 1910.430(a), (b)(4), (c)(1)(iii), (c)(3)(i), (f)(3)(ii), and (g)(2), and 1910.440(a)(2) and (b).

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 1218–0069. The current OMB approval is scheduled to expire on January 31, 2012; however, it should be noted that existing information collection requirements 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 November 1, 2011 (76 FR 67480).

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 help ensure appropriate consideration, comments should reference OMB Control Number 1218–0069. 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: Occupational Safety and Health Administration (OSHA).

Title of Collection: Commercial Diving Operations Standard.

OMB Control Number: 1218–0069.

Affected Public: Private Sector—Business or other for-profits.

Total Estimated Number of Respondents: 3,000.

Total Estimated Number of Responses: 4,002,365.

Total Estimated Annual Burden Hours: 205,096.

Total Estimated Annual Other Costs Burden: $0.

Dated: January 26, 2012.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2012–2270 Filed 2–1–12; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL SCIENCE FOUNDATION

Public Availability of the National Science Foundation FY 2011 Service Contract Inventory

AGENCY: National Science Foundation.

ACTION: Notice of Public Availability of FY 2011 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the National Science Foundation is publishing this notice to advise the public of the availability of the FY 2011 Service Contract inventory. This inventory provides information on service contract actions over $25,000 that were made in FY 2011. The information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 and December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf* and *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventory-guidance.pdf.* The National Science Foundation has posted its inventory and a summary of the inventory on the National Science Foundation homepage at the following link: *http://www.nsf.gov/publications/pub_summ.jsp?ods_key=nsf12038.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Richard Pihl in the BFA/DACS at (703) 292–7395 or *rpihl@nsf.gov.*

Dated: January 30, 2012.

Suzanne Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2012–2330 Filed 2–1–12; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2012–0009]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 62—''Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-Level Waste Disposal Facilities.''

2. *Current OMB approval number:* 3150–0143.

3. *How often the collection is required:* The collection would only be required upon application for a Commission emergency access determination when access to a non-Federal or regional low-level waste disposal facility is denied, which results in an immediate public health and safety and/or common defense and security concern.

4. *Who is required or asked to report:* Generators of low-level radioactive waste, or the Governor of a State on behalf of any generator or generators located in his or her State who are denied access to a non-Federal or regional low-level radioactive wastes and who wish to request emergency access for disposal at a non-Federal or regional LLW disposal facility pursuant to 10 CFR part 62.

5. *The number of annual respondents:* 1.

6. *The number of hours needed annually to complete the requirement or request:* 233.

7. *Abstract:* 10 CFR part 62 sets out the information which must be provided to the NRC by any low-level waste generator or Governor of a State on behalf of generators seeking emergency access to an operating low-level waste disposal facility. The information is required to allow the NRC to determine if denial of disposal constitutes a serious and immediate threat to public health and safety or common defense and security. 10 CFR Part 62 also provides that the Commission may grant an exemption from the requirements in this Part upon application of an interested person or upon its own initiative.

Submit, by April 2, 2012, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee, publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2012–0009. You may submit your comments by any of the following methods. Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2012–0009. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at (301) 415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 27th day of January 2012.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2012–2230 Filed 2–1–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0023]

Service Contracts Inventory

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing for public information its Inventory of Contracts for Services for Fiscal Year (FY) 2011. The inventory includes service contract actions over $25,000 that were awarded in FY 2011.

ADDRESSES: You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1 (800) 397–4209, (301) 415–4737, or by email to *pdr.resource@nrc.gov.* The Inventory of Contracts for Services for FY 2011 can be accessed under ADAMS accession number ML11339A134.

The inventory was published on the NRC Web site at the following location: *http://www.nrc.gov/about-nrc/contracting.html.*

FOR FURTHER INFORMATION CONTACT: Lori Konovitz, Office of Administration, Mail Stop TWB–01–B10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Telephone: (301) 492–3627, or email: *lori.konovitz@nrc.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Section 743 of Division C of the FY 2010 Consolidated Appropriations Act, Public Law 111–117, the NRC is providing for public information its Inventory of Contracts for Services for FY 2011. The inventory includes service contract actions over $25,000 that were awarded in FY 2011. The inventory contains the following data:

1. A description of the services purchased;

2. The total dollar amount obligated for the services under the contract, and the funding source for the contract;

3. The contract type and date of the award;

4. The name of the contractor and place of performance;

5. Whether the contract is a personal services contract; and

6. Whether the contract was awarded on a non-competitive basis.

The NRC will analyze the data in the inventory for the purpose of determining if its contract labor is being used in an effective and appropriate manner and if the mix of federal employees and contractors in the agency is effectively balanced. The NRC developed the inventory by pulling data from the Federal Procurement Data

System—Next Generation. The inventory does not include contractor proprietary or sensitive information.

Dated at Rockville, Maryland, this 27th day of January 2012.

For the Nuclear Regulatory Commission.

James C. Corbett,

Director, Division of Contracts, Office of Administration.

[FR Doc. 2012–2312 Filed 2–1–12; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket ID: NRC–2012–0022]

State-of-the-Art Reactor Consequence Analyses Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; public meeting and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is holding public meetings concerning the release of Draft NUREG–1935, ''State-of-the-Art Reactor Consequence Analyses (SOARCA) Report,'' for public comment. The purpose of Draft NUREG–1935 is to report a pilot study of best estimate analyses of the offsite radiological health consequences for potential severe reactor accidents for the Peach Bottom Atomic Power Station and the Surry Power Station.

To facilitate public review of this report, the following associated contractor reports are also now available to the public: NUREG/CR–7110, ''SOARCA Project, Volume 1: Peach Bottom Integrated Analysis''; and NUREG/CR–7110, ''SOARCA Project, Volume 2: Surry Integrated Analysis.'' Additionally, NUREG/BR–0359, ''Modeling Potential Reactor Accident Consequences,'' a plain language public information brochure about the SOARCA project, is now available.

DATES: Submit comments on Draft NUREG–1935 by March 1, 2012. The first public meeting will be held on February 21, 2012, in Surry, VA; and the second meeting will be held on February 22, 2012, in Delta, PA.

ADDRESSES: Please include Docket ID NRC–2012–0022 in the subject line of your comments. For additional instructions on submitting comments and instructions on accessing documents related to this action, see ''Submitting Comments and Accessing Information'' in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2012–0022. Address questions about NRC dockets to Carol Gallagher, telephone: (301) 492–3668; email: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at (301) 492–3446.

FOR FURTHER INFORMATION CONTACT: Jonathan Barr, Division of Systems Analysis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: (301) 251–7538; email: *Jonathan.Barr@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1 (800) 397–4209, (301) 415–4737, or by email to *pdr.resource@nrc.gov.* Draft NUREG–1935, Volume 1 of NUREG/CR–7110, Volume 2 of NUREG/CR–7110, and NUREG/BR–0359 are available in ADAMS under Accession Nos. ML120250406, ML120260675, ML120260681, and ML12026A470, respectively.
- *Federal Rulemaking Web site:* Public comments and supporting materials related to this document can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2012–0022.

Discussion

The SOARCA project analyzed a select set of potential severe reactor accidents at the Surry Power Station near Surry, VA and the Peach Bottom Atomic Power Station near Lancaster, PA. The project, which began in 2007, combined up-to-date information about the plants' layout and operations with local population data and emergency preparedness plans. This information was then analyzed using state-of-the-art computer codes that incorporate decades of international research into severe reactor accidents.

Public Meetings

The first public meeting will be held on February 21, 2012, at 5 p.m. to 9 p.m., Surry Courthouse, General District Courtroom, 45 School Street, Surry, VA 23883. The second meeting will be held on February 22, 2012, at 5 p.m. to 9 p.m., Peach Bottom Inn, 6085 Delta Road, Delta, PA 17314. The SOARCA team will present the project's findings, answer questions, and take comments on the draft report. The meeting agendas will be published on the NRC's Public Meeting Schedule Web site, *http://www.nrc.gov/public-involve/public-meetings/index.cfm,* 10 days prior to the meeting dates. Any changes regarding the meetings will be available on the previously stated Web site.

Dated at Rockville, Maryland, this 26th day of January, 2012.

For the Nuclear Regulatory Commission.

Patricia Santiago,

Chief, Accident Analysis Branch, Division of Systems Analysis, Office of Nuclear Regulatory Research.

[FR Doc. 2012–2313 Filed 2–1–12; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

National Science and Technology Council

ACTION: Notice of Public Meeting.

SUMMARY: The National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), will hold an ''International Symposium on Assessing the Economic Impact of Nanotechnology'' on March 27–28, 2012. This symposium will bring together key policy makers, academics, industry representatives, and other interested stakeholders to examine the current status of nanotechnology in the marketplace and discuss metrics that might accurately portray the economic benefit of nanotechnology to individual country economies and the global economy.

The proposed symposium, hosted by the American Association for the Advancement of Science (AAAS) and jointly organized by the Organization for Economic Cooperation and Development (OECD) and the National Nanotechnology Initiative (NNI), aims to explore a wide range of issues that underpin the dynamism of national innovation initiatives and, in particular, how improved estimates of return on investment in nanotechnology may shape future funding opportunities and national policy development.

Dates and Addresses: The symposium will be held at AAAS, 1200 New York Avenue, Washington, DC 20005 on Tuesday, March 27, 2012 from 8:30 a.m. until 6 p.m. and on Wednesday, March 28, 2012 from 8:30 a.m. until 6 p.m. For directions, please visit *www.aaas.org.*

Registration: Due to space limitations, pre-registration for the workshop is required. Individuals planning to attend the workshop should register online at *http://www.nano.gov/syposiumregistration.* Written notices of participation by email should be sent to *symposium@nnco.nano.gov* or mailed to the International Symposium on Assessing the Economic Impact of Nanotechnology, c/o NNCO, 4201 Wilson Blvd., Stafford II, Suite 405, Arlington, VA 22230. Registration is on a first-come, first-served basis until capacity is reached; otherwise registration will close on March 23, 2012 at 5 p.m. EDT.

Those interested in presenting 3–5 minutes of public comments at the meeting should also register at *http://www.nano.gov/syposiumregistration.* Written or electronic comments should be submitted by email to *symposium@nnco.nano.gov* until March 23, 2012.

Meeting Accommodations: Individuals requiring special accommodation to access this public meeting should contact Diana Petreski (telephone 703–292–8626) at least ten business days prior to the meeting so that appropriate arrangements can be made.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice, please contact Diana Petreski or Kristin Roy at National Nanotechnology Coordination Office, by telephone (703) 292–8626) or email (*symposium@nnco.nano.gov*). Additional information about the meeting, including the agenda, is posted at *www.nano.gov.*

Ted Wackler,

Deputy Chief of Staff, OSTP.

[FR Doc. 2012–2326 Filed 2–1–12; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension:

Rule 17g–3; SEC File No. 270–565; OMB Control No. 3235–0626.

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'') is soliciting comments on the existing collection of information provided for in Rule 17g–3 (17 CFR 240.17g–3) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17g–3 contains reporting requirements. The collection of information obligations imposed by the rule is mandatory. The requirements of Rule 17g–3, however, apply only to credit rating agencies that are registered with the Commission as a nationally recognized statistical rating organization (''NRSRO)'', and registration is voluntary. Under Rule 17g–3 each NRSRO must submit annual audited financial statements. The Commission previously estimated that approximately 30 credit rating agencies would register with the Commission as NRSROs under section 15E of the Exchange Act.[1] Currently, there are nine credit rating agencies that have registered with the Commission as NRSROs. Consequently, while the Commission expects more credit rating agencies may become registered as NRSROs over the next few years, the Commission believes that the estimated number of ten NRSROs should be used for purposes of the Paperwork Reduction Act. Thus, the Commission estimates that the adjusted current industry-wide annual burden for Rule 17g–3 would be 2,033 hours, which includes a one-time reporting burden for processing reports.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; and (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

Please direct your written comments to: Thomas Bayer, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 6432 General Green Way, Alexandria, Virginia 22312 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: January 27, 2012.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–2238 Filed 2–1–12; 8:45 am]

BILLING CODE 8011–01–P

[1] *See Oversight of Credit Rating Agencies Registered as Nationally Recognized Statistical Rating Organizations,* 34–55857 (June 5, 2007), 72 FR 33564 at 33607 (June 18, 2007).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66261; File No. SR–CME–2012–02]

Self-Regulatory Organizations; Chicago Mercantile Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding Fees for Its Cleared-only OTC FX Clearing Offering

January 26, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 24, 2012, Chicago Mercantile Exchange Inc. (''CME'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II and III below, which items have been prepared primarily by CME. CME filed the proposed rule change pursuant to Section 19(b)(3)(A)[3] of the Act and Rule 19b–4(f)(2)[4] thereunder.

I. Self-Regulatory Organization's Statement of Terms of Substance of the Proposed Rule Change

CME is proposing to make certain fee-related changes that would apply to its cleared-only OTC foreign exchange (''FX'') swap clearing offering. The text of the proposed changes[5] is as follows:

CME OTC FX Fee Waiver Program

Program Purpose

The purpose of this Program is to incentivize market participants to submit transaction in the OTC FX products listed below to the Clearing House for clearing. The resulting increase in volume benefits all participant segments in the market.

Product Scope

The following cleared only OTC FX products (''Products''):

1. CME Cleared OTC FX—Emerging Markets

a. USDBRL, USDCLP, USDCNY, USDCOP, USDIDR, USDINR, USDKRW, USDMYR, USDPEN, USDPHP, USDRUB, USDTWD Non-Deliverable Forwards

b. USDCZK, USDHUF, USDHKD, USDILS, USDMXN, USDPLN, USDSGD, USDTHB, USDTRY, USDZAR Cash-Settled Forwards

2. CME Cleared OTC FX—Majors

a. AUDJPY, AUDUSD, CADJPY, EURAUD, EURCHF, EURGBP, EURJPY, EURUSD, GBPUSD, NZDUSD, USDCAD, USDCHF, USDDKK, USDJPY, USDNOK, USDSEK Cash-Settled Forwards.

Eligible Participants

The temporary reduction in fees will be open to all market participants and will automatically be applied to any transaction in the Products submitted to the Clearing House for clearing.

Program Term

Start date is February 1, 2012. End date is June 30, 2012.

Hours

The Program will be applicable regardless of the transaction time.

Program Incentives

Fee Waivers. All market participants that clear the Products will have their clearing fees waived.

* * * * *

The text of the proposed changes is also available at the Exchange's Web site at *http://www.cmegroup.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CME included statements concerning the purpose 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. CME 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 Purpose of, and Statutory Basis for, the Proposed Rule Change

CME currently offers clearing for certain cleared-only OTC FX swap products. The filing proposes to implement a fee waiver program that will apply to the following cleared-only OTC FX products (''Products''):

1. CME Cleared OTC FX—Emerging Markets

a. USDBRL, USDCLP, USDCNY, USDCOP, USDIDR, USDINR, USDKRW, USDMYR, USDPEN, USDPHP, USDRUB, USDTWD Non-Deliverable Forwards

b. USDCZK, USDHUF, USDHKD, USDILS, USDMXN, USDPLN, USDSGD, USDTHB, USDTRY, USDZAR Cash-Settled Forwards

2. CME Cleared OTC FX—Majors

a. AUDJPY, AUDUSD, CADJPY, EURAUD, EURCHF, EURGBP, EURJPY, EURUSD, GBPUSD, NZDUSD, USDCAD, USDCHF, USDDKK, USDJPY, USDNOK, USDSEK Cash-Settled Forwards.

The fee waiver will be open to all market participants and will automatically be applied to any transaction in the Products submitted to CME's clearinghouse for clearing. The proposed changes that are the subject of this filing are related to the fees CME charges for clearing and therefore will become effective upon filing. However, the changes will become operative on February 1, 2012.

Pursuant to Commodity Futures Trading Commission (''CFTC'') regulations, the proposed changes are subject to CFTC Regulation 40.6(d), requiring a self-certification filing to the CFTC, although no change to text of the CME rulebook is required. CME notes that it has already certified the proposed changes that are the subject of this filing to its primary regulator, the CFTC. The text of the CME proposed changes is set out in Section I above.

The proposed changes establish or change a member due, fee or other charge imposed by CME under Section 19(b)(3)(A)(ii) of the Securities Exchange Act of 1934 and Rule 19b–4(f)(2) thereunder. CME believes that the proposed changes are consistent with the requirements of the Securities Exchange Act of 1934 and the rules and regulations thereunder and, in particular, to 17A(b)(3)(iv), in that it provides for the equitable allocation of reasonable dues, fees and other charges among participants. CME notes that it operates in a highly competitive market in which market participants can readily direct business to competing venues.

B. Self-Regulatory Organization's Statement on Burden on Competition

CME does not believe that the proposed rule change will have any impact, or impose any burden, on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

CME has not solicited, and does not intend to solicit, comments regarding this proposed rule change. CME has not received any unsolicited written comments from interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change was filed pursuant to Section 19(b)(3)(A) of the Act and paragraph (f)(2) of Rule 19b–4 and became effective on filing. At any time within sixty days of the filing of such rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(2).

[5] The text of the proposed changes does not appear in CME's rulebook but is available on CME's Web site at *http://www.cmegroup.com/market-regulation/rule-filings.html.*

necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

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 may be submitted by using the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*), or send an email to *rule-comments@sec.gov.* Please include File No. SR–CME–2012–02 on the subject line.
- Paper comments should be sent in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CME–2012–02. This file number should be included on the subject line if email 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, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of CME. 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–CME–2012–02 and should be submitted on or before February 23, 2012.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[6]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–2231 Filed 2–1–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66266; File No. SR–OCC–2012–01]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change Relating to Public Directors

January 27, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder[2] notice is hereby given that on January 20, 2012, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by OCC. The Commission is publishing this Notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of Terms of Substance of the Proposed Rule Change

The proposed rule change would modify the corporate governance structure of OCC by (i) increasing the number of public directors on the Board from one to three and (ii) adding a public director to the Nominating Committee.

II. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning the purpose 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. OCC 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 Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this proposed rule change is to modify the corporate governance structure of OCC by (i) increasing the number of public directors on the Board from one to three and (ii) adding a public director to the Nominating Committee. OCC believes that the proposed changes will be beneficial as a matter of good corporate governance. In addition, OCC is proposing a nonsubstantive amendment to both the By-Laws and the Certificate of Incorporation to remove obsolete provisions relating to Directors elected prior to 1999 that no longer have any effect.

I. Background

The OCC Board currently has 16 members consisting of nine Clearing Member directors (''Member Directors''), five directors nominated by the stockholder exchanges (''Exchange Directors''), one director who is not affiliated with any national securities exchange, national securities association or broker or dealer in securities (''Public Director''), and the Chairman of the Board, who is the Management Director. See Article II, Section 7 of OCC's By-Laws. Member Directors are divided into three equal classes elected for staggered three-year terms and are nominated by the Nominating Committee. Each Exchange Director serves a one-year term and is nominated by one of the five stockholder exchanges although a single Exchange Director may represent more than one exchange. The Public Director serves a three-year term and is nominated by the Chairman with the approval of the Board. The Management Director serves a one-year term. Section 1 and Section 3 of Article III of the By-Laws generally provide that if the combined number of Exchange Directors and the Public Director exceeds eight, the number of Member Directors will be increased to exceed the combined number of Exchange Directors and the Public Director by at least two Member Directors.

The Nominating Committee is composed of six members who are divided into two equal classes elected for staggered two-year terms. Prior to each annual meeting of stockholders, the Nominating Committee nominates a slate of nominees for election to the class of Member Directors and to the class of Nominating Committee members whose terms expire at that meeting. In selecting such nominees, the Nominating Committee seeks to achieve balanced representation among Clearing Members, giving due consideration to the various business activities of different categories of Clearing Members and their geographical distribution.

This governance structure was carefully designed to meet the statutory

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[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

requirements of ''fair representation'' of OCC stockholders and Clearing Members in the selection of directors and administrators of OCC's affairs, and to facilitate the performance of the Corporation's role as a market utility.

2. Proposed By-Law Changes

Article III of OCC's By-Laws governs the composition of the Board, the qualifications of directors and the procedures for nominating and electing directors. OCC proposes to amend Article III such that, beginning with OCC's 2012 annual meeting, the number of Public Directors on the Board will be increased from one to three. The Public Directors will be divided into three equal classes, will be elected for staggered three-year terms, and will continue to be nominated by the Chairman with the approval of the Board of Directors. Accordingly, OCC proposes to remove reference to the two-year term of office for Public Directors elected prior to 1999, which references will no longer be applicable to any Public Director. OCC proposes to amend Section 1 and Section 3 of Article III of the By-Laws to provide that the number of Member Directors will generally exceed the combined number of Exchange Directors and Public Directors by one Member Director (presently by two Member Directors) if the combined number of Exchange Directors and Public Directors exceeds nine (presently eight) in order to accommodate the increased number of Public Directors without automatically requiring a further increase in the number of Member Directors. Additionally, OCC proposes to increase the number of members of the Nominating Committee from six to seven by adding a Public Director member. The Public Director member of the Nominating Committee will be nominated by the Chairman with the approval of a majority of the Board and will serve a three-year term. A vacancy in the position of Public Director member of the Nominating Committee will be filled with another Public Director by a majority vote of the directors then in office.

3. Proposed Amendment to OCC's Certificate of Incorporation

OCC also intends to make amendments to the provision of OCC's Certificate of Incorporation governing Directors to (i) remove reference to the term of office of Public Directors elected prior to 1999 and (ii) provide that Public Directors may only be removed from office for cause. The proposed amendments to OCC's Certificate of Incorporation are included as Exhibit 5 to OCC's filing.

Effectiveness of Proposed Rule Change

OCC will delay effectiveness of the proposed rule change following Commission approval until the proposed amendments to OCC's Certificate of Incorporation are filed with the Secretary of State of Delaware.

* * * * *

The proposed changes to OCC's By-Laws are consistent with the purposes and requirements of Section 17A of the Act because by enhancing the corporate governance structure of OCC through the addition of two Public Directors and the addition of a Public Director to the Nominating Committee they are designed to better protect investors and the public interest. The proposed rule change is not inconsistent with any rules of OCC, including any proposed to be amended.

B. Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe that the proposed rule change would impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) Institute proceedings to determine whether the proposed rule change should be 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 may be submitted by using the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*), or send an email to *rule-comments@sec.gov.* Please include File No. SR–OCC–2012–01 on the subject line.
- Paper comments should be sent in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2012–01. This file number should be included on the subject line if email 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, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at *http://www.theocc.com/components/docs/legal/rules_and_bylaws/sr_occ_12_01.pdf.* 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–OCC–2012–01 and should be submitted on or before February 23, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[3]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–2288 Filed 2–1–12; 8:45 am]

BILLING CODE 8011–01–P

[3] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66265; File No. SR–CBOE–2011–007]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving a Proposed Rule Change To Adopt Rules Governing S&P 500 Option Variance Basket Trades

January 27, 2012.

I. Introduction

On October 26, 2011, Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt rules in connection with a mechanism to quote for, and trade, at a single aggregate price, a basket of S&P 500 Index Options comprising a pre-specified series of listed calls and puts that are constructed to assist market participants who use such baskets of options as part of a trading strategy to obtain or hedge variance exposure on the S&P 500 Index. The proposed rule change was published for comment in the **Federal Register** on November 16, 2011.[3] The Commission received one comment letter on the proposed rule change.[4] This order approves the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange is proposing a new offering, called S&P 500 Variance Trades (''Variance Trades''), which will allow market participants to trade a basket of pre-specified series of S&P 500 Index options (''SPX options'') in a single transaction. Each pre-specified basket of series of options offered by the Exchange will be constructed using a methodology designed to produce options baskets that can be used by market participants as part of a trading strategy to obtain or hedge variance exposure on the S&P 500 Index.[5] Currently, a trader would need to separately purchase or sell each of the options in a pre-specified Variance Trade basket to acquire this type of options exposure. In its filing, the Exchange notes that demand for volatility products has increased in recent years, and believes that the proposed Variance Trades would provide investors with an additional way to efficiently trade S&P 500 volatility.[6]

A Variance Trade consists of a basket of SPX options across different series, where the constituent options of the basket are put and call options with the same expiration date that are centered around an at-the-money strike price.[7] The Exchange will make one or more Variance Trade baskets available for trading each day. Each basket will consist of a portfolio of SPX options defined by the Exchange the day before it is available for trading. Each basket will have a unique ticker symbol.

Unlike a typical multi-legged option transaction whose price is expressed as a net dollar price, the price of a Variance Trade will be quoted in ''volatility terms'' (*i.e.,* a single number that reflects an aggregate implied volatility for the entire options basket). Trade quantities will be expressed in contracts, and each contract will have a multiplier of $10,000 or more, as determined and announced by the Exchange in advance.[8] The Exchange expects typically to specify a higher multiplier than $10,000, but has proposed to establish a $10,000 minimum to allow greater flexibility for short-dated options and low volatility levels.[9]

A participant will submit a Variance Trade order with a limit price expressed in terms of volatility (market orders would not be permitted) and a contract size.[10] Market makers also will be allowed to provide quotes for Variance Trade baskets. Orders and quotes will be ranked pursuant to one of the matching algorithms set forth in CBOE Rule 6.45A, which may be different from the matching algorithm in place for other option products, including SPX. Once a Variance Trade match occurs, the Exchange will use a formula to deconstruct the trade into individual trades in the constituent SPX options that compose the basket, and those individual trades each will be sent to OPRA as separate trades.[11]

The algorithm that deconstructs a Variance Trade into its constituent SPX option legs uses a two step process. First, based on the matched implied volatility (*i.e.,* the price of the trade), the system will calculate the exact number of contracts for each SPX option series composing the Variance Trade.[12] Second, the system will calculate resulting trade prices for each SPX option series through an iterative process in which current implied volatilities for each option series are collectively adjusted upwards or downwards until the aggregate implied volatility of the overall basket equals the matched implied volatility as quoted. The individual price of any given option series in the basket generally would not be the same as (or directly related to) the prevailing market price for that series because the entire basket will be priced in the aggregate in order to reflect the desired volatility level.

The Exchange's proposal will allow the constituent SPX option trades of a Variance Trade to be executed and reported without regard to existing bids and offers on the Exchange in the individual SPX options series at the time of the transaction.[13] Once prices are determined for a trade in each constituent series, the system will execute and report the constituent trades to OPRA.[14] In addition, the executions in the individual constituent series will be sent to the Options

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 65725 (November 10, 2011), 76 FR 71092 (''Notice'').

[4] *See* Letter dated December 14, 2011, from Angelo Evangelou, Assistant General Counsel, Legal Division, CBOE, to Elizabeth M. Murphy, Secretary, Commission (''CBOE Letter'').

[5] The Exchange notes that Variance Trades do not replicate variance swaps. *See* Notice, *supra* note 3, 76 FR 71092, n.4. The Commission understands that Variance Trades could be useful to market participants who employ trading strategies to hedge or replicate variance swaps on the S&P 500 Index. A variance swap is a derivative in which two counterparties agree to exchange future cash flows based on the realized level of volatility of a tradable financial instrument over a pre-specified, future period of time.

[6] *See* Notice, *supra* note 3, 76 FR 71092, text accompanying n.4. *See also* CBOE Letter, *supra* note 4, at 3.

[7] Detailed examples of how Variance Trades would be constructed and executed on the Exchange are provided in the Notice. *See* Notice, *supra* note 3.

[8] The multiplier for Variance Trades represents the aggregate ''vega'' exposure of the SPX option series that comprise the Variance Trade portfolio. Vega describes the change in value of a contract corresponding to a one-point change in volatility.

[9] *See* Notice, *supra* note 3, at n.6.

[10] Variance Trades will trade only electronically.

[11] *See* Notice, *supra* note 3, 76 FR 71093 (setting forth the formula).

[12] Unlike a typical complex order, the terms of a Variance Trade order would not pre-specify the number of contracts for each individual series composing the trade. These quantities instead depend on the implied volatility of the options basket itself, which is not known until a matched implied volatility for a trade has been determined.

[13] *See* Notice, *supra* note 3, 76 FR 71093.

[14] To highlight that executions of Variance Trades are not associated with the quoted prices in the respective SPX series at the time of execution, each constituent SPX option execution will be reported to OPRA with the ''benchmark'' indicator. The benchmark indicator was created to facilitate the execution of benchmark orders as contemplated by the Options Order Protection and Locked/Crossed Market Plan (the ''Linkage Plan''). A benchmark order is an order for which the price is not based, directly or indirectly, on the quoted price of the option at the time of the order's execution and for which the material terms were not reasonably determinable at the time a commitment to trade the order was made.

Clearing Corporation (''OCC'') for clearing.

As there are no position limits for SPX options, the Exchange did not propose any position limits for executions associated with Variance Trades. Reporting limits applicable to SPX options will apply pursuant to CBOE Rule 24.4, Interpretation and Policy .03.

The Exchange expects Variance Trades to appeal to institutional users and not to retail customers.[15] Because of the complex nature of Variance Trades, the Exchange will only allow orders in Variance Trades to be submitted by members who have affirmatively communicated to the Exchange a desire to submit orders in Variance Trades. Thus, retail brokerage firms (or any other firms) that have not specifically opted to submit orders in Variance Trades will not be allowed to send such orders to CBOE (any such orders from such firms will be rejected).

The Exchange represents that appropriate surveillance will be in place in connection with Variance Trades.[16] Further, the Exchange states that it has analyzed its capacity and represents that it and the Options Price Reporting Authority have the necessary systems capacity to handle the additional traffic that it expects will be associated with Variance Trades.[17]

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act[18] and the rules and regulations thereunder applicable to a national securities exchange.[19] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[20] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The introduction of Variance Trades is designed to allow professional market participants to more efficiently trade an entire option portfolio to obtain or hedge variance exposure on the S&P 500 Index. Such traders otherwise would need to purchase or sell each option individually to acquire exposure to such a basket of options in a complex web of simultaneously-executed transactions that is very difficult to reproduce as a series of individual trades. To the extent that traders currently seek out similar products offered on the over-the-counter securities markets, the proposed rule change will permit them to trade Variance Trades on a registered national securities exchange. The Commission believes that the proposal will benefit participants by providing an alternative to the over-the-counter market through the functionality to trade these baskets of exchange-listed options in a national securities exchange environment that offers the potential of enhanced liquidity, transparency, and oversight, and where counterparty risk can be mitigated through the role of OCC. Moreover, the requirement that permit holders affirmatively indicate to the Exchange a desire to transact in Variance Trades before the Exchange accepts and processes orders from such firms will serve as an additional safeguard to protect against the inadvertent submission of Variance Trade orders.

In the Notice, the Commission sought comment on two particular issues relating to the proposed Variance Trades: (1) Allowing the constituent SPX option trades of a Variance Trade to be executed and reported without regard to existing bids and offers on the Exchange in SPX at the time of the transaction; and (2) use of the benchmark indicator when reporting the constituent legs of a Variance Trade.[21] CBOE submitted a letter in response to the Commission's request for comments, urging the Commission to approve its proposal.[22] The Commission did not receive any other comments.

On the first point, the Commission requested commenters' opinions on whether allowing the constituent SPX option legs of a Variance Trade to be executed and reported without regard for existing bids and offers on the Exchange in SPX at the time of the transaction would be consistent with the Exchange Act and what, if any, potential impact this proposal might have on market participants.[23] As noted above, the Commission received no comments except from CBOE.

While multi-leg complex orders can trade on CBOE at the same price as existing booked interest on CBOE for one or more legs only if they improve the price on another leg,[24] Variance Trades will have no similar restrictions, and the constituent legs could thus trade without regard to quotes and orders with priority on CBOE's book.[25] Exceptions from intra-market priority can raise concerns relating to the protection of resting quotes and orders on an exchange's book and the potential impact on the price discovery process.[26]

In its letter, the Exchange argues that orders and quotes in individual SPX options series would not be disadvantaged when the various legs of a deconstructed Variance Trade execute, because traders in the individual SPX option series are not bidding for or offering the entire Variance Trade, which is the relevant order being executed.[27] While true, that argument is inconsistent with the treatment of other complex orders, noted above, which are required to interact with resting orders with priority except under limited circumstances.

In addition, CBOE believes that requiring the deconstructed components of a Variance Trade to interact with orders resting on the CBOE's SPX book would impede and frustrate traders' desire to enter into Variance Trades and achieve their investment objectives.[28] Rather, CBOE argues that introducing an exchange-traded functionality that allows investors to place a single order expressed in volatility terms and that permits those investors to establish a specific volatility profile is consistent with Section 6(b)(5) of the Act in that it removes impediments to, and perfects the mechanism for, a free and open market.[29] The Exchange asserts that if some constituent trades were required to be executed separately from the Variance Trade it would materially alter the pricing of the Variance Trade as well as its variance exposure, and would require the investor to execute separate trades in one or more constituent SPX options in an attempt to achieve the

[15] *See id.* at 71101.

[16] *See id.*

[17] *See id.*

[18] 15 U.S.C. 78f.

[19] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 15 U.S.C. 78f(b)(5).

[21] *See* Notice, *supra* note 3, 76 FR 71102.

[22] *See* CBOE Letter, *supra* note 4.

[23] *See* Notice, *supra* note 3, 76 FR 71102.

[24] *See* CBOE Rule 6.45(B)(b)(ii).

[25] Because SPX options are singly-listed on CBOE, and because the only components of a Variance Trade will be SPX options, CBOE's proposal does not implicate inter-market order protection concerns.

[26] *See e.g.,*Securities Exchange Act Release No. 63955 (February 24, 2011), 76 FR 11533, at 11540 (March 2, 2011) (SR–ISE–2010–73).

[27] *See* CBOE Letter, *supra* note 4, at 2.

[28] *See id.* at 3.

[29] *See id.*

objective variance exposure.[30] The Exchange also states that requiring that positions in the individual constituent series be assigned different prices than those assigned by the algorithm would mean that either the Variance Trade execution price must be modified or a different and less efficient algorithm would be required to assign prices to certain constituent SPX options to reach the trade's stated execution price.[31] The Exchange believes both alternatives would destroy the appeal of the Variance Trade process.[32] According to the Exchange, its proposal is narrowly crafted to prevent abuse and would facilitate beneficial volatility trading and hedging activity that would serve the needs of the marketplace.[33]

Further, CBOE argues that the prices of the constituent option series are unrelated to quotes and orders on CBOE's book and that requiring the constituent legs of a Variance Trade to interact with the book could introduce inefficiencies in the pricing of Variance Trades.[34] The Commission notes that the fact that a given trade in a constituent option series may trade through the price of resting interest is a consequence of the Variance Trade methodology and the fact that a Variance Trade is priced not in net dollar terms but in volatility terms. Unlike complex orders (as defined in CBOE's rules),[35] the terms of a Variance Trade order would not pre-specify a quantity for each individual series. Rather, since the exact size (number of contracts) in each constituent series is a function of the matched implied volatility, it can only be computed once a match has occurred. In addition, the trade prices of the individual legs are derived simultaneously using a complex iterative process that is conducted after a match has occurred.

Requiring the component legs of a Variance Trade basket to interact with resting orders in CBOE's SPX book would materially alter the computed prices for each component leg and therein would frustrate the ability of participants to consummate such transactions and undermine the objective of the trade. Specifically, the Variance Trade algorithm calculates a series of contract sizes and prices that span a considerable number of series and the interaction of these trades with resting orders would impact that process to an extent that could make it difficult, if not impossible, to consummate a Variance Trade transaction. Accordingly, in light of the unique structure and calculation methodology of the Variance Trade, as discussed more fully above, the Commission believes that allowing Variance Trades to execute without interacting with pre-existing interest on CBOE is appropriate and consistent with the Act.

The second point on which the Commission requested comment in the Notice relates to the use of the benchmark trade reporting indicator when reporting the constituent legs of a Variance Trade. The Exchange's proposal seeks to use the ''benchmark'' indicator for informational purposes when reporting executions of the constituent legs of a Variance Trade transaction, even though such trades would not be ''benchmark'' trades pursuant to Section 5(b)(xi) of the Linkage Plan, which by its terms applies only to inter-market (not intra-market) order protection.[36] The Commission received no comments except from CBOE.

The Exchange believes that the benchmark indicator, while it was created for the reporting of multiply-listed option executions, nevertheless would be useful to append to the execution of constituent series of a Variance Trade so SPX traders know that the executions were not related to the quoted price at the time of the print.[37] In its letter, the Exchange argues that the rationale behind the benchmark indicator also applies to Variance Trades.[38] Specifically, the Exchange believes that the constituent SPX options executions clearly fall within the definition of a benchmark trade in that they are not related to the quoted SPX prices at the time of execution, which is how the benchmark indicator would be used in the context of multiply-listed options.[39] Further, CBOE believes that the fact that SPX options only trade on CBOE should not alter the conclusion that benchmark trades be exempt from certain priority considerations because they utilize transparent pricing methods that do not take into account the quoted market in the applicable security.[40] The Exchange believes that the proposed use of the benchmark trade indicator would appropriately alert SPX market participants that the prices of the executed SPX constituent trades were not related to the quoted SPX prices at the time of the execution, in a way that would avoid any market confusion. The Exchange also believes that it would facilitate its surveillance of the constituent trades.[41]

The Commission believes that the use of an indicator for the trades in the constituent series of a Variance Trade is appropriate to alert market participants that the executions are not regular market transactions in order to guard against investor confusion in seeing individual options trade at prices that may be above or below prevailing market prices.

CBOE has informed the Commission that, at the present time, the benchmark indicator is not used in the options markets.[42] In reliance on this representation, the Commission believes the potential for investor confusion by marking the constituent trades as benchmark trades would be minimal, and that the use of the benchmark indicator for these purposes is reasonable at this time. The Commission notes, however, that use of another indicator may be preferable given that the benchmark indicator was intended for use in the context of inter-market order protection and therefore was not necessarily contemplated for use in the context of singly-listed SPX options that only trade on CBOE. Further, as noted above, a benchmark trade is defined as an order for which the price is not based, directly or indirectly, on the quoted price of the option at the time of the order's execution and for which the material terms were not reasonably determinable at the time a commitment to trade the order was made. As also noted above, however, the price of each leg of a Variance Trade actually would take into account the market price of each series as part of the proposed

[30] *See id.* at 4.

[31] *See id.*

[32] *See id.*

[33] *See id.*

[34] *See id.* The Commission notes that despite CBOE's assertion that the prices of the constituent option series of a Variance Trade would be unrelated to quotes and orders on CBOE's book, the proposed methodology CBOE would use for determining option prices in connection with Variance Trades starts with the actual quoted option prices themselves and then adjusts them upwards or downwards as needed. Thus, the price of each option leg of a Variance Trade actually would take into account the market price of each series.

[35] *See* CBOE Rule 6.53C.

[36] A benchmark order is an order for which the price is not based, directly or indirectly, on the quoted price of the option at the time of the order's execution and for which the material terms were not reasonably determinable at the time a commitment to trade the order was made. *See* CBOE Rule 6.81(b)(10) and Section 5(b)(xi) of the Linkage Plan.

[37] Currently, CBOE does not offer functionality or order types that utilize the benchmark exception to the Linkage Plan. *See* Notice, *supra* note 3, 76 FR 71093, n.7.

[38] CBOE Letter, *supra* note 4, at 3.

[39] CBOE Letter, *supra* note 4, at 5.

[40] *See id.* at 3. *See also supra* note 34.

[41] *See* CBOE Letter, *supra* note 4, at 5.

[42] *See* email from Angelo Evangelo, CBOE, to Richard Holley, Assistant Director, Commission, dated January 26, 2012.

methodology in which the quoted price for a series is adjusted upwards or downwards as necessary.[43] CBOE should monitor for the future use of the benchmark indicator in the options markets, and if CBOE or any other options market begins to use the benchmark indicator pursuant to the Linkage Plan, then CBOE should consider the impact of the potential for investor confusion, and whether to seek approval for use of a different indicator for Variance Trades to avoid investor confusion.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[44] that the proposed rule change (SR–CBOE–2011–007) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–2237 Filed 2–1–12; 8:45 am]

BILLING CODE 8011–01–P

[43] *See supra* note 34.

[44] 15 U.S.C. 78s(b)(2).

[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–66245; File No. SR–BX–2012–006]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating To Amend the Definition of Theoretical Price

January 26, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 20, 2012, NASDAQ OMX BX, Inc. (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Chapter V, Section 20 (Obvious and Catastrophic Errors) of the Rules of the Boston Options Exchange Group, LLC (''BOX'') to amend the definition of theoretical price. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://nasdaqomxbx.cchwallstreet.com/NASDAQOMXBX/Filings/.*

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 Exchange is proposing a change to Chapter V, Section 20 (Obvious and Catastrophic Errors). An obvious error occurs when the execution price of a transaction is above or below the Theoretical Price for the series by a specified amount. The Exchange recently submitted an immediately effective rule change to amend the definition of Theoretical Price.[5] Under the recently effective rule, the ''Theoretical Price'' of an option series is defined, if the series is traded on at least one other options exchange, as the mid-point of the National Best Bid or Offer (''NBBO''), just prior to the trade in question. If there are no quotes for comparison, the Theoretical Price is determined by the Market Regulation Center (''MRC'').[6]

The rule change proposed in BX–2011–086 was immediately effective upon filing, but not operative for 30 days. As such, it is not yet operative. The goal of the rule change in BX–2011–086 was to improve the BOX process for addressing potentially erroneous trades to the benefit of all BOX market participants. While proposing the rule change, BOX discussed BX–2011–086 with several BOX Options Participants, and has continued these discussions following the effective date of the proposal. Based on these discussions with its Participants, BOX, after considering the potential impact of the change on BOX market participants and the liquidity on BOX, believes there is sufficient reason to reverse the rule change proposed in BX–2011–086. In addition, BOX will continue analyzing potential refinements to the BOX process for addressing potentially erroneous trades.

As such, the Exchange is proposing to amend the definition of Theoretical Price so that when the series is traded on at least one other options exchange, the Theoretical Price will be the ''National Best Bid with respect to an erroneous sell transaction, and National Best Offer with respect to an erroneous buy transaction, just prior to the trade in question.'' Alternatively, if there are no quotes for comparison, the Theoretical Price will continue to be determined by the MRC. This proposed rule change would reverse the effective rule change identified in note 1 [sic] and amend this provision of the BOX Rules so that the Theoretical Price continues to be the National Best Bid or Offer.

2. Statutory Basis

This proposed rule change is designed to provide the personnel of the MRC (*i.e.,* BOXR) with a clearly defined measure of the price on which to base a determination as to whether or not a particular transaction was the result of an obvious error and continue utilizing the rule that BOX has had in place prior to the operative date of BX–2011–086. The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder and, in particular, the requirements of Section 6(b) of the Act.[7]

Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be

[5] *See* Securities Exchange Act Release No. 66093 (January 4, 2012), 77 FR 1543 (January 10, 2012) (SR–BX–2011–086) Notice of Filing and Immediate Effectiveness of a Proposal To Amend the Definition of Theoretical Price (''BX–2011–086'').

[6] MRC is defined in the BOX Rules to mean the Exchange's facilities for surveilling and regulating the conduct of business for options on BOX. MRC personnel are employees of BOXR and are not affiliated with BOX Options Participants.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by maintaining the obvious error process in existence on BOX.

The Exchange believes that using the NBBO as the Theoretical Price will maintain an objective approach in determining obvious errors that is consistent with other options exchanges. The Exchange believes that continuing to use an objective standard when making adjustment decisions would benefit investors and market participants that are members of multiple exchanges participating in a national market system. The Exchange, after considering the potential impact of the rule change proposed in BX–2011–086 on BOX market participants and the liquidity on BOX, believes continuing to use its current process for evaluating potentially erroneous trades is appropriate for BOX. As such, the Exchange believes that its process for rendering and reviewing trade adjustment determinations is consistent with the Act, and with the maintenance of a fair and orderly market and the protection of investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition 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 neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) [11] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay and make the proposed rule change effective and operative upon filing.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, because such waiver would allow the Exchange to immediately revert back to the definition of ''Theoretical Price'' that was in place prior to the recent proposed rule change, BX–2011–086,[12] before the changes in such rule filing become operative. As such, waiver of the operative delay will ensure that the definition of ''Theoretical Price'' remains consistent, thereby maintaining operational continuity of the rule on the BOX market. For these reasons, the Commission designates the proposed rule change as operative immediately upon filing with the Commission.[13]

At any time within 60 days of the filing of the 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.

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 email to *rule-comments@sec.gov.* Please include File Number SR–BX–2012–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2012–006. This file number should be included on the subject line if email 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, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. 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–BX–2012–006 and should be submitted on or before February 23, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–2337 Filed 2–1–12; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[11] *Id.*

[12] *See supra* note 5 and accompanying text.

[13] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Thermo Tech Technologies Inc., T.V.G. Technologies Ltd., and Visual Frontier, Inc.; Order of Suspension of Trading

January 31, 2012.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Thermo Tech Technologies Inc. because it has not filed any periodic reports since the period ended April 30, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of T.V.G. Technologies Ltd. because it has not filed any periodic reports since the period ended December 31, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Visual Frontier, Inc. because it has not filed any periodic reports since the period ended September 30, 2004.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed companies is suspended for the period from 9:30 a.m. EST on January 31, 2012, through 11:59 p.m. EST on February 13, 2012.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2012–2411 Filed 1–31–12; 11:15 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 7783]

The Designation of Monir Chouka, also Known as Mounir Chouka, Also Known as Abu Adam, Also Known as Abu Adam From Germany, also Known as Abu Adam aus Deutschland, as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Monir Chouka, also known as Mounir Chouka, also known as Abu Adam from Germany, also known as Abu Adam aus Deutschland, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in Section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: January 20, 2012.

Hillary Rodham Clinton,

Secretary of State.

[FR Doc. 2012–2346 Filed 2–1–12; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 7782]

The Designation of Mevlut Kar, Also Known as Mivlut Kar, Also Known as Mavlut Kar, Also Known as Mawlud Kar, Also Known as Meluvet Kar, Also Known as Mevlut Zikara, Also Known as Abdullah the Turk, Also Known as Mulfit Kar Iiyas Al Ubayda, Also Known as Abu Obeidah Al Turki, as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Mevlut Kar, also known as Mivlut Kar, also known as Mavlut Kar, also known as Mawlud Kar, also known as Meluvet Kar, also known as Mevlut Zikara, also known as Abdullah the Turk, also known as Mulfit Kar Iiyas Al Ubayda, also known as Abu Obeidah Al Turki, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in Section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: January 20, 2012.

Hillary Rodham Clinton,

Secretary of State.

[FR Doc. 2012–2347 Filed 2–1–12; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 7784]

The Designation of Yassin Chouka, Also Known as Yasin Chouka, Also Known as Abu Ibrahim, Also Known as Abu Ibraheem the German, also Known as Abu Ibrahim al Almani, as a Specially Designated Global Terrorist pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Yassin Chouka, also known as Yasin Chouka, also known as Abu Ibrahim, also known as Abu Ibraheem the German, also known as Abu Ibrahim al Almani, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in Section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because

to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: January 20, 2012.

Hillary Rodham Clinton,

Secretary of State.

[FR Doc. 2012–2348 Filed 2–1–12; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF STATE

[Public Notice: 7720]

Advisory Committee on Historical Diplomatic Documentation; Notice of Meeting

Summary: The Advisory Committee on Historical Diplomatic Documentation will meet on February 27, June 4–5, and December 10–11, 2012, at the Department of State, 2201 ''C'' Street NW., Washington, DC. The Committee's sessions in the afternoon of Monday, February 27, 2012; in the afternoon of Monday, June 4, 2012; in the morning of Tuesday, June 5, 2012; in the afternoon of Monday, December 10, 2012; and in the morning of Tuesday, December 11, 2012, will be closed in accordance with Section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463). The agenda calls for discussions of agency declassification decisions concerning the *Foreign Relations* series and other declassification issues. These are matters properly classified and not subject to public disclosure under 5 U.S.C. 552b(c)(1) and the public interest requires that such activities be withheld from disclosure.

The Committee will meet in open session from 11 a.m. until 12 noon on the following dates: Monday, February 27, 2012, in the Department of State, 2201 ''C'' Street NW., Washington, DC, in Conference Room 1205; Monday, June 4, 2012, in the Department of State, 2201 ''C'' Street NW., Washington, DC, in Conference Room 1482; and Monday, December 10, 2012, in the Department of State, 2201 ''C'' Street NW., Washington, DC, in Conference Room 1205, to discuss declassification and transfer of Department of State records to the National Archives and Records Administration and the status of the *Foreign Relations* series.

Prior notification and a valid government-issued photo ID (such as driver's license, passport, U.S. government or military ID) are required for entrance into the building. Members of the public planning to attend the meeting on the following dates, please RSVP as follows: for February 27, please notify Colby Prevost, Office of the Historian (202) 663–3529) no later than February 23, 2012; for June 4, please notify Colby Prevost, Office of the Historian (202) 663–3529) no later than May 31, 2012; and for December 10, please notify Colby Prevost, Office of the Historian (202) 663–3529) no later than December 6, 2012. When responding, please provide date of birth, valid government-issued photo identification number and type (such as driver's license number/state, passport number/country, or U.S. government ID number/agency or military ID number/branch), and relevant telephone numbers. If you cannot provide one of the specified forms of ID, please consult with Colby Prevost for acceptable alternative forms of picture identification.

In addition, any requests for reasonable accommodation should be made no later than the following dates: February 21 for the February 27 meeting; May 29 for the June 4–5 meeting; and December 4 for the December 10–11 meeting. Requests for reasonable accommodation received after those dates will be considered, but might be impossible to fulfill.

Personal data is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities. The data will be entered into the Visitor Access Control System (VACS–D) database. Please see the Privacy Impact Assessment for VACS–D at *http://www.state.gov/documents/organization/100305.pdf,* for additional information.

Questions concerning the meeting should be directed to Ambassador Edward Brynn, Executive Secretary, Advisory Committee on Historical Diplomatic Documentation, Department of State, Office of the Historian, Washington, DC 20520, telephone (202) 663–1123, (email *history@state.gov*).

Dated: January 23, 2012.

Edward Brynn,

Ambassador, Executive Secretary, Advisory Committee on Historical, Diplomatic Documentation, Department of State.

[FR Doc. 2012–2351 Filed 2–1–12; 8:45 am]

BILLING CODE 4710–11–P

DEPARTMENT OF STATE

[Public Notice: 7760]

U.S. Department of State Advisory Committee on Private International Law (ACPIL): Notice of Public Meeting of Its Study Group on the Hague Convention on Choice of Court Agreements

The Office of the Assistant Legal Adviser for Private International Law, Department of State, hereby gives notice of a public meeting of the ACPIL Study Group on the Hague Convention on Choice of Court Agreements. The meeting will take place on Monday, March 5, from 1 p.m. to 5 p.m., at the main State Department building (Harry S Truman Building). This is not a meeting of the full Advisory Committee.

The Study Group will meet to discuss the draft federal legislation that has been developed to implement the Convention. It is proposed that the Convention would be implemented through a ''cooperative federalism'' approach whereby states could elect to enact a uniform state act, which would apply in that state in lieu of the federal statute.

Key issues to be discussed include: the scope of federal court jurisdiction in actions brought to recognize or enforce the judgment of a foreign chosen court; provisions on the statute of limitations for bringing recognition/enforcement actions; and whether to prescribe the basis for quasi in rem jurisdiction in recognition/enforcement actions. Participants may comment also on other provisions of the draft federal legislation.

Prior to the Study Group meeting, we will send out the latest federal and state drafts to all those who indicate that they intend to attend the meeting or participate by telephone or who otherwise express an interest in commenting on the draft federal text. Those who cannot attend but wish to comment are welcome to do so by email to Keith Loken at *lokenk@state.gov.*

Time and Place: The meeting will take place in Room 1406, Harry S Truman Building, 2201 C Street NW., Washington, DC 20520. Participants should plan to arrive by 12:30 p.m. for visitor screening. If you are unable to attend the public meeting and would like to participate from a remote location, teleconferencing will be available.

Public Participation: This study group meeting is open to the public, subject to the capacity of the meeting room. Access to the building is strictly controlled. For pre-clearance purposes, those planning to attend should phone

Tricia Smeltzer (202) 776–8423 or Niesha Toms (202) 776–8420 and provide your full name, address, date of birth, citizenship, driver's license or passport number, email address. This will greatly facilitate entry into the building. Participants will be met inside the diplomatic entrance at C Street and, once badges are obtained, escorted to the meeting room. A member of the public needing reasonable accommodation should advise Ms. Smeltzer or Ms. Toms not later than February 27. Requests made after that date will be considered, but might not be able to be fulfilled. If you would like to participate by telephone, please contact Ms. Smeltzer or Ms. Toms to obtain the call-in number and other information.

Data from the public is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities. The data will be entered into the Visitor Access Control System (VACS–D) database. Please see the Privacy Impact Assessment for VACS–D at *http://www.state.gov/documents/organization/100305.pdf* for additional information.

Dated: January 20, 2012.

Keith Loken,

Assistant Legal Adviser, Private International Law, Department of State.

[FR Doc. 2012–2350 Filed 2–1–12; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2012–0089]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before February 22, 2012.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–0089 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:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility 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.

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 our docket Web site, anyone can find and read the 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).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility 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: Robert Hawks, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–7143; email: *rob.hawks@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on January 27, 2012.

Rebecca B. MacPherson,

Assistant Chief Counsel for Regulations.

Petition for Exemption

Docket No.: FAA–2012–0089.

Petitioner: Sun Country Airlines.

Section of 14 CFR Affected: 14 CFR 93.123(a).

Description of Relief Sought: Sun Country Airlines requests an exemption from the slot limit for Ronald Reagan Washington National Airport (DCA) set forth in § 93.123(a), to permit the FAA to create air carrier slots during certain limited hours for Sun Country's use. The proposed air carrier slots would replace two slot exemptions under DOT Order 2010–12–16 awarded to Sun Country. On January 6, 2012, the United States Court of Appeals for the District of Columbia Circuit vacated the DOT Order, and Sun Country will lose its existing service between DCA and Lansing's Capital Region International Airport. Specifically, Sun Country desires one daily slot during each of the 1000 and 1100 hours. The proposed exemption would permit Sun Country to continue operating its existing services and avoid an inequitable result of the Court's order.

[FR Doc. 2012–2241 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2012–0005]

Establishment of an Emergency Relief Docket for Calendar Year 2012

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of establishment of public docket.

SUMMARY: This Notice announces the establishment of FRA's emergency relief docket (ERD) for calendar year 2012. The designated ERD for calendar year 2012 is docket number FRA–2012–0005.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for further information regarding submitting petitions and/or comments to Docket No. FRA–2012–0005.

SUPPLEMENTARY INFORMATION: On May 19, 2009, FRA published a direct final rule addressing the establishment of ERDs and the procedures for handling petitions for emergency waivers of safety rules, regulations, or standards during an emergency situation or event. 74 FR 23329. That direct final rule became effective on July 20, 2009 and made minor modifications to § 211.45 to the FRA's Rules of Practice published at 49 CFR part 211. Paragraph (b) of § 211.45 provides that each calendar year FRA will establish an ERD in the publicly accessible DOT docket system (available on the Internet at *http://*

www.regulations.gov). Paragraph (b) of § 211.45 further provides that FRA will publish a notice in the **Federal Register** identifying by docket number the ERD for that year. As noted in the rule, FRA's purpose for establishing the ERD and emergency waiver procedures is to provide an expedited process for FRA to address the needs of the public and the railroad industry during emergency situations or events. This Notice announces that the designated ERD for calendar year 2012 is docket number FRA–2012–0005.

As detailed § 211.45, if the FRA Administrator determines that an emergency event as defined in 49 CFR 211.45(a) has occurred, or that an imminent threat of such an emergency occurring exists, and public safety would benefit from providing the railroad industry with operational relief, the emergency waiver procedures of 49 CFR 211.45 will go into effect. In such an event, the FRA Administrator will issue a statement in the ERD indicating that the emergency waiver procedures are in effect and FRA will make every effort to post the statement on its Web site at *http://www.fra.dot.gov/.* Any party desiring relief from FRA regulatory requirements as a result of the emergency situation should submit a petition for emergency waiver in accordance with 49 CFR 211.45(e) and (f). Specific instructions for filing petitions for emergency waivers in accordance with 49 CFR 211.45 are found at 49 CFR 211.45(f). Specific instructions for filing comments in response to petitions for emergency waivers are found at 49 CFR 211.45(h).

Privacy

Anyone is able to search all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 665, Number 7, Pages 19477–78). The statement may also be found at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC on January 30, 2012.

Michael W. Lestingi,

Acting Director for the Office of Safety Assurance and Compliance.

[FR Doc. 2012–2356 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2012–0008]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 of the Code of Federal Regulations (CFR), this document provides the public notice that by a document dated December 20, 2011, the Port Authority Trans-Hudson Corporation (PATH) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 235. FRA assigned the petition Docket Number FRA–2012–0008.

PATH seeks relief from the requirements of 49 CFR 235.5 to expedite successful installation of Positive Train Control (PTC), mandated by the Rail Safety Improvement Act of 2008. In preparation for PTC, PATH needs to install new microprocessor interlocking controls and digital audio frequency track circuits, and add, relocate, remove, and/or modify existing wayside signals, train stops, track circuits, interlocking, and non-vital automatic train supervision controls.

This work initially includes certain tracks within PATH's Harrison Yard and South Street Yard for testing purposes, but will eventually include all mainline revenue tracks, other yard tracks, and terminals as the Automatic Train Control (ATC, which is a type of PTC) system installation progresses.

In conjunction with the request, PATH proposes to modify the existing signal system while maintaining compliance with 49 CFR part 236 as provided for under 49 CFR 235.7(c)(24)(vi). This relief would reduce the approval time while still providing FRA review and oversight of the proposed changes in the same manner as pole line elimination projects. PATH's request would be akin to adding the wording, ''modification of existing signal systems in preparation for the installation and testing of PTC,'' or the first sentence in 49 CFR 235.7(c)(24)(vi).

The relief sought would allow for expedited modification of the existing signal system directly associated with the installation and testing of PTC. This would also reduce the administrative workload for both FRA and PATH.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by March 19, 2012 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or online at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on January 30, 2012.

Michael W. Lestingi,

Acting Director for the Office of Safety Assurance and Compliance.

[FR Doc. 2012–2357 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Over-the-Road Bus Accessibility Program Announcement of Project Selections

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The U.S. Department of Transportation (DOT) Federal Transit Administration (FTA) announces the selection of projects to be funded under Fiscal Year (FY) 2011 appropriations for the Over-the-Road Bus (OTRB) Accessibility Program, authorized by Section 3038 of the Transportation Equity Act for the 21st Century (TEA–21). The OTRB Accessibility Program makes funds available to private operators of over-the-road buses to help finance the incremental capital and training costs of complying with DOT's over-the-road bus accessibility rule, published in the **Federal Register** on September 24, 1998.

FOR FURTHER INFORMATION CONTACT: The appropriate FTA Regional Office for grant-specific issues; or Blenda Younger, Office of Program Management, 202–366–4345, for general information about the OTRB Program. Contact information for FTA Regional Offices can be found at *http://www.fta.dot.gov/.*

SUPPLEMENTARY INFORMATION: A total of $8.8 million was made available for the program in FY 2011: $6.6 million for intercity fixed-route providers and $2.2 million for all other providers, such as commuter, charter, and tour operators. A total of 136 applicants requested $40.9 million. Project selections were made on a discretionary basis, based on each applicant's responsiveness to statutory project selection criteria published in the July 13, 2011 Notice of Funding Availability.

Project Implementation: Due to the high demand for the funds available, most successful applicants received less funding than they requested. The selected projects will provide funding for the incremental cost of adding at least one new lift to vehicles, retrofitting vehicles, and not to exceed $2,250 to provide training. FTA did not fund reimbursements for lifts or retrofits purchased before this announcement. Each of the following 97 awardees, as well as the 39 applicants who were not selected for funding, will receive a letter that explains how funding decisions were made.

Grantees selected for competitive discretionary funding should work with their FTA regional office to finalize the electronic grant application in FTA's Transportation Electronic Awards Management System (TEAM) for the projects identified in Tables I and II. A discretionary project identification number has been assigned to each project for tracking purposes and must be used in the TEAM application. Awardees who are new to FTA should contact their regional office immediately for guidance about becoming an FTA grantee. Regional office contact information can be found at *http://www.fta.dot.gov/.*

The grant applications will be sent to the U.S. Department of Labor (DOL) for certification under labor protection requirements pursuant to 49 U.S.C. 5333(b). After referring applications to affected employees represented by a labor organization, DOL will issue a certification to FTA. Terms and conditions of the certification will be incorporated in the FTA grant agreement under the Special Warranty Provisions of the Department of Labor Guidelines ''*Section 5333(b), Federal Transit Law*'' *at 29 CFR 215.7.*

The grantee must comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal requirements in carrying out the project supported by the FTA grant. Funds allocated in the announcement must be obligated in a grant by September 30, 2014.

Issued in Washington, DC, this 27th day of January, 2012.

Peter Rogoff,

Administrator.

BILLING CODE P

Table I
Federal Transit Administration
FY 2011 Over-the-Road Bus Discretionary Program
Other Projects

State	Project IDs	Recipient	Project Description	Allocation
AL	D2011-OTRB-001	J.A.T. Inc.	Retrofits	$26,770
AL	D2011-OTRB-002	Capital Motor Lines dba Capital Trailways	Retrofits	$35,000
AL	D2011-OTRB-003	Colonial Trailways	Retrofits	$56,610
AL	D2011-OTRB-004	Spirit Coach LLC	Retrofits	$29,738
AR	D2011-OTRB-005	Eventure America, Inc. dba Little Rock Tours	Retrofits	$35,000
AZ	D2011-OTRB-006	Mountain View Tours, INC	New Lifts and Retrofits	$35,000
CA	D2011-OTRB-007	Bauer's Limousine Service, Inc.	New Lifts	$29,700
CA	D2011-OTRB-008	CUSA AWC LLC	Retrofits	$25,200
CA	D2011-OTRB-009	Hot Dogger Tours, INC	New Lifts	$35,000
CA	D2011-OTRB-010	Pacific Coachways Charter Service, Inc	New Lifts	$35,000
CA	D2011-OTRB-011	Silverado Stages, Inc.	New Lifts	$32,778
CT	D2011-OTRB-012	Post Road Stages, Inc.	New Lifts	$33,000
FL	D2011-OTRB-013	American Coach Lines of Miami, Inc.	New Lifts	$70,000
FL	D2011-OTRB-014	Astro Travel and Tours, Inc.	New Lifts	$34,350
FL	D2011-OTRB-015	Escot Bus Lines, Inc.	New Lifts and Training	$13,595
FL	D2011-OTRB-016	Florida Cruise Connection, Inc.	Retrofits	$25,200
FL	D2011-OTRB-017	Florida Trails, Inc	New Lifts	$28,283
FL	D2011-OTRB-018	Midnight Sun Tours, Inc.	Retrofits	$25,833
FL	D2011-OTRB-019	Treasure Coast Motor Coach, Inc. dba Magic Carpet Ride	New Lifts	$32,960
GA	D2011-OTRB-020	American Coach Lines of Atlanta, Inc.	Retrofits	$23,244
HI	D2011-OTRB-021	Polynesian Adventure Tours, Inc	New Lifts	$71,036
IL	D2011-OTRB-022	TRT Transportation Inc dba Chicago Trolley	New Lifts	$25,200
IL	D2011-OTRB-023	Vandalia Bus Lines, INC.	New Lifts	$29,700
IN	D2011-OTRB-024	Kaser Enterprises, Inc. dba Royal Excursions Chauffeur	New Lifts	$26,877

Other Projects

State	Project IDs	Recipient	Project Description	Allocation
IN	D2011-OTRB-025	Star of America, LLC dba Star of Indiana Charter Service	Retrofits	$29,700
IN	D2011-OTRB-026	The Free Enterprise System, Inc.	Retrofits	$35,000
KY	D2011-OTRB-027	Shockey Tours, Inc.	New Lifts	$33,000
LA	D2011-OTRB-028	Calco Travel, Inc.	New Lifts	$29,700
LA	D2011-OTRB-029	Gatens Adventures Unlimited, LLC	Retrofits	$27,000
LA	D2011-OTRB-030	Tri-City Charter of Bossier, Inc.	Retrofits	$20,376
MA	D2011-OTRB-031	Cavalier Coach Corporation	New Lifts	$35,000
MA	D2011-OTRB-032	DATTCO, INC	New Lifts	$70,000
MA	D2011-OTRB-033	Wilson Bus Lines, Inc.	Retrofits	$29,700
MD	D2011-OTRB-034	Arthur Peterson dba AP Xpress	New Lifts	$35,000
MD	D2011-OTRB-035	Golden Ring Travel & Transportation Inc	New Lifts	$35,000
MD	D2011-OTRB-036	Woodlawn Motor Coach, Inc.	Retrofits	$29,900
ME	D2011-OTRB-037	Isherwood Enterprises, Inc dba Custom Coach	Retrofits	$25,504
MI	D2011-OTRB-038	Indian Trails, Inc.	New Lifts	$28,175
MN	D2011-OTRB-039	Trobec's Bus Service, Inc	New Lifts	$22,500
MO	D2011-OTRB-040	Mid-American Coaches, Inc	Retrofits	$35,000
NC	D2011-OTRB-041	American Charters, Limited	New Lifts	$70,000
NJ	D2011-OTRB-042	Coastal Charter Service Corp.	New Lifts	$35,000
NV	D2011-OTRB-043	Celebrity Coaches of America, Inc.	New Lifts	$35,000
NY	D2011-OTRB-044	Excellent Bus Service, Inc.	Retrofits	$34,508
NY	D2011-OTRB-045	Paradise Travel, Inc. Charter and Tours	New Lifts	$31,500
NY	D2011-OTRB-046	Upstate Transit of Saratoga, LLC	Retrofits	$29,700
NY	D2011-OTRB-047	Yankee Trails, Inc	New Lifts	$29,700
OH	D2011-OTRB-048	Lakefront Lines, Inc.	New Lifts	$53,568
OH	D2011-OTRB-049	Precious Cargo Transportation Inc.	New Lifts and Retrofits	$35,000
OR	D2011-OTRB-050	CUSA RAZ, LLC	Retrofits	$29,700
PA	D2011-OTRB-051	Central Cab Company	Retrofits	$25,331
PA	D2011-OTRB-052	Transportation Management Services, INC	Retrofits	$27,668
SC	D2011-OTRB-053	Champion Coach, Inc	New Lifts	$25,834

Other Projects

State	Project IDs	Recipient	Project Description	Allocation
TN	D2011-OTRB-054	RLCL Acquisition, LLC	New Lifts	$34,349
TX	D2011-OTRB-055	HME EXECUTIVE COACH INC	Retrofits	$30,297
TX	D2011-OTRB-056	Lone Star Coaches, Inc.	New Lifts	$35,000
TX	D2011-OTRB-057	Star Shuttle, Inc. dba Star Shuttle and Charter	Retrofits	$29,700
VA	D2011-OTRB-058	James River Bus Lines	New Lifts	$25,830
VA	D2011-OTRB-059	M and C Enterprise, Inc. dba Chariots for Hire	New Lifts	$35,000
VA	D2011-OTRB-060	Venture Tours, INC.	Retrofits	$21,771
VT	D2011-OTRB-061	Bristol Tours, Inc	New Lifts	$32,785
WI	D2011-OTRB-062	Kobussen Buses, Ltd.	New Lifts	$27,450
WI	D2011-OTRB-063	Lamers Bus Lines, Inc.	New Lifts	$68,600
WI	D2011-OTRB-064	Riteway Bus Service, Inc.	Retrofits	$35,000
WV	D2011-OTRB-065	COACH USA, INC. dba MOUNTAINEER COACH	Retrofits	$26,080
			Total	**$2,200,000**

Table II
Federal Transit Administration
FY 2011 Over-the-Road Bus Discretionary Program
Intercity Fixed-Route Projects

State	Project IDs	Recipient	Project Description	Allocation
CA	D2011-OTRB-066	CUSA CC, LLC	Retrofits and Training	$105,582
CA	D2011-OTRB-067	CUSA PCSTC, LLC	New Lifts and Training	$52,650
FL	D2011-OTRB-068	Daytona-Orlando Transit Services, Inc.	New Lifts	$25,200
GA	D2011-OTRB-069	Southeastern Stages, Inc	New Lifts	$64,513
IA	D2011-OTRB-070	Burlington Stage Lines, LTD	New Lifts	$70,153
IN	D2011-OTRB-071	Tri-State Coach Lines, Inc.	Retrofits and Training	$77,500
LA	D2011-OTRB-072	Hotard Coaches, Inc.	New Lifts and Training	$210,150
MA	D2011-OTRB-073	Bloom's Bus Lines, Inc.	Retrofits	$50,400
MN	D2011-OTRB-074	Jefferson Partners L.P. dba Jefferson Lines	New Lifts and Retrofits	$129,025
MN	D2011-OTRB-075	Lorenz Bus Service, Inc	Retrofits and Training	$74,534
MN	D2011-OTRB-076	Voigt's Bus Service, INC	New Lifts and Training	$52,650
MS	D2011-OTRB-077	Coach Ride, LLC	Retrofits and Training	$31,200
NE	D2011-OTRB-078	Busco, Inc dba Arrow Stage Lines	New Lifts and Training	$227,250
NJ	D2011-OTRB-079	Academy Express, LLC	New Lifts and Retrofits	$761,029
NJ	D2011-OTRB-080	Suburban Trails, Inc	Retrofits	$245,506
NM	D2011-OTRB-081	Industrial Bus Lines, Inc. dba All Aboard America!	New Lifts and Training	$136,193
NY	D2011-OTRB-082	Adirondack Transit Lines, Inc.	New Lifts and Retrofits	$225,794
NY	D2011-OTRB-083	Chenango Valley Bus Lines, Inc.	Retrofits	$30,000
NY	D2011-OTRB-084	Hampton Jitney, INC.	New Lifts	$86,017
PA	D2011-OTRB-085	Carl R. Bieber, Inc.	Retrofits	$116,481

Intercity Fixed-Route Projects

State	Project IDs	Recipient	Project Description	Allocation
PA	D2011-OTRB-086	David Thomas Tours, Inc.	New Lifts and Training	$35,500
PA	D2011-OTRB-087	Frank Martz Coach Company	New lifts and Retrofits	$331,523
PA	D2011-OTRB-088	Trans-Bridge, Inc.	New lifts and Retrofits	$123,649
RI	D2011-OTRB-089	Bonanza Acquisition LLC	New Lifts	$173,690
TX	D2011-OTRB-090	Americanos USA, LLC	Retrofits	$236,546
TX	D2011-OTRB-091	Autobuses Ejecutivos, LLC	New Lifts	$35,840
TX	D2011-OTRB-092	CUSA EE, LLC	New Lifts and Retrofits	$66,305
TX	D2011-OTRB-093	CUSA KBC, LLC	New Lifts and Retrofits	$129,025
TX	D2011-OTRB-094	Greyhound Lines, Inc.	New Lifts	$2,444,312
WA	D2011-OTRB-095	GTO LLC	New Lifts	$81,540
WI	D2010-0TRB-028 ($18,308) D2011-OTRB-096 ($60,541)	Badger Coaches Inc	New Lifts and Retrofits	$78,849
WI	D2011-OTRB-097	Wisconsin Coach Lines, Inc.	New lifts	$91,393
			Total	**$6,600,000**

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[FR Doc. 2012–2243 Filed 2–1–12; 8:45 am]
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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0005; Notice 1]

Ford Motor Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of petition.

SUMMARY: Ford Motor Company [1] (Ford) has determined that certain model year 2011 Ford E–150, E–250, E–350 and E–450 motor vehicles manufactured between May 12, 2011 and May 25, 2011, do not fully comply with paragraph S5.1 of Federal Motor Vehicle Safety Standard (FMVSS) No. 205, *Glazing Materials.* Ford has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports* (dated August 22, 2011).

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Ford has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Ford's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Affected are approximately 4,532 model year 2011 Ford E–150, E–250, E–350 and E–450 trucks manufactured between May 12, 2011 and May 25, 2011 at Ford's Ohio assembly plant are affected.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, these provisions only apply to the 4,532 [2] subject vehicles that Ford no longer controlled at the time it determined that the noncompliance existed.

Ford described the noncompliance as the formation of air bubbles in the windshields when subjected to high temperatures specified in paragraph S5.1 of FMVSS No. 205.

Paragraph S5.1 of FMVSS No. 205 requires in pertinent part:

> S5.1 Glazing materials for use in motor vehicles must conform to ANSI/SAE Z26.1–1996 unless this standard provides otherwise.
>
> S5.1.1 Multipurpose passenger vehicles. Except as otherwise specifically provided by this standard, glazing for use in multipurpose passenger vehicles shall conform to the requirements for glazing for use in trucks as specified in ANSI/SAE Z26.1–1996 * * *

Ford expressed its belief that only approximately 100 of the 4,532 subject vehicles may actually develop air bubbles in their windshields.

Ford argues that paragraph S5.1 of FMVSS No. 205 specifies meeting the requirements of ANSI Z26.1–1996 Section 5.4 Boil, Test 4. The affected paragraph 5.4.3 ''Interpretation of Results'' states ''The glass itself may crack in this test, but no bubbles or other defects shall develop more than 13 mm from the outer edge of the specimen or from any cracks that may develop.'' Although the affected windshields may develop air bubbles, Ford believes this condition does not present a risk to motor vehicle safety for the reasons described below.

The initiation of the air bubbles will most likely occur when the vehicle is parked in the sun with ambient temperatures greater than 80 °F, and they occur very early in the life of the vehicle. This was the case for the initial vehicles that exhibited the condition while still at the assembly plant, that was experiencing high seasonal temperatures at the time. Of the 41 field reports of the condition that had occurred as of August 16, 2011, only one occurred subsequent to delivery to a customer. All other field reports were found during pre-delivery vehicle preparation.

The appearance of the air bubbles is a slow process, and there are no reports of air bubbles affecting the entire windshield. If bubbles do occur in the driver vision zone, the vision zone is initially only partially affected. This condition would be noticed by the customer prior to a significant spread of the air bubbles, and the customer would seek repair under Ford's normal 3/36 warranty.

Ford is not aware of accidents or injuries attributed to this condition.

In summation, Ford believes that the described noncompliance of its vehicles to meet the requirements of FMVSS No. 225 is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Comments: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. *By mail addressed to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

b. *By hand delivery to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. *Electronically:* by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to 1 (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the

[1] Ford Motor Company is a motor vehicle manufacturer incorporated under the laws of the state of Delaware.

[2] Ford's petition, which was filed under 49 CFR part 556, requests an agency decision to exempt Ford as a vehicle manufacturer from the notification and recall responsibilities of 49 CFR part 573 for the 4,532 affected vehicles. However, a decision on this petition cannot relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Ford notified them that the subject noncompliance existed.

Federal Register published on April 11, 2000 (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

DATES: Comment closing date: March 5, 2012.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8.

Issued on: January 27, 2012.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2012–2306 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0004; Notice 1]

Ford Motor Company, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of Petition.

SUMMARY: Ford Motor Company [1] (Ford) has determined that certain model year 2012 Ford Focus model passenger cars manufactured between May 12, 2011 and May 18, 2011, do not fully comply with paragraph S5.2.1 of Federal Motor Vehicle Safety Standard (FMVSS) No. 101, *Controls and Displays* and paragraphs S5.5.5 of FMVSS No. 135, *Light Vehicle Brake Systems.* Ford has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports* (dated July 7, 2011).

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Ford has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Ford's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Affected are approximately 485 model year 2012 Ford Focus model passenger cars that were manufactured between May 12, 2011 and May 18, 2011.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, these provisions only apply to the 485 [2] model year 2012 Ford Focus model passenger cars that Ford no longer controlled at the time it determined that the noncompliance existed.

Paragraph S5.2.1 of FMVSS No. 101 requires:

S5.2.1. Except for the Low Tire Pressure Telltale, each control, telltale and indicator that is listed in column 1 of Table 1 or Table 2 must be identified by the symbol specified for it in column 2 or the word or abbreviation specified for it in column 3 of Table 1 or Table 2. If a symbol is used, each symbol provided pursuant to this paragraph must be substantially similar in form to the symbol as it appears in Table 1 or Table 2. If a symbol is used, each symbol provided pursuant to this paragraph must have the proportional dimensional characteristics of the symbol as it appears in Table 1 or Table 2. The Low Tire Pressure Telltale (either the display identifying which tire has low pressure or the display which does not identify which tire has low pressure) shall be identified by the appropriate symbol designated in column 4, or both the symbol in column 4 and the words in column 3. No identification is required for any horn (i.e., audible warning signal) that is activated by a lanyard or by the driver pressing on the center of the face plane of the steering wheel hub; or for a turn signal control that is operated in a plane essentially parallel to the face plane of the steering wheel in its normal driving position and which is located on the left side of the steering column so that it is the control on that side of the column nearest to the steering wheel face plane. However, if identification is provided for a horn control in the center of the face plane of the steering wheel hub, the identifier must meet Table 2 requirements for the horn.

Paragraphs S5.5.5 of FMVSS No. 135 requires in pertinent part:

S5.5.5. Labeling. (a) Each visual indicator shall display a word or words in accordance with the requirements of Standard No. 101 (49 CFR 571.101) and this section, which shall be legible to the driver under all daytime and nighttime conditions when activated. Unless otherwise specified, the words shall have letters not less than 3.2 mm (⅛ inch) high and the letters and background shall be of contrasting colors, one of which is red. Words or symbols in addition to those required by Standard No. 101 and this section may be provided for purposes of clarity.

(b) Vehicles manufactured with a split service brake system may use a common brake warning indicator to indicate two or more of the functions described in S5.5.1(a) through S5.5.1(g). If a common indicator is used, it shall display the word ''Brake.'' * * *

Ford explained that the noncompliance is that the telltales used for Brake Warning, Park Brake Warning and Antilock Braking System (ABS) failure warnings are displayed using International Organization for Standardization (ISO) symbols instead of the telltale symbols required by FMVSS Nos. 101 and 135.

Ford stated its belief that although the instrument cluster telltale symbols are displayed using ISO symbols the noncompliance is inconsequential to motor vehicle safety for the following reasons:

(1) The Owners Guide for the subject vehicles is written for multiple markets and depicts both the ''BRAKE'' and ISO symbol telltales for brake warning conditions.

(2) Paragraph S5.5.1 of FMVSS No. 135 states that the warning indicator must identify a gross loss of fluid or fluid pressure and identify if the parking brake is applied and is satisfied by a separate ABS lamp which complies with all requirements of FMVSS No. 135 and FMVSS No. 101.

(3) In the event that the brake fluid level in the master cylinder reservoir is less than the recommended safe level, the ISO symbol will illuminate and a warning message will display in the Message Center that states ''BRAKE FLUID LEVEL LOW SERVICE NOW'' and an initial warning chime will sound. The message will stay continuously displayed until acknowledged by the operator, provided there are no other serious message(s), which would result in the messages alternating. If the brake fluid is still low on subsequent key cycles the message will be redisplayed in the message center. If the message is acknowledged by the operator a red ''i'' is illuminated on the instrument cluster noting that an

[1] Ford Motor Company is a motor vehicle manufacturer incorporated under the laws of the state of Delaware.

[2] Ford's petition, which was filed under 49 CFR part 556, requests an agency decision to exempt Ford as a vehicle manufacturer from the notification and recall responsibilities of 49 CFR part 573 for 485 of the affected vehicles. However, a decision on this petition cannot relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Ford notified them that the subject noncompliance existed.

important message is stored and can be re-accessed by requesting a System Check.

(4) The parking brake in the subject vehicle is set by pulling up on the parking brake handle, which is located on the center console adjacent to the gear shift lever. Thus the application of the parking brake is in full view of the operator. When the parking brake is engaged it illuminates the ISO symbol and should the operator proceed with the parking brake engaged, a warning message ''PARK BRAKE APPLIED'' and an initial audible chime will sound when the vehicle is driven at six miles per hour or greater for more than five seconds, in addition to the vehicle feedback of a lack of acceleration. The warning message will time out after ten seconds but a red ''i'' remains illuminated noting that an important message is stored and can be re-acessed by requesting a System Check. If the operator continues to drive with the parking brake engaged, after 30 seconds the warning message ''PARK BRAKE APPLIED'' will return, along with a warning chime.

(5) In all cases the ISO symbol for the brake telltale illuminates and remains illuminated in accordance with the requirements of FMVSS No. 135.

(6) Ford is unaware of any field or owner complaints regarding the issue of non compliant telltales.

In summation, Ford believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Comments: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. *By mail addressed to:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

c. *Electronically:* By logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

DATES: Comment closing date: March 5, 2012.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8.

Issued on: January 27, 2012.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2012–2307 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2011–0181, Notice 1]

Notice of Receipt of Petition for Decision That Nonconforming 1999 Volkswagen Bora Passenger Cars Manufactured for Sale in the Europe Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that nonconforming 1999 Volkswagen Bora passenger cars manufactured for sale in the Europe (nonconforming 1999 European Volkswagen Bora passenger cars) that were not originally manufactured to comply with all applicable Federal Motor Vehicle Safety Standards (FMVSS), are eligible for importation into the United States because they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards (the U.S.-certified version of the 1999 New Jetta passenger cars) and they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is March 5, 2012.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to http://www.regulations.gov. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Instructions: Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of 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).

How To Read Comments Submitted to the Docket: You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

FOR FURTHER INFORMATION CONTACT: George Stevens, Office of Vehicle Safety Compliance, NHTSA ((202) 366–5308).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register.**

US SPECS, of Havre de Grace, Maryland (Registered Importer 03–321) has petitioned NHTSA to decide whether nonconforming 1999 European Volkswagen Bora passenger cars are eligible for importation into the United States. The vehicles which US SPECS believes are substantially similar are 1999 Volkswagen New Jetta passenger cars that were manufactured for sale in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it compared non-U.S. certified nonconforming 1999 European Volkswagen Bora passenger cars to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

US SPECS submitted information with its petition intended to demonstrate that non-U.S. certified nonconforming 1999 European Volkswagen Bora passenger cars as originally manufactured, conform to many FMVSS in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified nonconforming 1999 European Volkswagen Bora passenger cars are identical to their U.S. certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect,* 103 *Windshield Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 106 *Brake Hoses,* 109 *New Pneumatic Tires,* 113 *Hood Latch System,* 116 *Motor Vehicle Brake Fluids,* 124 *Accelerator Control Systems,* 135 *Light Vehicle Brake Systems,* 202 *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 207 *Seating Systems,* 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Mounting,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* and 302 *Flammability of Interior Materials.*

The petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls Telltales, and Indicators:* (a) Inscription of the word ''brake'' on the dash in place of the international ECE warning symbol; and (b) replacement of the speedometer with a unit reading in miles per hour, or modification of the existing speedometer so that it reads in miles per hour.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* installation of the following components on vehicles that are not already so equipped: (a) U.S.-model front sidemarker lamps; (b) U.S.-model headlamps; (c) U.S.-model tail lamps with integral rear side marker lamps; (d) U.S.-model high-mounted stop lamp; and (e) front and rear side-mounted reflex reflectors to meet the requirements of this standard.

Standard No. 110 *Tire Selection and Rims for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less:* installation of a tire information placard.

Standard No. 111 *Rearview Mirrors:* installation of a U.S.-model passenger side rearview mirror, or inscription of the required warning statement on the face of the existing mirror.

Standard No. 114 *Theft Protection:* installation of a supplemental key warning buzzer, or installation or activation of U.S.-version software to meet the requirements of this standard.

Standard No. 118 *Power-Operated Window, Partition, and Roof Panel Systems:* installation or activation of U.S.-version software in the vehicle's computer system, or installation of a supplemental system to meet the requirements of this standard.

Standard No. 201 *Occupant Protection in Interior Impact:* replacement of non U.S.-model upper interior components with U.S.-model components to meet the requirements of this standard on vehicles that are not already so equipped.

Standard No. 206 *Door Locks and Door Retention Components:* replacement of non U.S.-model door lock components with U.S.-model components on vehicles that are not already so equipped.

Standard No. 208 *Occupant Crash Protection:* inspection of all vehicles and replacement of any non U.S.-conforming model seat belts, air bag control units, air bags, and sensors with U.S.-model components on vehicles that are not already so equipped; and (b) installation or activation of U.S.-version software, or installation of a supplemental system to ensure that the seat belt warning system meets the requirements of this standard.

Standard No. 209 *Seat Belt Assemblies:* inspection of all vehicles and replacement of any non U.S.-certified model seat belts with U.S.-model components.

Standard No. 225 *Child Restraint Anchorage Systems:* inspection of all vehicles and installation of non U.S.-model child restraint anchorage system components on vehicles not already not so equipped.

Standard No. 301 *Fuel System Integrity:* inspection of all vehicles and replacement of any non U.S.-model fuel system components with U.S.-model components.

The petitioner additionally states that a vehicle identification plate must be affixed to the vehicles near the left windshield post to meet the requirements of 49 CFR part 565.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: January 27, 2012.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2012–2308 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2011–0283; Notice No. 12–2]

Hazardous Materials: Special Permit and Approval Applicant Fitness Determinations; Public Meeting

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice is to advise interested persons that PHMSA will conduct a public meeting to discuss Special Permit and Approval applicant fitness determinations. The public meeting, to be held on February 29, 2012, in Washington, DC, is intended to provide interested persons with an opportunity to submit oral comments and participate in discussions concerning the criteria used when determining an applicant's minimum level of fitness.

DATES: Public Meeting: Wednesday, February 29, 2012; starting at 1 p.m. and ending by 4 p.m.

ADDRESSES: The meeting will be held at the U.S. DOT Headquarters, West Building, 1200 New Jersey Avenue SE., Washington, DC 20590. The main visitor's entrance is located in the West Building, on New Jersey Avenue and M Street. Upon entering the lobby, visitors must report to the security desk. Visitors should indicate that they will be attending the Special Permit and Approval Applicant Fitness Determinations Public Meeting and wait to be escorted to the meeting location.

Notification: Any person wishing to participate in the public meeting should send an email to *approvals@dot.gov* and include their name and contact information (Organization/Address/Telephone Number) no later than the close of business on February 22, 2012. Providing this information will facilitate the security screening process for entry into the building on the day of the meeting.

Conference Call Capability/Live Meeting Information: Conference call-in and ''live meeting'' capability will be provided for this meeting. Specific information on the call-in and live meeting access will be posted when available at: *http://www.phmsa.dot.gov/hazmat.*

Documentation: Copies of documents for the Special Permit and Approval Applicant Fitness Determinations Public Meeting and the meeting agenda will be posted by February 15, 2012, at: *http://www.phmsa.dot.gov/hazmat.*

Comment Submission: Stakeholders may submit comments prior to, or after the February 29, 2012 public meeting, by identification of the docket number (PHMSA–2011–0283) by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 1–(202) 493–2251.
- *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.
- *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.

Instructions: All submissions must include the agency name and docket number for this public meeting notice at the beginning of the comment. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information.

Docket: For access to the dockets to read background documents or comments received, go to *http://www.regulations.gov* or DOT's Docket Operations Office (see Comment Submission).

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Pollack, Approvals and Permits Division, Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, DC 20590; (202) 366–4512 and *arthur.pollack@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Pipeline and Hazardous Materials Safety Administration (PHMSA) has the primary responsibility for the issuance of DOT special permits and approvals under the 49 CFR parts 100–185. A Special Permit is a document that authorizes a person to perform a function that is not otherwise permitted under the Hazardous Materials Regulations (HMR). An Approval is a written consent, including a competent authority approval, to perform a function that requires prior consent under the HMR.

Applicants are required by the HMR to request an approval from PHMSA for the classification of explosives, fireworks, organic peroxides, and self-reactive materials. Approvals are also required when package design types vary from the design or test standards specified in the regulations and for persons performing certain activities requiring approval (*e.g.,* visual cylinder re-qualifiers). An Approval can only be issued if there is a specific approval citation in the HMR.

In accordance with 49 CFR 107.113(f), PHMSA may grant a special permit on a finding that an applicant is fit to conduct the activity authorized by the special permit. In accordance with 49 CFR 107.709(d), PHMSA may grant an approval on a finding that an applicant is fit to conduct the activity authorized by the approval. PHMSA may determine an applicant's fitness through the information in the application, prior compliance history of the applicant, and other information available to the Associate Administrator.

On August 19, 2010, PHMSA held a public meeting to provide for public participation in the discussion concerning the criteria used to determine an applicant's minimum level of fitness. The meeting allowed interested parties to inform PHMSA of the concerns about its fitness evaluation process.

Since the meeting, PHMSA has been working collaboratively and diligently with its partners in other DOT operating administrations to obtain the necessary fitness data to conduct accurate and efficient fitness determinations. PHMSA has in addition been working closely with its regulatory (modal) partners to deliver quantitative data that can be used to further develop an automated fitness review process.

II. Purpose of Public Meeting

PHMSA is considering revising the fitness determination criteria to streamline the application process while maintaining the focus on safety. PHMSA is holding a public meeting to provide an opportunity for all interested parties to comment on the fitness review process.

Specifically, PHMSA seeks comments relative to the use of the U.S. DOT's Hazmat Intelligence Portal (HIP) data, the potential use of alternative sources of fitness data, and other information that should be considered during the fitness review process.

Please note that stakeholders are encouraged to submit their comments to the Docket (PHMSA–2011–0283) prior to the February 29, 2012 meeting, and through a 30 day comment period ending on March 30, 2012. (Please see the Comment Submission section above.) Furthermore, in order to collect the verbal comments quickly and accurately, PHMSA will be employing a stenographer (court reporter) to transcribe the meeting dialogue into written notes. The notes (meeting minutes) will be placed in the Docket at a later date, when ready.

Issued in Washington, DC, on January 27, 2012.

Magdy El-Sibaie,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2012–2305 Filed 2–1–12; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activity; Proposed Collection

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)).

DATES: Written comments should be received on or before April 2, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this regulation should be directed to R. Joseph Durbala, at (202) 622–3634, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Adjusted Current Earnings.

OMB Number: 1545–1233.

Regulation Project Number: IA–14–91 (TD 8454-final).

Abstract: Section 1.56(g)–1(r) of the regulation sets forth rules pursuant to section 56(g) of the Internal Revenue Code that permit taxpayers to elect a simplified method of computing their inventory amounts in order to compute their alternative minimum tax.

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.

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: January 24, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–2248 Filed 2–1–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4461, 4461–A, and 4461–B

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 Form 4461, Application for Approval of Master or Prototype Defined Contribution Plan; Form 4461–A, Application for Approval of Master or Prototye Defined Benefit Plan; Form 4461–B, Application for Approval of Master or Prototype Plan, Mass Submitter Adopting Sponsor.

DATES: Written comments should be received on or before April 2, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette 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 form and instructions should be directed to R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3634, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Form 4461, Application for Approval of Master or Prototype Defined Contribution Plan; Form 4461–A, Application for Approval of Master

or Prototype Defined Benefit Plan; Form 4461–B, Application for Approval of Master or Prototype Plan, Mass Submitter Adopting Sponsor.

OMB Number: 1545–0169.

Form Number: Forms 4461, 4461–A, and 4461–B.

Abstract: The IRS uses these forms to determine from the information submitted whether the applicant plan qualifies under section 401(a) of the Internal Revenue Code for plan approval. The application is also used to determine if the related trust qualifies for tax exempt status under Code section 501(a).

Current Actions: There are no changes being made to these forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 5,250.

Estimated Number of Respondent: 12 hours, 31 minutes.

Estimated Total Annual Burden Hours: 65,765.

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: January 30, 2012.

Yvette Lawrence,

IRS Reports Clearance Office.

[FR Doc. 2012–2331 Filed 2–1–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activity; Proposed Collection

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)).

DATES: Written comments should be received on or before April 2, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette 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 regulations should be directed to R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3634, or through the internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Transfers of Securities Under Certain Agreements.

OMB Number: 1545–0770.

Regulation Project Number: FI–182–78.

Abstract: Section 1058 of the Internal Revenue Code provides tax-free treatment for transfers of securities pursuant to a securities lending agreement. The agreement must be in writing and is used by the taxpayer, in a tax audit situation, to justify nonrecognition treatment of gain or loss on the exchange of the securities.

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, individuals, and not-for-profit institutions.

Estimated Number of Respondents: 11,742.

Estimated Time per Respondent: 50 minutes.

Estimated Total Annual Burden Hours: 9,781.

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: January 24, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–2263 Filed 2–1–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activity; Proposed Collection

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)).

DATES: Written comments should be received on or before April 2, 2012 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette 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 regulations should be directed to R. Joseph Durbala at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3634, or through the Internet at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Excise Tax Relating to Gain or Other Income Realized By Any Person on Receipt of Greenmail.

OMB Number: 1545–1049.

Regulation Project Number: IA–7–88 [TD 8379—final].

Abstract: The regulations provide rules relating to the manner and method of reporting and paying the nondeductible 50 percent excise tax imposed by section 5881 of the Internal Revenue Code with respect to the receipt of greenmail. The reporting requirements will be used to verify that the excise tax imposed under section 5881 is properly reported and timely paid.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and business or other for-profit organizations.

Estimated Number of Respondents: 4.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 2.

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: January 24, 2012.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2012–2265 Filed 2–1–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Quarterly Publication of Individuals, Who Have Chosen To Expatriate, as Required by Section 6039G

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice is provided in accordance with IRC section 6039G, as amended, by the Health Insurance Portability and Accountability Act (HIPAA) of 1996. This listing contains the name of each individual losing their United States citizenship (within the meaning of section 877(a) or 877A) with respect to whom the Secretary received information during the quarter ending December 31, 2011.

Last name	First name	Middle name/initials
ADELSON	MELANIE	R
ANDERSON	ALLEN	W
ANDERSON	NANCY	S
ANG	PENG–HUAT	
ANG	RYANNA	JIA–MIN
BARCLAY–GRUNDLER	CURTIS	RICHARD
BARLOW III	CHARLES	BUDFORD
BASSETT–BLAIR	HEIDI	
BASTIANI	ADOLFO	
BEAN	HAROLD	M
BEAUDET	PHILIPPE	
BEAUREGARD	CATHERINE	
BEHLER	ALBERT	P
BERG	SHANE	DAVID
BERGER	THOMAS	JAN
BERNHEIM	ELENA	ROSA
BESSON	MATHIEU	JACQUES PHILIPPE
BHUTANI	JASMINDER	K
BIELBY	CHRISTINE	SARAH JANE
BIELBY	JOHN	HENRY
BINDER	PETER	ERIK PHILLIPPE
BISTRICER	MARC	YEHUDA
BLACK	JENNIFER	MARY–LOUISE
BLAIR	CHRISTOPHER	R
BONNIER	ADAM	F
BOUCHIER	DAVID	IAN
BRACHER	CLAUDIA	RUTH

Last name	First name	Middle name/initials
BRANSCHI	GIAN	RETO
BRICKWOOD	MALCOLM	
BRICKWOOD	SYLVIA	
BROD	IVAN	
BROUWER	PIET	
BUIJTENDORP	ERIK	L
BURGESS	TREVOR	M
BURSTIN	LARRY	MIGUEL REIDER
BYRNE	MARIE	ANN
CAMERON	AUDREY	MAE
CAMPBELL	LYNDSAY	
CAOUETTE	RICHARD	
CARDONA	SUSAN	
CERRONE	GABRIEL	M
CHAN	VIVIENNE	W
CHANG	PAMELA	Y
CHANG	RAYMOND	S
CHANTRE	ALEXANDER	ECKES
CHATEAU	BEATRICE	
CHENG	NICOLE	MIU YEE
CHENG	RAYMOND	SHU SHING
CHIU	MAN	KEI ELAINE
CHIU	MICHAEL	MAN YAT
CHOA	TAK	FUNG DAVID
CHOW	STELLA	ZONG JE
CHRISTEN	BONNIE	WOODWARD
CHRISTIANSON	ERIC	DUANNE
CHUN	MIMI	MEI LOR
COHEN	RAPHAEL	MAYER
COHEN	WILLIAM	ALBERT MAYER
CONNOLLY	WINSTON	
COOKSON	GORDON	POWER
COONEY	JOHN	
CUBAUD	NICOLAS	EDGARD
CUDDY	DAVID	R
CUNNINGHAM	ELENA	RENATA
CUNNINGHAM	JUDITH	A
CUNNINGHAM JR	ALLAN	FRANCIS
CZAPKA	JENNIFER	M
CZAPKA	RICHARD	A
D'ABO	MARYAM	
DAS	SOMA	
DE LA PINTIERE	FRANCOISE	
DE LA PINTIERE	LOUIS	
DE SAINT VINCENT	GERARD	P
DEAN–BREWER	JANET	
DEFAUCONVAL	CHARLES	P M
DEGENSZEJN	DEBORA	
DEL ROSAL	MARIA	C MIRANDA
DEL ROSAL	ROBERTO	RADAMES
DELESSERT	YVES	
DENT–BROCKLEHURST	HENRY	C
DENTINO	VERENA	SYBILLE
DEROSEN	LAURENCE	
DHADUK	GHANSHYAM	
DIMITROVA–POURSAFAR	DESSISLAVA	
DOLFEN	MARC	CHRISTOPHER
DONALDSON	EDWARD	G
DONALDSON	LYNDA	
DUERST	ANN	ELIZABETH
DUQUE	LUIZ	H
DURHAM	CHRISTABEL	MARY
EHRHARDT	STEFAN	CHRISTOPHER
EHRKE–HARF	MARIE	HELENE
EKLUND	CHARLES	A
ELLIOTT	PATRICK	
ERGEN	CHARLES	EDWARD
EUSTACE	CHRISTINA	EMILY
FELIX	NADINE	G
FITZSIMMONS	TREVOR	MORRISON
FLECKENSTEIN	EMILIA	
FLECKENSTEIN	RONALD	PAUL
FONG	JENNIFER	
FONG	RICHARD	CHUN YIU

Last name	First name	Middle name/initials
FONTANA	PETER	THOMAS
FORSTER	CAROLE	A
FORTES	RODRIGO	LOSADA
FOSTER III	ROBERT	PORTER
FOSTER, NEE WIELANDT	DORA	
FOURNIER	JOHN	L
FRANZ	ANGELIKA	
FREEMAN	PETER	FRANCIS
FUENTES	ANGELICA	
FUNG	MAGNUS	MAN KIT
FURTH	JOHANNA	CHARLOTTE
GALE	HYACINTH	SHYAMALA
GALE	WILLIAM	FRANCIS
GALLU	SIMEON	
GARDNER	SARAH	
GAVIN	NANCY	J
GETTY	ANNA	C
GOLDTHWAITE	DANALEE	
GORDON	GILDAD	
GRAF	HANS	MARTIN
GREEN	MICHAEL	N
GREER	JOAN	M
GRETCHEN–PETERS	NANCY	
GRIBBLE	ELIZABETH	M
GRIBBLE	MICHAEL	I
GRIMM	CHRISTOPH	
GRIMM	KATJA	
GROENEN	FRANK	
GRONER	ELIYAHU	DAVID
GRONING	MARC	E
GUNNARSSON	GUNNAR–THOR	BJORNSSON
GUREN–BERMAN	MICHELE	ANNE
GUTZWILLER	FIONA	MARIA
GUTZWILLER	NICOLE	SYLVIA
GUTZWILLER	NINA	GEORGIA
HACHE	JEAN–MICHEL	
HADDAD–KOENIG	CHARLES	
HAEBERLING–PFENNINGER	KATHARINA	ESTHER
HANES	ROLF	ARTHUR
HANSSON	KARL	STEFAN
HARPER–VANDAMME	BRENDA	CHRISTIAN
HARVEY	BRUCE	E
HARVEY	RALPH	DIETER
HASLER	PASCAL	ERIC
HAXELL	IAN	
HERNE	DAVID	ALEXANDER
HERRING	MARIO	T
HERRMANN	MARTINE	SYLVIE
HESS	CLINTON	A
HILLIARD	ELAINE	GARDINER WELCH
HO	LESLIE	SAI KIT
HOCHHEIMER	SUZANNE	TRUDY
HOLUB	BARBARA	RENE
HRYNIUK	LYNN	E
HRYNIUK	WILLIAM	
HUSTON	JULIEN	VINCENT C
HUTTON	MICHAEL	L
HUYNH	HENRY	
IRVINE	LESLEY	ELIZABETH
JACQUES	BENOIT	
JAN	YAHYA	
JAUW	JANIE	APRIL
JOWITT	JANET	GARBARINO
KATO	HIROMITSU	
KELLENBERGER	LISA	J
KELLENBERGER	PIERRE	
KELLERMANN	GOTTFRIED	HEINRICH
KHATTAB	MOHAB	T
KINDLE	MARION	VANESSA
KINZEL	CAROLINE	J
KNOX	ROBERT	JAY
KOMMULA	VENKATA	
KOSTERS	OLGA	
KRALL	TANJA	SILVIE

Last name	First name	Middle name/initials
KROPF	MICHAEL	DAVID
KUEMPER	THORSTEN	
KULLMAN	ANNAKARIN	LINA
KWANG	SIMON	C
KWONG	CHU	TONG
LA VANCE	MONIQUE	
LABELLE	JULIE	A
LEE	HYANGLY	
LEE	PETER	WAI LING
LEE	YAT	HUNG
LELAND	JACQUELINE	
LEMOS	MICHAEL	
LERVIK	ANNE	SOPHIE LORANGE
LEWICKI	PAWEL	M
LIN	HSIAO–CHUAN	
LIPPER	NAOMI	ISHIDO
LOMP	CHANA	MIRIAM
LORANGE	PER	FRITHJOF
LOSADA JR	ANGEL	
LOURO	BENTO	J
LU	LI	MIN
LUBENEC	STEPHANE	
MANEVICH	CESAR	
MANEVICH	SARAH	
MARSDEN	RENATE	B
MARTIN	KENNETH	
MARTINET	CHANTAL	VICTOIRE PORTER
MASTERS	MICHAEL	WENDELIN
MCCRAY	SANDRA	
MCFADYEN	LISA	M
MCFADYEN	MICHAEL	K
MCGOWAN	EILEEN	
MCGRAIL	ELAINE	
MCKENZIE	BRUCE	D
MCKENZIE	MARILYN	I
MCLEISH	DAVID	E
MCLEISH	NATALIE	C
MELCHIORRI	CRISTINA	MARIA
MERCADO	LEANNE	
MERCIER	GUY	H
MILANO	MIGUEL	
MILLER	RALPH	WILLIAM
MINNETIAN	OHANNES	MARGOS
MINTY	FATIMA	
MINTY	MUHAMMED	
MIONE	LAN	ZHOU
MIRANDA	MARIA	C
MISRA	SOM	A
MODE	JUTTA	E
MORLAND	GUISLAINE	VINCENT
MURPHY	MICHAEL	N
MURRAY	MURRAY	J
MUSIL	ANDREA	
NAGATA	HIROKO	
NEEMAN	KEREN	
NEEMAN	YOEL	
NEVILLE–GALVIN	MARIAN	G
NIEMANN	CHRISTOPH	
NISHIMURA	YOSHIHARU	
NIZET	ANDRE	
NOORPURI	MARUF	H KHAN
OERTLI	KATHARINA	E
OOMS	EDWIN	
ORF	ROGER	GERARD
ORTEGA	JAMES	ADRIAN
PASSERELLE	NARIKO	
PATON	CHARLES	R MATTHEW
PAVAGEAU	BENJAMIN	
PEDERCINI	PIERANTONIO	
PEPPER	MARK	E
PETERS	DOUG	
PFENNINGER	ROLF	ALAN
PHILLIPS	OWEN	MARTIN
PIRCHER	BETTY	

Last name	First name	Middle name/initials
PIRCHER	PETER	A
PISTOR	LUDGER	
PLAZ	ERIKA	MARIA
PRATT	HELENE	J
PUERTA–GARCIA	FRANCISCO	JAVIER
QUILTY	ROBERT	F
RASKA	ROXANA	
RASMUSSEN	PATRICIA	CAROL MACKAY
REED	KUN	TIN
REIDER	LARRY	MIGUEL
REUTIMANN	BRIAN	
ROBBINS	CHRISTOPHER	J
ROSSIANOL	STEPHANIE	J
ROUNDELL	CANDICE	DAWN GAELIE
RUDELOFF	THOMAS	RUSSELL
RUEBSAMEN	MARGUERITE	ANNABELLE
SABO	DEAN	
SABO	TIMOTHY	J
SACKS	YAAKOV	E
SAITO	MIEKO	
SAITO	TAIJI	
SANDFORT	HORST	G
SARAN	PHILLIP	HOWARD HASENFUS
SAYE	GALINA	K
SCHAELLIBAUM–PFENNINGER	ISABEL	ANN
SCHLATTER	TENIE	MCCUTCHEN
SCHNORR	KIRK	MATTHEW
SCOTT	JUNE	E
SCOTT	ROBERT	P
SEKAR	SEKAR	VISWANATHAN
SEVERGNINI	MADDALENA	JOHNS
SHAH	PARI	
SHAH	SEETA	VISHAL
SHERRINGTON	YVONNE	ROSE
SHIOMI	MAKOTO	
SHONHAN	ROSS	LEIGH
SHOSTAK	LISA	CLARE
SIM	ANDREW	YUN WEN
SIMS	CHARLES	R
SIMS	JULIA	I
SIMS	LAURIE	E
SMIRIN	SUSAN	A
SNG	DANIEL	E K
SOBOCINSKI	SOPHIE	EVE
SOBOCINSKI	THOMAS	CHARLES
SPEYER	MICHEL	HENRI HONORE
STABBERT	KAREN	GAYLE
STASSINOPOULOS	ELIAS	NICHOLAS
STEAR	GUY	BENEDICT
STENBECK	DESTINY	SOPHIA
STEPHENS	GARY	LEE
STRANDE	MAJA	V
STUCKI	VERA	C
SUFALKO	FRANK	BENJAMIN
SUH	MARION	
SUN	CHUEN	YOUNG
SUZUKI	RYOKO	
SUZUKI	YOSHIKATSU	
SWEET	ROBERT	BENJAMIN
SWEETBAUM	JAMES	WM
TAGAMI	MARIKO	K
TAKEUCHI	ERIKA	
TAN	AH–SWAT	
TAN	YEW	KHUAN
TANG	MISI	
TANNER	DAVID	A
TANNER	JACQUELINE	A
TAUSCH	HENRI	
TEO	AVERY	
THOMSON	MIRIAM	SUSAN
THOMSON	STEPHEN	DAVID
TIMASHEV	ANTON	RATMIROVICH
TOBIN	HANNAH	F
TRESHAM	WILLIAM	R

Last name	First name	Middle name/initials
TROMP–PLAZ	DANIELA	GABRIELA
TROYAN	BORIS	MICHAEL
TURVEY	NICHOLAS	
ULEMAN	PAULUS	A
VALE	DEBORAH	
VERKHOVSKY	ALEXANDER	
VERLINDEN	PIERRE	JACQUES
VIEGAS	RENZO	C
VON SCHWARC	HENRY	MORAVIA
VON TRENTINI	FLORIAN	
WALKER	ANNABELLE	CLAUDINE
WATERS	KARIN	DENISE
WEBER	KAREL	ZDENEK
WHIITEHEAD	ELLIS	WINSTON
WIDMER	HANS	
WIEDERKEHR	STEPHAN	PETER
WITTICH	GUNTER	
WOHLGROTH	LESLIE	SHEILA
WOHLGROTH	LUISA	BARONI
WONG	PETER	K
WOODS	JOHN	PAUL
WRIGHT	JOHN	FRANKLIN
WUTHRICH	BERNHARD	ANDREW
WYATT	GUILLAUME	PASCAL
YAMADA	SETSUKO	
YAMADA	TAKESHI	
YANG	MELODY	
YEUNG	DING	FONG
YEUNG	ERIC	CHUNG–KIT
YEUNG	GERALD	K
YOSHINO	CHIYOKO	O
YOSHINO	MICHAEL	Y
YU	VINCENT	HOK YAN
ZEITZ	LISA	
ZEKRYA	DAOUD	
ZHU	MAIYUIN	PANG
ZULLIGER	MARTIN	A

Dated: January 13th, 2012.

Ann V. Gaudelli,

Manager Team 103, Examinations Operations—Philadelphia Compliance Services.

[FR Doc. 2012–2258 Filed 2–1–12; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, February 22, 2012.

FOR FURTHER INFORMATION CONTACT: Susan Gilbert at 1–(888) 912–1227 or (515) 564–6638.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Wednesday, February 22, 2012, 2 p.m., Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Notification of intent to participate must be made with Susan Gilbert. For more information please contact Ms. Gilbert at 1–(888) 912–1227 or (515) 564- 6638 or write: TAP Office, 210 Walnut Street, Stop 5115, Des Moines, IA 50309 or contact us at the web site: *http://www.improveirs.org.*

The agenda will include various IRS topics.

Dated: January 24, 2012.

Shawn Collins,

Director, Taxpayer Advocacy Panel.

[FR Doc. 2012–2186 Filed 2–1–12; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Amendment of System of Records.

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(e)(4)) requires that all agencies publish in the **Federal Register** a notice of the existence and character of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is amending the system of records entitled ''Alternative Dispute Resolution Tracking System-VA'' (116VA09). The Department is re-publishing the system of records notice in its entirety.

DATES: Comments on this amended system of records must be received no later than March 5, 2012. If no public comment is received, the amended system will become effective March 5, 2012.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand

delivery to the Director, Office of Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4938 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS).

FOR FURTHER INFORMATION CONTACT: Gregory A. Burke, Ombudsman, Office of Resolution Management (08), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–0225.

SUPPLEMENTARY INFORMATION:

The Department established the system of records entitled ''Alternative Dispute Resolution Tracking System-VA'' (116VA09) in 67 FR 49392–49395 (July 30, 2002). The system of records tracked alternative dispute resolution (ADR) activity within VA. VA placed the responsibility for managing the system of records upon the Dispute Resolution Specialist (DRS), then the Chairman of the Department's Board of Contract Appeals (09) (the Chairman). The ''09'' designation within ''116VA09'' reflected the designation of the Chairman (09) within the Department. The Administrative Dispute Resolution Act, as amended, requires the designation by each Federal agency of a senior official to serve as its DRS. Public Law 101–552, Sec. 3(b), 104 Stat. 2737 (1990).

On January 6, 2006, Congress enacted Public Law 109–163. Section 847 of that Act terminated the VA Board of Contract Appeals on January 6, 2007. Consequently, the position of Chairman of the VA Board of Contract Appeals also terminated on January 6, 2007.

In anticipation of the termination of the VA Board of Contract Appeals, on July 14, 2006, the VA's Deputy Secretary approved the reassignment of the DRS function to the Assistant Secretary for Human Resources and Administration. Authority for Workplace ADR was further delegated to the Deputy Assistant Secretary for Resolution Management, also known as Deputy DRS for Workplace ADR (08). In that capacity, the Deputy DRS for Workplace ADR became responsible for the system of records entitled ''Alternative Dispute Resolution Tracking System-VA'' (116VA09), including management, notification, and record access procedures.

The Department intends to modify the system of records entitled ''Alternative Dispute Resolution Tracking System-VA'' (116VA09) to: (1) Rename and renumber the system of records as ''Historical Alternative Dispute Resolution Data-VA'' (116VA08); (2) designate the Deputy DRS Workplace ADR (08) as the system's manager and official responsible for maintaining the system of records; and (3) reflect that the Deputy DRS Workplace ADR (08) will manage the renamed ''Historical Alternative Dispute Resolution Data-VA'' (116VA08) system of records in lieu of the then DRS and Chairman of the VA Board of Contract Appeals (09).

When adopted in 2002, the currently named ''Alternative Dispute Resolution Tracking System-VA'' (116VA09) was the sole method used to collect ADR data VA-wide. VA is establishing a new system of records titled the ''Alternative Dispute Resolution (ADR) Tracking System-ADRTracker-VA'' for collection of ADR data. These two systems of records are separate and incompatible. Although the systems of records contain similar data elements, such data are collected and used for different purposes. VA now uses the ''Alternative Dispute Resolution Tracking System-VA'' (116VA09) for historical reference and reports.

VA has determined to rename the ''Alternative Dispute Resolution (ADR) Tracking System-VA'' (116VA08), the earlier system of tracking ADR data, as the ''Historical Alternative Dispute Resolution Data-VA'' (116VA08) system of records to reflect its primarily historical use and to minimize confusion.

VA is also proposing to amend two routine uses and establish two new routine use disclosures of information maintained in the ''Historical Alternative Dispute Resolution Data-VA'' (116VA08) system of records, as renamed and renumbered:

1. VA is amending use 2 to permit disclosure to the General Services Administration (GSA) in connection with records management inspections conducted under title 44, U.S.C.

2. VA is amending routine use 5 to reflect the limitations of the names and home addresses of Veterans and their dependents contained in 38 U.S.C. 5701(a), which provides that the agency may disclose this information only as permitted by that statute. VA may not promulgate a routine use authorizing disclosure of information that is barred by another confidentiality statute applicable to that information.

3. VA is adding routine use 12 to the system of records to authorize the agency to disclose information to other Federal agencies when they need the information to prevent fraud or abuse of their programs by individuals.

4. In December 2006, Congress enacted the Veterans Benefits, Health Care and Information Technology Act of 2006 (the Act), Public Law 109–461, 120 Stat. 3403. Section 902(b) of the Act also added a new subchapter III, Information Security, to Chapter 57 of title 38, United States Code. Section 5724 requires VA to conduct an independent risk analysis (IRA) when VA has experienced a data breach involving the sensitive personal information of those individuals. The section also requires VA to provide credit protection services to those individuals if VA determines after the IRA that there is a reasonable risk for potential misuse of the individuals' sensitive personal information. In order to conduct the IRA and provide credit protection services, if appropriate, VA will have to disclose the sensitive personal information of these individuals to the entities performing the IRA and providing the credit protection services.

Further, the Office of Management and Budget (OMB) also directed all Federal agencies in OMB Memorandum 07–16 to promulgate routine uses to be able to disclose Privacy Act-protected information where necessary to respond to data breaches. The OMB Memorandum is available at *http://www.whitehouse.gov/omb/memoranda/fy2007/m07-16.pdf.*

VA is adding routine use 13 to the system of records to implement section 5724 of title 38 and to comply with the guidance issued by OMB.

The Privacy Act permits VA to disclose information about individuals without their consent for a routine use when the information will be used for a purpose that is compatible with the purpose for which we collected the information. In all of the routine use disclosures described above, the recipient of the information will use the information in connection with a matter relating to one of VA's programs or will use the information to provide a benefit to VA, or disclosure is required to protect VA records, the subjects of those records, or the integrity of Federal programs. The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Approved: October 21, 2011.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

116VA08

SYSTEM NAME: ''HISTORICAL ALTERNATIVE DISPUTE RESOLUTION DATA-VA''.

SYSTEM LOCATION:

VA stores data from the System of Records at the Capital Region Data Center, 882 T J Jackson Drive, Falling Waters, WV 25419. The originals of related documents are maintained in the Office of the Assistant Secretary for Resolution Management, 810 Vermont Avenue NW., Washington, DC 20420, under lock and key.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information about VA employees and other individuals who have participated in a VA alternative dispute resolution program or dispute resolution.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records may contain information related to the name, grade, and step of the ADR requesters and respondents; the type of ADR requested, *e.g.,* mediation or arbitration; the type of ADR used; the source of the individual(s) conducting the ADR, *e.g.,* another Federal agency; the grades and steps of the individuals conducting the ADR process; administrative data on the particular ADR case, *e.g.,* date requested; date concluded and total hours spent on the ADR; the nature of the dispute, *e.g.,* discrimination or harassment; the stage in the dispute in which ADR is inserted; the jurisdictional forum in which the dispute was located when ADR was requested; any waiver of rights under 29 CFR part 1614; the terms of any settlement agreement, *e.g.,* damages, attorneys fees, reassignment; and the satisfaction of the parties with the ADR process and the source of the neutral third party who conducted the procedure, *e.g.,* the facility's program, a local shared neutral's program, the national program, or a private, non governmental program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 5, United States Code, sections 571–584; Federal Acquisition Regulation; Part 33, Protests, Disputes, and Appeals and/or VA Acquisition Regulation, Part 833, Protests, Disputes, and Appeals; and Title 29, Code of Federal Regulations, Part 1614.

PURPOSE(S):

VA will use the information to track and monitor agency dispute resolution activities at the local level. VA also intends to analyze the data to evaluate ADR utilization VA-wide, identify agency ADR best practices, and determine whether certain forms of ADR may be more appropriate in various types of cases.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

2. VA may disclose information from this system to the National Archives and Records Administration (NARA) and General Services Administration (GSA) in records management inspections conducted under the authority of title 44, U.S.C.

3. Records from this system of records may be disclosed to the Department of Justice (DOJ) or in a proceeding before a court, adjudicative body, or other administrative body before which the agency is authorized to appear when: (1) The agency, or any component thereof; (2) any employee of the agency in his or her official capacity, where DOJ or the agency has agreed to represent the employee; or (3) the United States, when the agency determines that litigation is likely to affect the agency or any of its components; is a party to litigation, and has an interest in such litigation, and the use of such records by DOJ or the agency is deemed by the agency to be relevant and necessary to the litigation, provided, however, that the disclosure is compatible with the purpose for which the records were collected.

4. Disclosure of relevant information may be made to individuals, organizations, private or public agencies, or other entities with whom VA has a contract or agreement or where there is a subcontract to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

5. VA may disclose on its own initiative any information in this system, except the names and home addresses of Veterans and their dependents, that is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal, or regulatory in nature and whether arising by general or program statute or by regulation, rule, or order issued pursuant thereto, to a Federal, State, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule, or order. VA may also disclose on its own initiative the names and home addresses of Veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal, or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, or order issued pursuant thereto.

6. Disclosure may be made to an appeal, grievance, hearing, or complaints examiner; an equal employment opportunity investigator, arbitrator, or mediator; and an exclusive representative or other person authorized to investigate or settle a grievance, complaint, or appeal filed by an individual who is the subject of the record.

7. Disclosure may be made to the Office of Personnel Management (OPM), the Office of Management and Budget (OMB), and the Government Accountability Office (GAO) in order for them to perform their responsibilities for evaluating Federal programs.

8. Information may be disclosed to officials of labor organizations recognized under 5 U.S.C. chapter 71, when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting working conditions.

9. Information may be disclosed to officials of the Merit Systems Protection Board or the Office of the Special Counsel when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions, promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

10. Information may be disclosed to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or for other functions of the Commission as authorized by law.

11. Information may be disclosed to the Federal Labor Relations Authority (including its General Counsel) when appropriate jurisdiction has been established and the information has been requested in connection with the investigation and resolution of allegations of unfair labor practices or in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; and

to the Federal Service Impasses Panel in matters they are considering.

12. VA may, on its own initiative, disclose information to other Federal agencies to assist them in preventing and detecting possible fraud or abuse by individuals in their operations or programs.

13. VA may, on its own initiative, disclose any information or records to appropriate agencies, entities, or persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise, there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by the Department to respond to a suspected or confirmed data breach, including the conduct of any risk analysis or provision of credit protect services as provided in 38 U.S.C. 5724 as the terms are defined in 38 U.S.C. 5727.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on the VA's Office of Resolution Management Web Server System in the Citizens Disaster Response Center (CDRC) in Falling Waters, West Virginia.

RETRIEVABILITY:

Records are retrieved by employee name, VA ADR case number, VA EEO case number, or VA facility number of the parties who participate in the VA ADR process.

SAFEGUARDS:

Access to and use of these records is limited to those persons whose official duties require such access. Access to the VA Historical Alternative Dispute Resolution Data system of records is controlled by using an individually unique user identification code. Physical access to the facility where the ''VA Historical Alternative Dispute Resolution Data'' is maintained and controlled at all hours by the Federal Protective Service, VA, or other security personnel and security access control devices. Public use files prepared for purposes of research and analysis are purged of personal identifiers.

RETENTION AND DISPOSAL:

Records are maintained during the employee participant's for a period of 20 calendar years and subsequently disposed of in accordance with records disposition authority processes established by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESS:

Official responsible for policies and procedures: Deputy Assistant Secretary for Resolution Management, also known as the Deputy Dispute Resolution Specialist for Workplace ADR (08), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

NOTIFICATION PROCEDURE:

Individuals who wish to determine whether this system of records contains information about them should address written inquiries to Deputy Dispute Resolution Specialist for Workplace ADR (08), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. Inquiries should include: (1) The individual's name and address; (2) VA ADR or EEO case number, if known; and VA facility or facility number where the individual was employed or applied for employment.

RECORD ACCESS PROCEDURE:

Individuals seeking information regarding access to and contesting of records in this system may write the Deputy Dispute Resolution Specialist for Workplace ADR (08), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

CONTESTING RECORD PROCEDURES:

(See Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by employees who serve as local ADR program coordinators who obtain information from the ADR program participants.

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicaid Program; Covered Outpatient Drugs; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2345–P]

RIN 0938–AQ41

Medicaid Program; Covered Outpatient Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act). This proposed rule would also revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program. Therefore, we are proposing to amend 42 CFR part 447, subpart I to implement specific provisions of the Affordable Care Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 2, 2012.

ADDRESSES: In commenting, please refer to file code CMS–2345–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–2345–P, P.O. Box 8016, Baltimore, MD 21244–8016.

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–2345–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 must 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. The comments delivered must also be stamped in to verify timeliness of submission.)

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 if received after the comment period closes may not be considered.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Angel Davis, (410) 786–4693, and Meagan Khau, (410) 786–1357, for issues related to rebates for line extensions.

Lisa Ferrandi, (410) 786–5445, for issues related to the Collection of Information Requirements.

Joseph Fine, (410) 786–2128, for issues related to the determination of Best Price, definition of covered outpatient drug and rebates for drugs dispensed by Medicaid managed care organizations.

Christine Hinds, (410) 786–4578, Kimberly Howell, (410) 786–6762, Terry Simananda, (410) 786–8144, or Wendy Tuttle, (410) 786–8690, for issues related to the determination of Average Manufacturer Price (AMP).

Meagan Khau, (410) 786–1357, for issues related to the offset of rebates.

Madlyn Kruh, (410) 786–3239, for issues related to authorized generics, nominal price, investigational drugs, and the coverage of tobacco cessation drugs under the Medicaid State Plan.

Bernadette Leeds, (410) 786–9463, for issues related to drug rebates.

Gail Sexton, (410) 786–4583, for issues related to Federal upper limits.

Marge Watchorn, (410) 786–4361, for issues related to the Regulatory Impact Analysis.

Wendy Tuttle, (410) 786–8690, for all other inquiries.

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

A. Introduction

Under the Medicaid program, States may provide coverage of outpatient drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for Federal financial participation (FFP) in State expenditures for these drugs. In general, in order for payment to be made available under section 1903 for covered outpatient drugs, manufacturers must enter into a Medicaid drug rebate agreement as set forth in section 1927(a)

of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for States for covered outpatient drugs.

This proposed rule would implement changes to section 1927 of the Act made by sections 2501, 2503, and 3301(d)(2) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), and sections 1101(c) and 1206 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152, enacted on March 30, 2010), (collectively known as the Affordable Care Act). It would also implement changes to section 1927 of the Act as set forth in section 202 of Pub. L. 111–226, enacted on August 10, 2010 (referred to as the Education Jobs and Medicaid Funding Act). This proposed rule would implement other miscellaneous provisions pertaining to covered outpatient drugs. It would implement changes to section 1927 of the Act as set forth in section 221 of Division F, Title II, of the Omnibus Appropriations Act, 2009, (Pub. L. 111–8, enacted on March 11, 2009). It would also codify other requirements in section 1927 of the Act pertaining to the Medicaid drug rebate (MDR) program and revise certain regulatory provisions presently codified at 42 CFR part 447, subpart I and make other changes concerning rebate requirements. As discussed below, these proposed revisions are consistent with the Secretary's authority set forth in section 1102 of the Act to publish regulations that are necessary to the efficient administration of the Medicaid program.

B. Changes Made by the Affordable Care Act

Section 2501(a) of the Affordable Care Act amended section 1927(c) of the Act by increasing the minimum rebate percentage for most single source and innovator multiple source drugs from 15.1 percent of the average manufacturer price (AMP) to 23.1 percent of AMP. Section 2501(a) of the Affordable Care Act also amended section 1927(c) of the Act by establishing a minimum rebate percentage of 17.1 percent of AMP for certain single source and innovator multiple source clotting factors and single source and innovator multiple source drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications. Section 2501(a) of the Affordable Care Act also added section 1927(b)(1)(C) to the Act to make changes to the non-Federal share of rebates by specifying that the amounts attributable to the increased rebate percentages be remitted to the Federal government. The amendments made by section 2501(a) of the Affordable Care Act were effective January 1, 2010.

Section 2501(b) of the Affordable Care Act amended section 1927(c) of the Act by increasing the rebate percentage for noninnovator multiple source drugs from 11 percent of AMP to 13 percent of AMP, effective January 1, 2010.

Section 2501(c) of the Affordable Care Act amended section 1903(m) of the Act by specifying new conditions for managed care organization (MCO) contracts, including that covered outpatient drugs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act. The Affordable Care Act also amended section 1903(m) of the Act to establish that MCO capitation rates shall be based on actual cost experience related to rebates and subject to Federal regulations at § 438.6 regarding actuarial soundness of capitation payments. The legislation also provided that MCOs are responsible for reporting to the State certain utilization data and such other data as the Secretary determines necessary for the State to access the rebates authorized by this provision.

Section 2501(c) of the Affordable Care Act also made conforming amendments to section 1927(b) of the Act by requiring manufacturers that participate in the MDR program to provide rebates for drugs dispensed to individuals enrolled with a MCO, if the MCO is responsible for coverage of such drugs. It also amended section 1927(b) of the Act by requiring States to include information on drugs paid for by Medicaid MCOs under the State plan during the rebate period when requesting rebates from manufacturers. Finally, section 2501(c) modified section 1927(j)(1) of the Act to specify that covered outpatient drugs are not subject to the rebate requirements if such drugs are both subject to discounts under section 340B of the Public Health Service Act (PHSA) and dispensed by health maintenance organizations (HMOs), including Medicaid MCOs. The amendments made by section 2501(c) were effective March 23, 2010.

Section 2501(d) of the Affordable Care Act, as revised by section 1206(a) of HCERA, added a new subparagraph (C) to section 1927(c)(2) of the Act, effective for drugs paid for by a State on or after January 1, 2010. This provision modifies the unit rebate amount (URA) calculation for a drug that is a line extension (new formulation) of a single source or innovator multiple source drug that is an oral solid dosage form.

Section 2501(e) of the Affordable Care Act amended section 1927(c)(2) of the Act by adding a new subparagraph (D) and establishing a maximum on the total rebate amount for each single source or innovator multiple source drug at 100 percent of AMP, effective January 1, 2010.

Section 2501(f) of the Affordable Care Act made conforming amendments to section 340B of the Public Health Service Act, which are not addressed in this proposed rule.

Section 2503(a) of the Affordable Care Act amended section 1927(e) of the Act by revising the Federal upper reimbursement limit to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Additionally, it specifies that the Secretary shall implement a smoothing process for AMP which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological under Medicare Part B. It amended section 1927(k) of the Act by revising the definition of AMP to mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

It also amended the definition of multiple source drug to specify, in part, that a covered outpatient drug qualifies as a multiple source drug if at least one other therapeutically equivalent drug product is sold or marketed in the United States, as opposed to in a State, during the rebate period. It added to section 1927(k) of the Act definitions of retail community pharmacy and wholesaler for purposes of section 1927 of the Act.

Section 2503(b) of the Affordable Care Act amended section 1927(b) of the Act by establishing a requirement that manufacturers report, not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly AMP for each covered outpatient drug. It also amended the preexisting requirement that the Secretary disclose

AMPs to instead require the Secretary to post, on a Web site accessible to the public, the weighted average of the most recently reported monthly AMPs and the average retail survey price determined for each multiple source drug in accordance with section 1927(f) of the Act.

Section 2503(c) of the Affordable Care Act amended section 1927(f) of the Act by clarifying that the survey of retail prices described in such subsection applies to retail community pharmacies.

Section 2503(d) of the Affordable Care Act specified that the amendments made by section 2503 of the Affordable Care Act were effective October 1, 2010. Section 2503(d) of the Affordable Care Act further specified that the amendments made by section 2503 shall take effect without regard to whether final regulations to carry out such amendments have been issued by October 1, 2010.

Section 3301(d)(2) of the Affordable Care Act included a conforming amendment to the definition of ''best price'' under Medicaid at section 1927(c)(1)(C) of the Act. This amendment provides that any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act are exempt from a manufacturer's best price calculation, effective for drugs dispensed on or after July 1, 2010.

Section 7101(a) of the Affordable Care Act expanded the drug discount program under section 340B of the Public Health Service Act (PHSA) to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals.

Section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) revised section 340B of the PHSA by removing children's hospitals from the orphan drug exclusion described in section 2302 of HCERA.

Section 1101(c) of HCERA also includes a conforming amendment to the definition of AMP under Medicaid at section 1927(k) of the Act by providing that discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act are excluded from a manufacturer's determination of AMP, effective March 30, 2010.

C. Final Rule With Comment Period Published July 17, 2007

On July 17, 2007, CMS published a final rule with comment period in the **Federal Register** (72 FR 39142). The purpose of the final rule with comment period was to finalize the provisions of the proposed rule CMS published in the **Federal Register** on December 22, 2006 (71 FR 77174) and to allow for further public comment on the AMP and Federal upper limit (FUL) outlier sections of the final rule. We received a variety of comments from drug manufacturers, membership organizations, wholesalers, law firms, PBMs, consulting firms and pharmacists in support of, and raising concerns with, the AMP and FUL provisions. However, we note that these regulatory provisions were withdrawn through the final rule published in the November 15, 2010 **Federal Register** (75 FR 69591). Accordingly, we will not be considering the comments received on the July 17, 2007, rule in this rulemaking document. Further, because the Affordable Care Act made substantial changes to the AMP and FUL provisions in section 1927 of the Act, we no longer expect to publish that final rule and we do not expect to address those comments in subsequent rulemaking.

D. Other Changes Concerning the Medicaid Drug Rebate Program

We are also proposing changes to address other program issues related to covered outpatient drugs, including key aspects of Medicaid payment and the MDR program, such as reimbursement to pharmacies for the ingredient cost of a drug, determination of AMP for authorized generic drugs, and the inclusion of territories in the MDR program. These changes are described in greater detail below under section II. Provisions of the Proposed Regulations.

II. Provisions of the Proposed Regulations

This proposed rule would revise regulations concerning the MDR program, set forth at section 1927 of the Act. It implements, consistent with our general rulemaking authority, sections 2501, 2503, and 3301(d)(2) of the Affordable Care Act and sections 1101(c) and 1206 of HCERA, which revise requirements concerning the rebate program and payments for prescription drugs under the Medicaid program. The specific provisions we propose are described in detail below.

A. Basis and Purpose (§ 447.500)

Section 2501(c) of the Affordable Care Act established new requirements for manufacturers that participate in the MDR program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs. We propose to add § 447.500(a)(4) which would specify sections 1903(m)(2)(A)(xiii) and 1927(b) of the Act as the basis for rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid MCOs. We propose to add § 447.500(a)(5) which would add section 1902(a)(30)(A) as an additional basis for calculating payments for covered outpatient drugs.

B. Definitions (§ 447.502)

1. Actual Acquisition Cost

States generally reimburse pharmacies for covered outpatient drugs that are prescribed and dispensed to Medicaid beneficiaries based on a two-part formula, which addresses the ingredient cost of a drug and a reasonable dispensing fee. Each State has the flexibility to determine the amount it will reimburse for each component of the formula based on the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular drug labeler and the cost associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. These reimbursement formulas are subject to review and approval by CMS through the State plan amendment (SPA) process.

In general, States currently reimburse for the covered outpatient drug based, in part, on the estimated acquisition cost (EAC). The EAC, as currently defined in Federal regulations at § 447.502 is the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. We are proposing to both rename and revise this definition in this proposed rule.

Section 1902(a)(30)(A) of the Act requires, in part, that States have methods and procedures to assure that payment for Medicaid care and services is consistent with efficiency, economy, and quality of care. In accordance with these provisions and in light of the OIG reports concerning published prices (OIG Audit reports—A–06–00–00023, A–06–01–00053, A–06–02–00041),[1] we believe it is necessary for States to have a more accurate reference price to base reimbursement for prescription drugs. Therefore, we propose to replace the term, ''estimated acquisition cost'' with ''actual acquisition cost'' (AAC). We believe that changing this definition for

[1] *http://oig.hhs.gov/oas/reports/region6/60000023.htm; http://oig.hhs.gov/oas/reports/region6/60100053.htm; http://oig.hhs.gov/oas/reports/region6/60200041.htm.*

the drug ingredient component of the reimbursement formula to AAC will be more reflective of actual prices paid, as opposed to estimates based on unreliable published compendia pricing. While we recognize that States may not be able to determine the actual price of each individual drug, payment based on an average of the actual acquisition costs from a number of representative pharmacies would still fit within this definition, as data used in the calculation of the average acquisition cost would be reflective of actual purchase prices for pharmacy providers. Within this framework, States can develop payment methodologies consistent with this regulatory definition for their Medicaid pharmacy reimbursement. Therefore, in § 447.502, we propose to define actual acquisition cost as the agency's determination of the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. This issue and its possible effects on ingredient cost reimbursement is discussed further in both § 447.512 Drugs: Aggregate upper limits of payment and § 447.518 State plan requirements, findings, and assurances.

2. Authorized Generic Drug

The definition of ''authorized generic drug'', presently set forth in § 447.506(a), applies to rebate calculations, as set forth in subpart I ''Payment for Drugs.'' Therefore, we propose to remove the definition of ''Authorized generic drug'' from § 447.506 and move this definition to § 447.502. We would continue to define the term ''Authorized generics drugs'' as any drug sold, licensed or marketed under an NDA approved by the FDA under section 505(c) of the Federal Food Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed brand drug.

For purposes of the MDR Program, an authorized generic is any drug product marketed under the innovator or brand manufacturer's New Drug Application (NDA) approved under section 505(c) of the FFDCA, but labeled with a different NDC than the innovator or brand product. Authorized generics are categorized as innovator multiple source drugs for the purpose of computing the drug rebate.

3. Bona Fide Service Fee

In the July 17, 2007 AMP final rule, we defined bona fide service fees as fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The Affordable Care Act specifies that the AMP shall exclude bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies including, but not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs). In § 447.502, we propose to revise our current definition of bona fide service fees to include these fees paid by manufacturers to wholesalers or retail community pharmacies.

4. Bundled Sales

In the AMP final rule published on July 17, 2007, bundled sale was defined as an arrangement, regardless of physical packaging, under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs in the bundle. In response to manufacturer questions regarding whether a discount and resulting price for each product in a single customer contract that is independent and not contingent on the discount or pricing of any other product in the contract should be applied across all products; we stated previously that where a discount or price concession is established independently and not conditioned upon any other purchase or performance requirement (for example the achievement of market share, inclusion or tier placement on a formulary), or where the discount is not greater than if purchased outside of multi-product arrangement, there is no bundle within the meaning described in § 447.502. Though this is not addressed in the Affordable Care Act, we continue to agree with our response to this issue and thus have decided to include it in this discussion in order to further clarify the bundled sale definition. Therefore, we propose to add the following clarifying statement to the definition of bundled sale: The discounts in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.

5. Clotting Factor

The Affordable Care Act established a minimum rebate percentage of 17.1 percent of AMP for a single source drug or an innovator multiple source drug that is a clotting factor for which a separate furnishing payment is authorized under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. Consistent with these provisions, we propose to define clotting factors as those drugs or products for which a separate furnishing payment is authorized under section 1842(o)(5) of the Act and which are included on a list of such factors specified and updated quarterly by CMS.

6. Covered Outpatient Drug

In accordance with section 1927 of the Act, manufacturers that have entered into a Rebate Agreement with the Secretary are responsible for paying rebates to States for their covered outpatient drugs for which payment has been made under the state plan. Manufacturers are responsible for submitting required drug product data, including each drug's NDC. This NDC information is placed on the MDR file and used for assuring compliance with the statutory requirements.

There have been products identified in the drug product data file that do not meet the definition of a covered outpatient drug. Therefore, we believe it is necessary to provide clarification regarding the definition of a covered outpatient drug in section 1927(k)(2) of the Act and the limiting definition at section 1927(k)(3) of the Act. Accordingly, we propose to add a definition of covered outpatient drug to § 447.502.

We propose that a drug is considered a covered outpatient drug when the drug may be dispensed only upon prescription (except as discussed below with respect to certain non-prescription drugs), and it meets the following criteria as described in section 1927(k)(2) of the Act:

- The drug has been approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA where the manufacturer has obtained a NDA or under section 505(j) of the FFDCA where the manufacturer has obtained an Abbreviated New Drug Application (ANDA);
- The drug was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962, or is identical, similar or related (within the meaning of section 310.6(b)(1) of title 21 of the CFR) to such a drug; and has not been the subject of a final determination by the Secretary that it is a ''new drug'' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act;
- The drug is one which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related to such a drug and for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended or suggested in its labeling;
- The drug is a biologic product, other than a vaccine which—

(1) May only be dispensed upon prescription,

(2) Is licensed under section 351 of the Public Health Service Act, and

(3) Is produced at an establishment licensed under such section to produce such product; or

- The drug is insulin certified under section 506 of the FFDCA.

Consistent with section 1927(k)(3) of the Act, we propose that, except as discussed below, a drug, biological product, or insulin would not be considered a covered outpatient drug when that drug or product is billed as a bundled service with, and provided as part of or incident to and in the same setting as, any of the following services:

- Inpatient Hospital Services;
- Hospice Services;
- Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
- Physician services;
- Outpatient hospital services;
- Nursing facility and services provided by an intermediate care facility for the mentally retarded;
- Other laboratory and x-ray services; or
- Renal dialysis.

We further propose that the above exemptions to the definition of covered outpatient drug for combined services would not apply if the drug is carved out and billed separately from the service (for example, an infusion drug and x-ray are billed separately, not as a composite radiology service; therefore, the infusion drug is a covered outpatient drug).

Additionally, section 1927(k)(3) of the Act provides that the definition of covered outpatient drug does not include any such drug or product for which a NDC number is not required by the FDA or a drug or biological used for a medical indication which is not a medically accepted indication. We note that for the purposes of the MDR we use an NDC format at either the NDC–9, which includes the labeler code and product code, to identify the product information, or the NDC–11, which includes the labeler code, product code, and the package code, to identify the product's package information. We are aware that FDA has a slightly different NDC format than what is used in the MDR program. (Please see the discussion under the definition of NDC.) For the purpose of the MDR program, we will continue to use the current NDC format of NDC–9, which includes the labeler code and the product code, to identify the product information and NDC–11, which includes the labeler code, product code, and package code, to identify the product's package information. However, if there is change to the current NDC format as a result of FDA action, then we will issue guidance, as necessary, to notify the public as well as to explain its impact on the MDR program.

We are not involved with and do not have oversight for the designation of the NDC. The FDA requires NDCs for drugs that must be listed with the FDA in accordance with Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85). (21 CFR 207.25(b)(8)). The FDAAA amended section 510(p) of the FFDCA (21 U.S.C 360) to explicitly require that registration and listing information (including the submission of updated information) required under section 510 of the FFDCA, which includes information from both domestic and foreign establishments, be submitted by electronic means, unless the Secretary of Health and Human Services grants a request for waiver of this requirement because use of electronic means is not reasonable for the person requesting the waiver.

Section 1927(k)(3) of the Act provides that a covered outpatient drug does not include any such drug or product for which an NDC number is not required by the FDA. However, in accordance with section 1927(k)(2), and the requirements of section 510 of the FFDCA, we propose that a drug, whether prescription or over-the-counter (OTC), would only be treated as a covered outpatient drug if the drug is both required to have an NDC and is listed electronically with the FDA. We believe this additional standard is needed to ensure compliance with the prescribed drug provisions, FDA approval provisions, and the NDC listing provisions. Furthermore, this proposal is necessary in order for us to assure compliance with the drug rebate submission requirements, for CMS to verify State utilization data and manufacturer product data, and to assure the correct calculation of the offset amounts mandated by the Affordable Care Act. Additionally, this proposal aligns with a proposal submitted as part of the fiscal year (FY) 2012 President's Budget to require drugs to be properly listed electronically with the FDA as a requirement to be covered under Medicaid.

Therefore, if a manufacturer is required to list all of its NDCs electronically with the FDA, this would ensure that all the products in the MDR program meet the definition of section 1927(k)(3) of the Act. In addition, it would permit us to verify State and manufacturer submissions by referencing the FDA's electronic drug listing information.

Manufacturers are required to update their registration and listing information electronically in accordance with FDA's current registration and listing requirements.

Additionally, in order for us to fully implement these provisions, we are requiring that manufacturers submit any relevant approved FDA application numbers. When a product is listed with the FDA, the manufacturer is required to provide to the FDA the NDC and the application number, if any, for the product (21 CFR 207.25(b)). An

application number will help CMS find information on the approval status to market a drug. See *http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.* The application number assists CMS in obtaining information from FDA as to whether a drug has been approved under a NDA under section 505 of FFDCA or an ANDA under section 505(j) of FFDCA. This information is critical to the definition of a covered outpatient drug under section 1927(k)(2) of the Act. Under the MDR program reporting requirements, drug manufacturers are required to report to CMS a drug category for each NDC. The drug category represents whether an NDC is classified as a brand name drug (single source drug (S) or innovator multiple source drug (I)) or a generic drug (noninnovator multiple source drug (N)). We use these drug category indications to determine the appropriate rebate percentage to calculate the unit rebate amounts, as well as the offset amounts under the Affordable Care Act.

We are also aware that some products that do not have an approved application number may be covered outpatient drugs. For example, we believe that certain products, such as prenatal prescription vitamins, potassium chloride, codeine sulfate, and hydrocortisone acetate may fall into this category. If a product does not have an FDA application number, in order to be considered a covered outpatient drug, the manufacturer must provide evidence demonstrating that its products meet the statutory definition of a covered outpatient drug under section 1927(k)(2) to 1927(k)(4). We will refer to this evidence of demonstration as covered outpatient drug status, or COD status. We are seeking public comments on this requirement, and in particular, comments identifying drugs or classes of drugs that do not have approved applications but should be deemed covered outpatient drugs.

This submission of data would provide critical information needed to calculate and verify the accuracy of such drug information.

Therefore, we propose that manufacturers report to CMS the number of an approved FDA application for a product or otherwise show that the product meets the statutory definition of a covered outpatient drug under sections 1927(k)(2) and (3) of the Act, in order for CMS to calculate the offset amounts and validate product data to ensure the correct rebate calculation for each NDC in the MDR Program. By having a correct approved FDA application number or the COD status, CMS can more accurately determine the unit rebate amounts and product classification, critical to the rebate percentage calculation.

7. Customary Prompt Pay Discounts

In § 447.502, we propose to add a definition of customary prompt pay discount to ensure consistent application of such discounts among manufacturers when calculating AMP. Therefore, we propose to define customary prompt pay discounts as any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a timeframe that is consistent with its customary business practices for payment.

8. Innovator Multiple Source Drug

As currently defined in § 447.502, an innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). In this rule, we propose to add multiple source drugs originally marketed under a BLA as the BLA approval process is a successor to the PLA and ELA and drugs sold under a BLA are explicitly referenced in the definition of single source drug. To ensure that the correct drug category is reported for an innovator multiple source drug, as was discussed in Manufacturer Release #82, we wish to remind manufacturers, as is consistent with current policy, that an innovator multiple source (I) drug should be reported to CMS for a brand name drug that has therapeutic equivalents available. To determine if therapeutic equivalents are available for a brand name drug or not, you can access the FDA's Drugs@FDA at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Addlsearch_drug_name* and search by the Application Number. If therapeutic equivalents are available, then you will see the link to ''Therapeutic Equivalents'' in the ''Drugs Details'' page. If there are therapeutic equivalents available for the NDA or BLA, then the brand name drug should be reported as an innovator multiple source drug (I) to CMS.

Additionally, over the course of the MDR program, questions have arisen regarding whether an ''original NDA'' is the same as an NDA and whether the drug category may be different if a drug is approved under an NDA. We are proposing to clarify that, for purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness. In light of this definition, we are also proposing to use the term ''NDA'' when addressing such application types for brand name drugs and not use the term ''original NDA'' when referring to such drugs throughout this proposed rule.

9. Line Extension Drug (New Formulation)

The Affordable Care Act established a separate calculation for the unit rebate amount for a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. Section 1927(c)(2)(C) of the Act, added by section 2501(d) of the Affordable Care Act, defines line extension to mean a new formulation of a drug, such as an extended release formulation. We propose to define line extension as a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA, listed in Drugs@FDA *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/application* file, as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, a new salt or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug. We propose that regardless of whether the drug is approved under an NDA or a supplemental NDA, if the change to the drug is assigned to one of the above changes, it will be considered a line extension drug.

These modifications to the initial brand name listed drug are often approved under section 505(b)(2) of the FFDCA. A section 505(b)(2) application is a new drug application submitted under section 505(b)(1) and approved under section 505(c) of the FFDCA. A section 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant to show whether a drug is safe and effective were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(b)(2), as described in FDA

regulations at 21 CFR 314.54, may be used in certain circumstances to seek approval of a drug product that represents a modification to a listed drug product. Examples of drugs that have been approved under the 505(b)(2) application include drugs with a new formulation, dosing regimen, change in active ingredient (such as a different salt or ester, combination product), and/or new drug indication. These types of drugs are assigned a Chemical Type by the FDA for the new drug application. A section 505(b)(2) application may be granted 3 years of exclusivity, may be eligible for orphan drug exclusivity or pediatric exclusivity. We have included these changes within our definition of line extension drugs. (See G.2. Treatment of New Formulations for further explanation of CMS' proposal.)

10. Manufacturer

For purposes of the MDR Program, we propose to clarify our current definition of manufacturer by revising it to state that a ''manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product''. This change in terminology is not intended change the scope of the definition.

11. Multiple Source Drug

On November 15, 2010, we published the ''Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'' final rule in the **Federal Register** (75 FR 69591). That final rule withdrew the regulatory definition of multiple source drug. As previously noted, section 2503(a)(3) of the Affordable Care Act amended the definition of multiple source drug set forth in section 1927(k)(7) of the Act.

Therefore, in accordance with section 1927(k)(7) of the Act, as revised, we propose to define multiple source drug in § 447.502 as a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, we will use the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is currently available at *http://www.fda.gov/cder/orange/default.htm* or which can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, Rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

12. National Drug Code

The Drug Listing Act of 1972 requires each registered drug establishment to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. (See section 510 of the FFDCA (21 U.S.C. 360)). Drug products are identified and listed with FDA using a unique identifier called the National Drug Code (NDC). Under FDA regulations in 21 CFR part 207, the NDC is identified as a 10-digit, 3-segment number. The first segment, the labeler code, is assigned by the FDA. A labeler is a firm that manufactures the drug, including a repacker or relabeler, or a firm that distributes the drug under its own trade name or label. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies the trade package size and type. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4–4–2, 5–3–2, or 5–4–1.

In this proposed rule, we clarify that even though FDA currently uses a unique 10-digit NDC, for the purposes of the MDR program and this subpart we will continue to use an NDC format with the NDC–9, which includes the labeler code and the product code, to identify the product information and the NDC–11, which includes the labeler code, product code, and package code, to identify the product's package information. Manufacturers may include a leading zero in the product code or the package code segments of the NDC in order to arrive at the 5–4 NDC–9 or 5–4–2 NDC–11 when reporting their product to the MDR program.

13. Noninnovator Multiple Source Drug

As currently defined in § 447.502, a noninnovator multiple source drug means: (1) A multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA (ANDA) or an abbreviated antibiotic drug application, and (3) a drug that entered the market before 1962 that was not originally marketed under an NDA.

In addition to a noninnovator multiple source drug as described, currently, there are other drugs on the market that have not gone through the FDA approval process, including but not limited to certain prescription pre-natal vitamins.

Therefore, we propose to amend the definition of a noninnovator multiple source drug to also include these other drugs that have not gone through FDA approval process but otherwise meet the definition of ''covered outpatient drug''. However, if any of the drug products listed in this amended definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product's drug category to correlate with the new product application type and furnish the appropriate information.

We also propose to amend the definition of noninnovator multiple source drug to clarify that for purposes of Medicaid payment and rebate calculations, the term shall include noninnovator drugs that are not therapeutically equivalent.

14. Oral Solid Dosage Form

CMS proposes to interpret oral solid dosage form in accordance to the FDA regulation at 21 CFR 206.3, which defines solid oral dosage form to mean capsules, tablets, or similar drug products intended for oral use. We also clarify that although FDA regulations at 21 CFR 206.3 uses the term ''solid oral dosage form,'' section 1927(c)(2)(C) specifically used the term ''oral solid dosage form'' in reference to the treatment of new formulations. Therefore, CMS will treat the term ''oral solid dosage form'' to mean the same as FDA's ''solid oral dosage form.''

CMS proposes to further interpret an oral route of administration as any drug that is intended to be taken by mouth. In accordance with these provisions, CMS is providing manufacturers with guidance in order to assist them in determining which drugs should be considered as oral solid dosage forms (please see Table 1). This list will be updated based on any changes to the FDA's definition of solid dosage forms.

TABLE 1—LIST OF ORAL SOLID DOSAGE FORMS

Bar, Chewable	Capsule
Capsule (Immediate/Complete Release) (Hard Or Soft Gelatin, Chewable Or Perle)	Capsule, Coated
Capsule, Coated (Hard Or Soft Gelatin)	Capsule, Coated Pellets
Capsule, Coated, Extended Release	Capsule, Delayed Action (Hard Or Gelatin, Coated, Enteric Coated)
Capsule, Delayed Release Pellets	Capsule, Enteric Coated Pellets
Capsule, Extended Release	Capsule, Film Coated (Hard Gelatin)
Capsule, Film Coated, Extended Release	Capsule, Gelatin Coated
Capsule, Hard Gelatin	Capsule, Liquid Filled
Capsule, Repeat Action	Capsule, Soft Gelatin
Capsule, Soft Gelatin Liquid-Filled	Capsule, Sustained Action (Hard Or Soft Gelatin, Coated, Film Coated)
Dispersible Tablet	
Granule, Delayed Release	Granule, Enteric Coated
Gum (Chewing, Medicated)	Lollipop
Lozenge	Pellet, Coated, Extended Release
Tablet	Tablet (Immediate/Complete Release) (Coated, Film Coated, Sugar Coated, Multilayer, Uncoated, Buccal, Chewable)
Tablet, Chewable	Tablet, Coated
Tablet, Coated Particles	Tablet, Controlled Release
Tablet, Delayed Action (Coated, Enteric Coated)	Tablet, Delayed Release
Tablet, Delayed Release Particles	Tablet, Dispersible
Tablet, Enteric Coated Particles	Tablet, Extended Release
Tablet, Film Coated	Tablet, Film Coated, Extended Release
Tablet, Multilayer (Coated, Film Coated)	Tablet, Multilayer, Extended Release
Tablet, Orally Disintegrating, Delayed Release	Tablet, Orally Disintegrating
Tablet, Repeat Action (Coated)	Tablet, Soluble
Tablet, Sugar Coated	Tablet, Sustained Action (Coated, Film Coated, Multilayer, Uncoated)
Tablet, Sustained Release, Film Coated	Tablet, Uncoated, Lozenge
Tablet, Uncoated, Lozenge, Lypophilized	Tablet, Uncoated, Troche
Tablet, Sustained Action, Membrane Controlled	Pastille
Troche/Lozenge	Wafer

CMS would not consider the following as oral solid dosage forms because these dosage forms are intended to be made into a liquid or suspension prior to oral consumption.

TABLE 2—LIST OF OTHER DOSAGE FORMS

Capsule, for Micro-emulsion	Granule, Effer-vescent, for Solu-tion
Granule Effervescent	Tablet, Effervescent
Granule, Effer-vescent, for Solu-tion	Tablet, for Solution
Granule Effervescent, for Suspension	Tablet Effervescent for Solution
Granule, for Oral Sus-pension	Tablet, for Suspen-sion

15. Over-the-Counter (OTC) Drug

With the exception of certain tobacco cessation drugs for pregnant women, or an EPSDT service, section 1927(d)(2) of the Act currently allows States to exclude from coverage or otherwise restrict coverage of OTC drugs. We propose to add a definition of OTC drugs in order to clarify which products would be treated as OTC drugs in the Medicaid program. This definition is consistent with our current policy and would not change how these drugs are treated for purposes of coverage under the Medicaid program. We propose to define OTC drugs as drugs that are appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription, although for Medicaid coverage a prescription continues to be required. OTC drugs may be marketed under an approved premarket application (NDA or ANDA) or in many cases, may be marketed under an OTC monograph. In some instances, FDA permits these drugs to be marketed under a monograph that is not yet final (such as where there is an OTC tentative final monograph), as stated in 21 CFR part 330 and FDA guidance. Unlike NDAs which are based on premarket approval of specific, finished drug products, monographs specify the active ingredients, indications, dosages, and claims that can be made by the OTC drug products.

16. Pediatric Indications

The Affordable Care Act established a minimum rebate percentage of 17.1 percent of AMP for single source and innovator multiple source drugs approved by the FDA exclusively for pediatric indications. To implement this requirement, we propose to clarify which drugs will be subject to this minimum rebate percentage. In regulations at 21 CFR 201.57 and 21 CFR 201.80, the FDA defines pediatric use for most drug labeling to mean use for pediatric populations and pediatric patients, that is, ''the pediatric age group, from birth to 16 years, including age groups often called neo-nates, infants, children, and adolescents.'' Accordingly, given the statutory amendments, we propose to define ''a drug approved by the Food and Drug Administration exclusively for pediatric indications'' to mean a drug product approved by the FDA exclusively with indications for pediatric use, with the pediatric age group defined from birth to 16 years. Drugs that are not approved and labeled exclusively for pediatric use, that merely reference use in children in any part of the labeling, or that receive a supplemental indication for pediatric use, will not qualify for the minimum rebate of 17.1 percent of AMP as specified in section 1927(c)(1)(B)(iii) of the Act. In accordance with the statute, we propose to apply this definition only to drug products whose FDA-approved labeling includes only indications for children from birth to 16 years of age. Drugs without this explicit age labeling will not satisfy the requirement that the drug be approved exclusively for pediatric use and will not qualify for the minimum rebate of 17.1 percent of AMP. We are proposing to apply such a definition only when this specific pediatric age cohort

appears in the ''Indication and Usage'' section of the FDA-approved labeling.

17. Professional Dispensing Fee

The definition of dispensing fee will remain unchanged as it already enumerates those costs to dispense a drug that the pharmacy incurs. However, we propose to replace the term ''dispensing fee'' with ''professional dispensing fee'' as drug ingredient cost is only one component of the two-part formula that States generally use to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries; and, we feel that this change from ''dispensing fee'' to ''professional dispensing fee'' reinforces our position that once the reimbursement for the drug is properly determined, the dispensing fee should reflect the pharmacist's professional services and costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Therefore, as States change their payment for ingredient cost, we also propose to require States to reconsider the dispensing fee methodology consistent with the revised requirements.

18. Single Source Drug

As currently defined in § 447.502, a single source drug means a covered outpatient drug that is produced or distributed under an NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a BLA, PLA, ELA, or ADA.

As previously stated in the discussion of the proposed changes to the definition of innovator multiple source drug, for purposes of the MDR program, we have defined an original NDA as an NDA filed by the manufacturer with the FDA for purposes of approval for safety and effectiveness. Further, we wish to remind a manufacturer that as long as it has an approved NDA number issued by the FDA, a drug is considered to be a single source drug and is required to be reported with as an ''S'' drug category to CMS under the MDR program unless there are FDA approved therapeutic equivalents. To determine if therapeutic equivalents are available, you can access the FDA's Drugs@FDA and search by the Application Number. If therapeutic equivalents are available for the NDA, then you will see the link to ''Therapeutic Equivalents'' in the ''Drugs Details'' page. If there are no therapeutic equivalents available for the NDA, then the brand name drug should be reported as an ''S'' to CMS.

19. States

Currently, for purposes of this subpart, the term ''States'' is defined as the 50 States and the District of Columbia. However, excluding the territories from this definition of States prevents them from receiving manufacturer rebates through the MDR program. We recognize that the territories have, over the years, expressed an interest in participating in the MDR program and that such rebates would in part offset the costs of providing Medicaid drugs. We have decided, in accordance with section 1101(a)(1) of the Act, to propose revising the definition of States to include the 50 States, the District of Columbia, and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa). Therefore, for drug rebates, we believe it is in the best interests of the Medicaid program to include the territories in the definition of States so that they may achieve the savings that drug rebates provide and we propose that the definition of States should be revised accordingly. We also acknowledge that there may be concerns with the territories participating in the MDR program; therefore, we request comments regarding the inclusion of the territories in the definition of States.

20. United States

Similar to our review of the term ''States'', we also examined our use of the term ''United States''. As with the term ''States,'' we defined United States only to mean the 50 States and the District of Columbia. However, section 1101(a)(2) of the Act provides that when used in a geographic sense, the term ''United States'' means, except where otherwise provided, the States. In accordance with this definition, we think it is reasonable to conclude that in this context, the term is used in the geographical sense in that it contemplates the sales of drugs in any of the States. (Please see section II.K. Upper limits for multiple source drugs (§ 447.514) of the preamble for further discussion on the sale of drugs on a nationwide basis.) Therefore, for the purposes of this subpart, we propose, in accordance with section 1101(a) of the Act, to define the ''United States'' to mean the 50 States plus the District of Columbia and the territories as described above.

21. Wholesaler

The Affordable Care Act added a definition of the term ''wholesaler'' at section 1927(k)(11) of the Act. We propose to adopt that definition and define wholesaler to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

We are not proposing that a wholesaler be licensed by the State inasmuch as that is not a requirement of the Act, in comparison to the definition of retail community pharmacy, where State licensing is required. In considering how to clarify this term, we reviewed the definition of ''wholesale distributor,'' that appears in section 510(g) of the FFDCA, and regulations at 21 CFR 807.3(s), which provide that the term ''wholesale distributor'' means ''any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.'' While this definition is helpful, it does not provide additional clarity to the definition in the Act. Therefore, we are proposing to define wholesaler as set forth in the Act, but are specifically seeking comment on further data sources or definitions we could apply here that would help to further clarify the term wholesaler.

C. Determination of Average Manufacturer Price (§ 447.504)

1. AMP Historical Background

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508) added section 1927 to the Act, which became effective on January 1, 1991. OBRA '90 established the MDR program and defined the AMP with respect to a covered outpatient drug of a manufacturer for a rebate period as the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers who entered into and had in effect a rebate agreement with CMS were required to report AMP on a quarterly basis. The AMP was used to calculate the rebates paid by manufacturers to the States for drugs

dispensed to their Medicaid beneficiaries.

The Deficit Reduction Act of 2005 (DRA) made significant changes to the Medicaid prescription drug provisions of the Act. The DRA amended section 1927(k)(1) of the Act to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers, effective January 1, 2007. The DRA defined AMP, in part, to mean, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

Section 6001(c)(3) of the DRA required the Office of Inspector General (OIG) to review the requirements for and manner in which AMP was to be determined and recommend changes to the Secretary by June 1, 2006. Section 6001(c)(3) of the DRA also required the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration the OIG's recommendation.

In May 2006, the OIG issued a report, ''Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005''. In this report the OIG recommended that CMS:

- Clarify the requirements in regards to the definition of retail pharmacy class of trade and treatment of pharmacy benefit manager (PBM) rebates and Medicaid sales; and
- Consider addressing issues raised by industry groups, such as:
  + Administrative and service fees,
  + Lagged price concessions for returned goods,
  + The frequency of AMP reporting,
  + AMP restatements, and
  + Base date AMP.

The OIG also recommended that the Secretary direct CMS to:

- Issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA; and
- Encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid Program appropriately reimburses pharmacies for estimated acquisition costs.

At that time, we recognized that there had been concerns expressed by the OIG and GAO in several prior reports regarding AMP because of inconsistencies in the way manufacturers determine AMP, changes in the marketplace, and the introduction of newer business practices such as payment of services fees. We also realized that, in light of the DRA amendments, AMP would serve two distinct purposes: determining rebates, and serving as the basis for establishing the FUL for multiple source drugs. As a result of a preliminary injunction that had been entered in a lawsuit challenging the definition of AMP, CMS had never used the AMP final rule as a basis for calculating FULs.

Following the enactment of the Affordable Care Act, in the November 15, 2010 **Federal Register** (75 FR 69591), ''Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'', we withdrew § 447.504 ''Determination of AMP'' from the AMP final rule following a period of notice and comment on the proposed withdrawal.

2. AMP Under the Affordable Care Act

On March 23, 2010, the Affordable Care Act was enacted. As noted above, section 2503 of the Affordable Care Act revised the definition of AMP. The Affordable Care Act was further amended by section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111–226), which was enacted on August 10, 2010.

For the determination of AMP, the Affordable Care Act revises the definition in section 1927(k) of the Act to eliminate the term ''retail pharmacy class of trade'' and adds a definition of the term ''retail community pharmacy'', as well as wholesaler. It identifies specific entities drug manufacturers are to include and exclude from the determination of AMP and (as amended by Pub. L. 111–226) clarifies exceptions to the excluded entities for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through a retail community pharmacy.

In this proposed rule, we propose a new § 447.504 ''Determination of AMP,'' which would be based on section 1927(k)(1) of the Act as amended by the Affordable Care Act. Below we provide a detailed discussion of the proposed definition of retail community pharmacy, other terms used in the determination of AMP, the entities proposed for inclusion and exclusion from AMP, and our proposed policy regarding the treatment of inhalation, infusion, instilled, implanted, or injectable drugs (also referred to as 5i drugs, defined in proposed § 447.507), that are not generally dispensed through a retail community pharmacy in the determination of AMP.

These provisions of the Affordable Care Act became effective on October 1, 2010 without regard to whether final regulations to carry out the provisions have been promulgated. Section 2503(a)(2) of the Affordable Care Act revised the definition of AMP to mean, for a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies, and by retail community pharmacies that purchase drugs directly from the manufacturer.

In accordance with section 1927(k)(1)(B)(i) of the Act, as amended by section 2503(a)(2)(B) of the Affordable Care Act, drug manufacturers are to exclude the following from the determination of the AMP:

- Customary prompt pay discounts extended to wholesalers;
- Bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
- Reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;
- Payments received from, and rebates or discounts provided to, PBMs, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.
- Discounts provided by manufacturers under the Medicare Coverage Gap Discount Program (section 1860D–14A of the Act).

Section 1927(k)(1)(B)(ii) of the Act specifies that, notwithstanding section 1927(k)(1)(B)(i) of the Act, manufacturers are to include in the determination of AMP for a covered outpatient drug any other discounts, rebates, payments, or other financial transactions that are received by, paid

by, or passed through to retail community pharmacies.

How AMP is defined and what sales are included in the determination of AMP affects manufacturers, pharmacy groups, the Federal and State governments and Medicaid beneficiaries, and often there are competing interests at play. The provisions of the Affordable Care Act regarding AMP serve two distinct purposes: Determining rebates and determining the basis for the FUL for multiple source drugs.

There is a direct relationship between which entities are to be included and excluded from AMP calculations and the basis for determining the FUL for multiple source drugs. The Affordable Care Act defines AMP to include prices paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. These sales are typically at higher prices than those of the specifically excluded entities such as the pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, and manufacturers. AMP calculations based on those sales to retail community pharmacies, as opposed to other pharmacies (such as mail order pharmacies), would likely result in a higher AMP value, given that AMP would be limited to higher priced sales. This higher AMP value would benefit the retail pharmacy industry because it is likely that the FUL, based on those AMPs, would be higher and in turn the maximum pharmacy reimbursement, based on those FULs, would be higher. On the other hand, a higher AMP would, in all likelihood, result in higher rebate payments from manufacturers. A broader definition of AMP, which would include sales to entities that purchase drugs at lower prices, would likely lower the AMP value, which in turn would lower drug manufacturer rebate liabilities.

AMP values also have an impact on States and potentially beneficiaries. Increasing AMP values and associated rebate payments would have a direct impact on State expenditures. However, increasing the FULs would also have a direct impact on State payments. On the other hand, if pharmacy reimbursement rates are too low, then it is conceivable that some pharmacies may elect not to participate in the Medicaid program, which could impact beneficiary access to pharmacy services. Similarly, States and the Federal government have an interest in assuring an appropriate level of rebates and beneficiaries' access to care.

3. Definitions

Following is a detailed discussion of the specific terms associated with AMP calculations that we propose to define at § 447.504(a).

a. Average Unit Price

We propose to define average unit price to mean a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter. The quarterly sales figure used in this definition represent sales of the drug unit in the lowest identifiable amount (for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by the manufacturer.

b. Charitable and Not-for-Profit Pharmacies

For the purposes of this subpart, we propose to define charitable and not-for-profit pharmacies as organizations described in section 501(c)(3) of the Internal Revenue Code of 1986.

c. Insurers

The DRA amended section 1902(a)(25) of the Act by modifying the definition of ''third parties'' and ''health insurers'' to clarify the inclusion of self-insured plans, managed care organizations, PBMs, or other parties that are by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service. Although, the DRA clarified ''third parties'', the Affordable Care Act referenced the term ''insurer'' in section 1927(k)(1)(B)(IV) of the Act and provided that payments received from many of these third party organizations (for example, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers) be excluded from the AMP calculation.

For the purposes of this subpart, we propose to define insurers as entities that are responsible for the payment of drugs but do not directly purchase drugs from manufacturers and are not in the supply chain to receive delivery of these drugs. Instead, insurers are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs.

d. Net Sales

We propose to define net sales to mean quarterly gross sales revenue to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from manufacturers less cash discounts allowed, and other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by section 1927 of the Act, or regulations under this subpart) which reduce the amount received by the manufacturer.

e. Retail Community Pharmacy

The Affordable Care Act eliminated the term ''retail pharmacy class of trade'' from the definition of AMP, and added section 1927(k)(10) of the Act to include a definition of the term ''retail community pharmacy.'' This change significantly narrows the entities previously included in the definition of retail pharmacy class of trade. In accordance with the Act, we propose to define retail community pharmacy to mean an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. We further propose to incorporate the requirement set forth in section 1927(k)(10) of the Act that such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

Section 1927(k)(1) of the Act as amended by the Affordable Care Act specifies that manufacturers are responsible for reporting the AMP based upon their sales to retail community pharmacies or wholesalers for drugs dispensed to retail community pharmacies.

In addition, the statutory provision for the determination of AMP suggests there are entities (for example, specialty pharmacies, home infusion pharmacies, and home health care providers), which are conducting business as wholesalers or retail community pharmacies which could be included in the determination of AMP. Section 1927(k)(1)(B)(i)(IV) of the Act excludes from the determination of AMP ''payments received from and rebates or discounts provided to * * * any other entity that does not conduct business as a wholesaler or a retail community pharmacy * * *''. We believe that to give the provision some meaning, the statute contemplates the inclusion of payments and discounts from those entities that actually conduct business as a wholesaler or retail community pharmacy. This

interpretation gives meaning to this broad exclusion, and provides for a calculation of AMP consistent with our reading of the statute. If an entity that does not conduct business as a wholesaler or retail community pharmacy is to be excluded from the determination of AMP, we considered whether or not it would be reasonable to conclude that payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy should be included in the determination of AMP. Based upon our understanding of the program, certain covered outpatient drugs may only be dispensed through such entities that are conducting business as wholesalers or retail community pharmacies, such as certain oral covered outpatient drugs approved by the FDA requiring a Risk Evaluation and Mitigation Strategy (REMS), to ensure that the benefits of a drug or biological product outweigh its risks. A list of REMS drugs is publically accessible on the FDA Web site at *http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm*.

Some REMS drugs are required to be dispensed by specially certified pharmacies, resulting in certain manufacturers utilizing a restricted network of certified specialty and home infusion pharmacies, which are not specifically included in the definition of retail community pharmacy at section 1927(k)(10) of the Act. In addition, certain oral covered outpatient drugs are dispensed solely through these specialty and home infusion pharmacies. Therefore, if these entities were to be excluded from AMP calculations, an AMP would not be available for these oral covered outpatient drugs. As a result, manufacturers would not be able to calculate rebates for these products and the statutory provisions requiring rebates for such drugs would, in essence, be rendered meaningless. We do not believe that the law should be read to create such a result. Section 1927(b)(1) of the Act requires that manufacturers must provide rebates for all of their covered outpatient drugs for which payment was made under the State plan. These provisions were not amended by the Affordable Care Act. Therefore, we believe in light of the provisions of section 1927(k)(1)(B)(i) of the Act, there is a basis for allowing sales, rebates, and discounts provided to entities conducting business as wholesalers or retail community pharmacies to be included in the determination of AMP for those drugs for which an AMP could not otherwise be calculated. Such an interpretation continues to give meaning to the rebate responsibilities of manufacturers in section 1927(b) of the Act. Therefore, we propose to include in the determination of AMP payments received from and rebates or discounts provided to an entity that conducts business as a wholesaler or retail community pharmacy, such as specialty and home infusion pharmacies, and home healthcare providers, since these entities dispense medications to segments of the general public at retail prices. We specifically invite comments on this part of the proposed rule.

Manufacturers contend that there is an administrative burden and difficulty in obtaining records assuring that their sales to wholesalers are distributed to retail community pharmacies. We took their concerns into consideration and considered whether or not to propose that the sales which cannot be definitely identified as sales to retail community pharmacies or wholesalers for drugs dispensed to retail community pharmacies would be eligible for inclusion in the sales that manufacturers use for AMP calculations. We received comments during the comment period for the Proposed Rule ''Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'' published in the **Federal Register** on September 3, 2010 (75 FR 54073) that raised issues regarding the implementation of the new definition of AMP. As these comments were outside the scope of that proposed rule, these comments were not specifically addressed as part of final rule published on November 15, 2010 (75 FR 69591). However, these comments do provide insight into issues of concern for the various stakeholders, especially in regards to the implementation of the new proposed definition of AMP.

One of the issues raised was whether manufacturers should be allowed to presume that sales of drugs are distributed to retail community pharmacies when those sales of drugs are to wholesalers that do not further differentiate their sales among end purchasers.

Based on information provided from these comments it is our understanding that wholesalers generally resell either to manufacturer-contracted customers (which would generate a chargeback or similar record), or to other purchasers with no contract discount arrangement with the manufacturer. In the case of sales to wholesalers where no chargeback record is generated, manufacturers contend that they have minimal to no verifiable information regarding the final transactions on this category of wholesaler re-sales. Manufacturers have expressed concern that they would not have adequate data regarding the wholesaler's actual purchaser to accurately determine if the drug was ultimately sold to retail community pharmacies. Therefore, we considered proposing a so-called ''presumed inclusion'' policy, where the manufacturer could (absent documentation to the contrary) presume that sales to wholesalers are for drugs distributed to retail community pharmacies, without data concerning that actual distribution. Based upon the comments we received from manufacturers we believe such a policy would be consistent with the market based on the typical chargeback arrangements that manufacturers have in place for institutional and other non-retail community pharmacy purchasers. The presumed inclusion policy would not require manufacturers to obtain data regarding the actual distribution to retail community pharmacies. Through the presumed inclusion policy, in the absence of chargeback or other verifiable data, manufacturers would be able to presume that the sales of drugs to wholesalers are for drugs that are distributed to retail community pharmacies.

However, we recognize that there could be concerns with respect to whether manufacturers should be permitted to presume, in the absence of adequate documentation to the contrary, that prices paid by wholesalers are for drugs that are actually distributed to retail community pharmacies. Allowing this practice of presumptive inclusion could affect the calculation of the FULs for multiple source drugs because it arguably would permit the inclusion of lower AMPs in that calculation based on sales that may not have been actually distributed to retail community pharmacies. It could be argued that if manufacturers are allowed to presume that all drug sales are distributed to retail community pharmacies, AMP would be lower because it could include sales to entities (for example, mail order pharmacies and hospitals) that are able to buy the drugs at lower prices than retail community pharmacies. On the other hand, it could also be argued that, despite these concerns, there would be no adverse consequences to the FULs if manufacturers could presume sales distribution to retail community pharmacies because the sales that would be captured using the presumptive inclusion policy are those sales that do not generate chargebacks. In comments

we received during the comment period for the Proposed Rule, ''Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'' published in the **Federal Register** on September 3, 2010 (75 FR 54073), manufacturers claim that allowing the presumed inclusion policy would not create any adverse consequences concerning pharmacy payments. They believe that these sales would, in all likelihood, have a higher net price than institutional or chargeback-generating sales. Additionally, they contend that the volume of AMP-eligible sales used in calculating the FUL could be increased because the additional sales to wholesalers without chargeback data would be added to the volume calculation for determining the weighted average of monthly AMPs. Therefore, they argue that calculating AMPs utilizing the presumptive inclusion policy could result in higher AMPs than AMPs based on actual data and those higher AMPs would be weighted more heavily in the FULs calculation.

We also considered instances where manufacturers are only including in their calculation of AMP those sales where there is adequate verifiable documentation showing that the drug was actually distributed to a retail community pharmacy, whether directly or through a wholesaler. However, we recognize that in this approach there may be instances where the wholesaler actually re-sells the drug to the retail community pharmacies but the manufacturer does not have documentation regarding that actual sale to the retail community pharmacy. Therefore, in contravention of the statute, those sales would not be included in the AMP calculation since the manufacturer does not have adequate documentation.

While we recognize such concerns, we have decided to propose that manufacturers report the AMP based upon their actual sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. Although we are not proposing a presumed inclusion policy, we did consider both approaches and recognize that there are obstacles with each. We acknowledge that a reasonable alternate approach would be one of presumed inclusion because the statute provides a more structured definition of what is to be included and excluded from AMP. However, we have concerns that a presumed inclusion policy would lead to the inclusion of sales by a manufacturer to entities not contemplated in the statutory definition. Accordingly, for purposes of this proposed rule, we are proposing that manufacturers must calculate AMP based on sales: (1) To wholesalers for drugs distributed to retail community pharmacies, or (2) to retail community pharmacies. We seek comments regarding this section and request information concerning distribution data, specifically data concerning wholesaler sales to the retail community pharmacies so that we can further consider this policy decision.

4. Sales Included in the Determination of AMP

Following is a discussion of specific sales, discounts, rebates, payments, nominal price sales, and other financial transactions that we propose to include in the determination of AMP at § 447.504(b).

a. Sales to Wholesalers (§ 447.504(b)(1))

The definition of AMP in section 1927(k)(1) of the Act, as amended by the Affordable Care Act, specifies that AMP is to be calculated, in part, based on the prices paid by wholesalers for drugs dispensed through retail community pharmacies. Therefore, we propose that sales to wholesalers for drugs distributed to retail community pharmacies are to be included in the determination of AMP.

b. Sales to Other Manufacturers (§ 447.504(b)(2))

We propose that sales to other manufacturers who act as wholesalers are to be included in the determination of AMP to the extent that such sales are for drugs distributed to retail community pharmacies. This provision should be read in concert with the definition of wholesaler found in section 1927(k)(11) of the Act.

c. Retail Community Pharmacies (§ 447.504(b)(3))

Section 1927(k)(1)(B)(ii) of the Act, as revised by the Affordable Care Act specifies that manufacturers are to include in the determination of AMP, discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies, as defined earlier in this section. Therefore, we propose to include in the determination of AMP, notwithstanding those price reductions specifically excluded by statute or this regulation, discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies. Again, we are unsure to what extent the manufacturer knows that such transactions occur. However, in accordance with our reading of the statute, the manufacturer must include such discounts where it has evidence or documentation demonstrating that such discounts have been passed through to the pharmacy.

d. Entities Conducting Business as Retail Community Pharmacies or Wholesalers, Including But Not Limited to Specialty Pharmacies, Home Infusion Pharmacies and Home Healthcare Providers (§ 447.504(b)(4))

As discussed earlier, we believe in light of the provisions of section 1927(k)(1)(B)(i) of the Act, there is a basis for allowing sales, rebates, and discounts provided to entities conducting business as wholesalers or retail community pharmacies to be included in the determination of AMP for those drugs for which an AMP could not otherwise be calculated. It is our understanding that certain covered outpatient drugs are dispensed primarily, if not solely, through such entities as specialty pharmacies, home infusion pharmacies, or home healthcare providers. We propose that these pharmacies be considered entities that are conducting business as wholesalers or retail community pharmacies. While not specifically identified in the statutory definition of retail community pharmacy, these pharmacies do conduct business as a retail community pharmacy inasmuch as they dispense medications to the general public at retail prices and are licensed by the State as a pharmacy. While they may be serving a specific part of the general public based on a certain medical condition, the drugs dispensed by these pharmacies are sold in the retail marketplace and are available to any member of the general public who has one of these medical conditions. Therefore, we propose that manufacturers are to include in the determination of AMP the sales of covered outpatient drugs that are dispensed through entities conducting business as wholesalers or retail community pharmacies, which include but are not limited to specialty pharmacies, home infusion pharmacies, and home healthcare providers.

5. Sales Excluded From the Determination of AMP

Following is a discussion of specific sales, discounts, rebates, payments and other payments that we propose to exclude from the determination of AMP at § 447.504(c).

a. Prices to Other Federal Programs Including TRICARE—(§ 447.504(c)(1)–§ 447.504(c)(3))

Manufacturers that participate in the MDR program can also participate in other Federal programs which set the prices and/or discounts for drugs, and these prices are not generally available to retail community pharmacies. We propose that in light of section 1927(k) of the Act, prices to Federal programs should be excluded from AMP. These Federal programs include the Indian Health Service (IHS), the DVA, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense (DoD), the Public Health Service (PHS), a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B (a)(4)(L) of the PHSA), the Federal Supply Schedule (FSS) of the General Services Administration (GSA); or any depot prices (including TRICARE) and single award contract prices, of any agency of the Federal government.

On March 17, 2009, the Department of Defense (DoD) issued a regulation entitled, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals (74 FR 11279). That regulation implements section 703 of the National Defense Authorization Act for fiscal year 2008 (NDAA, Pub. L. 110–181) which states that for any prescription filled on or after the date of enactment of the NDAA, the TRICARE Retail Pharmacy Program will be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.). In accordance with that provision as well as the revised definition of AMP in section 1927(k)(1) of the Act, we propose that TRICARE Retail Pharmacy Program prices should be treated as prices to DoD and therefore excluded from the calculation of AMP.

b. Sales Outside the 50 States, the District of Columbia and Territories (§ 447.504(c)(4))

The proposed definition of ''United States'' in § 447.502 would define ''United States'' to mean the 50 States, the District of Columbia and the territories. We, therefore, propose that sales to entities outside the 50 States, the District of Columbia and the territories are not within the scope of the definition of sales to retail community pharmacy, and that drugs sold to these entities would not be considered eligible sales within the definition of AMP. Therefore, we propose that sales to entities not within the 50 States, the District of Columbia or the territories be excluded from the manufacturers' determination of AMP.

c. Hospitals and Hospital Pharmacy Sales (§ 447.504(c)(5))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to hospitals are excluded from the determination of AMP. Further, the term ''retail community pharmacy'' excludes hospital pharmacies. Therefore, we propose to clarify that sales to hospitals, including direct and indirect sales where the drug is used in either the inpatient setting or the outpatient pharmacy for outpatient hospital use are excluded from the determination of AMP.

d. Sales to Health Maintenance Organizations (HMOs) (Including Managed Care Organizations (MCOs)) (§ 447.504(c)(6))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to HMOs and MCOs are excluded from the determination of AMP. The Affordable Care Act does not specifically address HMO/MCO operated pharmacies. However, given the broad reference in the statute to HMOs and MCOs, we propose to clarify that sales and associated rebates and discounts to HMO/MCO operated pharmacies are excluded from the determination of AMP.

e. Long-Term Care Facility Pharmacies (§ 447.504(c)(7))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales and associated rebates and discounts to long-term care providers are excluded from the determination of AMP. Further, the term retail community pharmacy excludes nursing home pharmacies and long-term care facility pharmacies. Therefore, we propose to clarify that sales and associated rebates and discounts to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, long-term care facilities pharmacies, contract pharmacies for the nursing facility where these sales can be identified, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities, be excluded from the determination of AMP.

f. Mail Order Pharmacies (§ 447.504(c)(8))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that the term retail community pharmacy excludes pharmacies that dispense prescription medications to patients primarily through the mail. We consider these to be mail order pharmacies and as such we propose to clarify that sales to mail order pharmacies are excluded from the determination of AMP.

g. Clinics and Other Outpatient Facilities (§ 447.504(c)(9))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that sales to clinics are excluded from the determination of AMP. In 42 CFR 440.90, clinic services is defined as preventative, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients: (a) Services furnished at the clinic by or under the direction of a physician or dentist, and (b) Services furnished outside the clinic by clinic personnel under the direction of a physician to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

Although the Affordable Care Act did not specifically address the treatment of outpatient facilities in the determination of AMP, we believe that in accordance with the definition of AMP in section 1927(k)(1) of the Act, as well as the definition of clinic in 42 CFR 440.90, sales to outpatient facilities such as surgical centers, ambulatory care centers, dialysis centers, End-Stage Renal Disease clinics, outpatient hospital clinics and mental health centers should be excluded from the AMP. Therefore, we propose to exclude sales and associated rebates and discounts to clinics and outpatient facilities from the determination of AMP.

h. Government Pharmacies (§ 447.504(c)(10))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that the definition of retail community pharmacy does not include government pharmacies. We propose to define government pharmacies as pharmacies operated or owned by Federal, state, county, and municipal governments. We also propose that sales to government

pharmacies are excluded from the determination of AMP.

i. Sales to Charitable and Not-for-Profit Pharmacies (§ 447.504(c)(11)–§ 447.504(c)(12))

Section 1927(k) of the Act, as revised by the Affordable Care Act specifies that the definition of retail community pharmacy does not include charitable or not-for-profit pharmacies. We propose to define charitable or not-for-profit pharmacies as section 501(c) organizations. Section 501(c) organizations are those described in the Internal Revenue Code and are tax-exempt, nonprofit corporations or associations. We propose that sales to these not-for-profit and charitable pharmacies be excluded from the determination of AMP.

j. Insurers § 447.504(c)(13))

The Affordable Care Act defined AMP by specifying that payments received from, and rebates or discounts provided to insurers are to be excluded from the determination of AMP. Therefore, we propose to exclude from the determination of AMP payments received from, and any rebates, discounts, or payments that are provided directly to insurers and that are not passed on to retail community pharmacies.

However, we note that drugs sold to wholesalers for distribution to retail community pharmacies or drugs sold directly to retail community pharmacies that are subsequently reimbursed by insurers when sold by the pharmacy to beneficiaries are part of the chain of sales from manufacturers to wholesalers or retail community pharmacies. In accordance with our reading of the statute, the sales to wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies would be included in AMP calculations, regardless of how the drug is ultimately reimbursed when provided to the beneficiary.

k. Administrative Fees, Including Bona Fide Service Fees, as Well as the Treatment of Group Purchasing Organizations (GPOs) (§ 447.504(c)(14))

As described earlier, we propose to revise the definition of bona fide service fees in § 447.502 to include fees provided as specific examples of bona fide service fees in the Affordable Care Act. The Affordable Care Act specifies that bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies include, but are not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

The current regulations define bona fide service fees, in part, to mean fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service. We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at ''fair market value'' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define ''fair market value'' at this time. Due to the rapidly changing market in which new types of arrangements arise, we believe that manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination. This is consistent with the 2007 AMP Final Rule (72 FR 39184) and the ASP reporting rule (71 FR 69667).

In accordance with the statute, we propose that bona fide service fees should be excluded from the calculation of AMP. We further propose that, in light of the statutory definition, administrative fees and other fees which are not specifically excluded by the Affordable Care Act, but which meet the definition of bona fide service fees, should also be excluded from the determination of AMP. We are not proposing to further define the type of fees used as examples in the definition of bona fide service fees because we believe that these terms can be read in concert with the current definition of bona fide service fee. As noted previously, they provide specific examples of what could qualify as a bona fide service fee. We note however that retroactive price adjustments, sometimes also known as price appreciation credits, do not meet the definition of a bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer.

The statute does not specifically exclude GPO fees from the AMP calculation. To the extent that bona fide service fees, including, but not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs) and other fees to GPOs meet the definition of ''bona fide service fee,'' we propose that such fees should be excluded from the determination of AMP and are not considered price concessions. However, as consistent with the definition of bona fide service fee at § 447.502 where these fees are passed on in whole or in part to a wholesaler or retail community pharmacy, the fees would not qualify as bona fide service fees. To the extent this occurs, such fees cannot be considered bona fide service fees and, in accordance with section 1927(k)(1)(B)(ii) of the Act, should be included in AMP.

l. Customary Prompt Pay Discounts (§ 447.504(c)(15))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that customary prompt pay discounts that are extended to wholesalers are to be excluded from the determination of AMP. Therefore, we are proposing that customary prompt pay discounts extended to wholesalers be excluded from the determination of AMP.

m. Returned Goods (§ 447.504(c)(16))

Section 1927(k) of the Act, as revised by the Affordable Care Act, specifies that reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of goods, and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction are excluded from the determination of AMP. We propose to incorporate this definition into this rule, but note that it is applicable only to the extent that payment for these returned goods covers the cost of returns and does not otherwise serve as payment to the pharmacy as a price concession. In addition, we propose to exclude the value of returned goods themselves from the determination of AMP when returned in good faith.

We are not proposing to define the terms recalled, damaged, and expired as we believe they are self-explanatory within the standard industry practice. We likewise are not defining unsalable, but would also base it on standard industry practice to determine under what conditions and/or circumstances drugs would be considered unsalable. We are requesting comments regarding whether we should define these terms or further define how these industry standards should be set. We also request examples of what would qualify as unsalable.

n. Medicare Coverage Gap Discount (§ 447.504(c)(17))

Section 3301 of the Affordable Care Act established the Medicare Coverage Gap Discount Program under sections 1860D–43 and 1860D–14A of the Act. Section 1101(c) of the Affordable Care Act further specified that discounts provided by manufacturers under the Medicare coverage gap discount program will be excluded from AMP. Therefore, we propose that discounts under the Medicare coverage gap discount program should be excluded from AMP.

o. PBM Price Concessions (§ 447.504(c)(18))

Section 1927(k)(1)(B) of the Act, as revised by the Affordable Care Act, revised the definition of AMP by excluding payments received from, and rebates or discounts provided to, pharmacy benefit managers (PBMs) and mail order pharmacies. Therefore, we propose to exclude from the calculation of AMP, payments received from and rebates or discounts provided to PBMs, including their mail order pharmacy's purchases to the extent that no part of the rebates, discounts or payments are received by, paid by, or passed through to retail community pharmacies.

p. Treatment of Medicaid Rebates in AMP (§ 447.504(c)(19))

We propose to exclude rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies from the determination of AMP. We are doing so in light of the definition of section 1927(k)(1) of the Act, because these rebates affect the manufacturer and the State, and there is no direct effect on the sale price of these drugs to retail community pharmacies.

Entities not specifically addressed in the statute.

q. Sales to Hospices (§ 447.504(c)(20))

The Affordable Care Act did not specifically address the treatment of sales to hospices in the determination of AMP. We propose, in light of the revisions in sections 1927(k)(1)(A) and 1927(k)(10) of the Act, to exclude hospice sales from the definition of AMP. Hospice pharmacies are outside the scope of the definition of retail community pharmacy. Further, these pharmacies serve a defined population and do not dispense medications to the general public at retail prices.

r. Sales to Prisons (§ 447.504(c)(21))

We propose that the sales to prisons are outside the scope of the definition of retail community pharmacy; drugs sold to these entities serve a defined population in that facility and are not available to the general public.

s. Direct Sales to Physicians (§ 447.504(c)(22) and § 447.504(d)(1))

Except for the sale of inhalation, infusion, instilled, implanted and injectable drugs (also referred to as the 5i drugs, and which are discussed in detail later in this section) we do not believe, in light of the definition of retail community pharmacy in section 1927(k)(10) of the Act, that physicians meet the definition of a retail community pharmacy. However, in light of the specific revisions to section 1927(k)(1)(B)(i)(IV) by section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111–226), we believe that certain sales to physicians should be included in AMP. Since we have defined the 5i drugs as those which are primarily physician-administered, we believe in light of the statutory amendments, the case can be made that the sale (and associated discounts) of these 5i drugs to physicians should be included in the determination of AMP. Therefore, we propose in § 447.504(d)(1) that for 5i drugs, sales (and associated rebates or discounts) to physicians are included in the determination of AMP. However, in the case of non-5i drugs, we propose at § 447.504(c)(26) that direct sales to physicians be excluded from the determination of AMP.

t. Direct Sales to Patients (§ 447.504(c)(23))

We propose that direct sales to patients be excluded from AMP as these sales are outside the scope of the definition of retail community pharmacy in section 1927(k)(10) of the Act.

u. Free Goods (§ 447.504(c)(24))

We propose that where a drug or any other item is given away, but not contingent on any purchase requirement, there is no sale and, therefore, that transaction would be excluded from the determination of AMP.

v. Manufacturer Coupons (§ 447.504(c)(25))

We propose in light of the revised definition of AMP that manufacturer coupons to a consumer redeemed by the manufacturer, agent, or another entity acting on behalf of the manufacturer should be excluded from AMP, but only to the extent that the full value of the coupon is passed on to the consumer and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer coupons.

w. Voucher Programs (§ 447.504(c)(26))

We propose that manufacturer vouchers would be excluded from the determination of AMP because the benefits of such vouchers are passed onto the patient and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer voucher programs. However, to the extent that the retail community pharmacy receives a discount, rebate, or other price concession, in accordance with section 1927(k)(1)(B)(ii) of the Act, it shall be included in AMP.

x. Manufacturer-Sponsored Drug Discount Card Programs (§ 447.504(c)(27))

We propose in light of the revised definition of AMP that prices negotiated under a manufacturer-sponsored drug discount program would be excluded from the determination of AMP, provided the discount is passed on to the patient and the retail community pharmacy does not receive any discount, rebate or price concessions in connection with the manufacturer-sponsored drug discount card program.

y. Manufacturer-Sponsored Patient Refund/Rebate Programs (§ 447.504(c)(28))

The Affordable Care Act did not explicitly address the treatment of prices negotiated under a manufacturer-sponsored patient refund or rebate program. To the extent the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the retail community pharmacy does not realize any discounts or rebates or receive any price concession in connection with the manufacturer-sponsored patient refund/rebate programs, we propose in light of the revised definition of AMP that prices negotiated under a manufacturer sponsored patient refund or rebate program would be excluded from the determination of AMP.

z. Copayment and Patient Assistance Programs (§ 447.504(c)(29))

The Affordable Care Act did not address the treatment of patient assistance programs, including copayment assistance programs. We believe in light of the revised definition of AMP that patient assistance programs, including copayment assistance programs that provide free goods that are not contingent on future purchases to patients would be

excluded from the determination of AMP. Therefore, we propose that such patient assistance programs and copayment assistance programs are excluded from the determination of AMP. However, to the extent that the retail community pharmacy receives a discount, rebate, or other price concession in connection with the copayment and patient assistance programs, in accordance with section 1927(k)(1)(B)(ii) of the Act, it shall be included in AMP.

6. Inhalation, Infusion, Instilled, Implanted, and Injectable Drugs (§ 447.504(d) and § 447.507)

In accordance to section 1927(k)(1)(B)(i)(IV) of the Act, manufacturers are to exclude from the determination of AMP for a covered outpatient drug for a rebate period, any payments received from, and other discounts or rebates, that are provided to any other entity that does not conduct business as a wholesaler or retail community pharmacy. Certain specialty covered outpatient drugs are not generally dispensed through retail community pharmacies and in those instances manufacturers would be unable to generate an AMP which would prevent rebate calculations for those drugs. Section 202 of the Education, Jobs and Medicaid Funding Act (Pub. L. 111–226), enacted August 10, 2010, amended the Affordable Care Act definition of AMP at section 1927(k)(1) of the Act to include sales for the 5i drugs that are not generally dispensed through retail community pharmacies. This provision was added to ensure that an AMP could be calculated and Medicaid rebates could be collected from manufacturers for the 5i drugs that are not generally sold at retail community pharmacies. (See 156 Cong. Rec. S6766 (Aug. 5, 2010)).

This provision went into effect on October 1, 2010 and revises a manufacturer's AMP calculation for the 5i drugs to include entities other than retail community pharmacies that dispense such drugs.

While the enactment of this legislation addressed the need to ensure that rebates would be collected for these 5i drugs that are ''not generally dispensed through retail community pharmacies,'' it also raised additional issues that were not directly addressed in the statute. Based upon section 1927(k)(1)(B)(i)(IV) of the Act, we have identified the following issues that would require further clarification: (1) Identification of 5i drugs, (2) clarification of the term ''not generally dispensed,'' (3) determination of sales, discounts and rebates included in the 5i calculation, and (4) identification of other entities included in the definition.

We also received requests from manufacturers and pharmacies requesting guidance on this provision; specifically regarding how to interpret ''not generally dispensed through a retail community pharmacy'' and how to identify these 5i drugs.

We considered issuing a list identifying the specific 5i drugs that are to be included in this category. Second, we considered how to define the term ''not generally dispensed.'' Finally, we considered clarifying which sales, discounts, and other financial transactions would be included in the determination of AMP for these drugs.

Based on our understanding of the market as well as other Federal programs, we believe most 5i drugs are administered parenterally or through an item of durable medical equipment (DME) and often require physician supervision during administration. We considered defining each type of administration route; however, we believe that it is not necessary to define the terms because the terms are essentially self explanatory. We are seeking comments on this decision.

We considered using the Medicare Part B standards to identify 5i drugs, given that Medicare Part B covers a limited number of outpatient prescription drugs that are not usually self-administered, such as those given in a hospital outpatient department or doctor's office. In addition, Medicare Part B covers outpatient prescription drugs provided through an item of durable medical equipment, such as an infusion pump or nebulizer, and injectable drugs administered by a licensed medical practitioner, if considered reasonable and necessary.

Medicare Part B does not have a comprehensive, all inclusive list of covered inhalation, infusion, injectable, instilled, or implanted drugs. However, it already has a publicly available reference which lists drugs that are ''not usually self-administered'' and could be considered for coverage under Medicare Part B. In addition, the Medicare Part B ASP NDC–HCPCS Crosswalk file identifies drugs that could be considered for coverage under Medicare Part B; it is publically accessible on the CMS Web site at *http://www.cms.gov/McrPartBDrugAvgSalesPrice/01a19_2010aspfiles.asp* and is updated on a quarterly basis. The Medicare Part B ASP NDC–HCPCS Crosswalk file also includes drugs which do not meet the 5i criteria, specifically those oral drugs covered by Part B following a transplant as well as Part B oral anti-emetics and oral cancer drugs. We considered using the Medicare Part B ASP NDC–HCPCS Crosswalk file to identify 5i drugs. However, we believe it would not be optimal because it is not an all inclusive list of inhalation, infusion, instilled, implanted and injectable drugs and therefore would likely miscategorize some 5i drugs.

We also considered whether CMS or the manufacturers should determine which drugs qualify as a 5i drug. In doing so, we considered whether or not it would be difficult for manufacturers to determine which drugs should be classified as an inhalation, infusion, instilled, implanted, or injectable drugs for the determination of AMP using the route of administration approved by the FDA or based upon the drug's NDC.

We also considered if we should identify the 5i drugs based upon their NDC number. If we were to identify the 5i drugs, we determined it would not provide reliable data and still require us to make available, as well as continuously update, a set of guidelines that would likely require an outside data source. In addition to the nuances of identifying existing drugs, it would be a continuous challenge to maintain a reliable list due to an evolving marketplace with the introduction of new drugs and removal of existing drugs.

Although we determined it would not be practical for CMS to provide a list identifying the 5i drugs, we considered providing a list of routes of administration as identified by the FDA that we believe would be applicable for 5i drugs. We believe this list would serve as a guide that manufacturers would use to determine if a drug could be considered as a 5i drug. We are proposing to add § 447.507 Identification of 5i drugs to indicate how 5i drugs are to be identified. In § 447.507(a) we propose to use the FDA's Routes of Administration as a guide to identify 5i drugs. Below is a list of FDA routes of administration that we are proposing manufacturers use to identify 5i drugs. It includes, but is not limited to, the routes of administration listed in Table 3. This list comes from the FDA Structured Product Labeling, Route of Administration data standards located at *http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm.*

TABLE 3—ROUTES OF ADMINISTRATION FOR 5I IDENTIFICATION

Auricular (Otic)	Intracavernous
Conjunctival	Intracavitary
Endocervical	Intracerebral
Endosinusial	Intracisternal

TABLE 3—ROUTES OF ADMINISTRATION FOR 5I IDENTIFICATION—Continued

Endotracheal	Intracorneal
Epidural	Intracoronal, Dental
Extra-Amniotic	Intracoronary
Hemodialysis	Intracorporus Cavernosum
Infiltration	Intradermal
Interstitial	Intradiscal
Intra-Abdominal	Intraductal
Intra-Amniotic	Intraduodenal
Intra-Arterial	Intradural
Intra-Articular	Intraepicardial
Intrabiliary	Intraepidermal
Intrabronchial	Intraesophageal
Intrabursal	Intragastric
Intracardiac	Intragingival
Intracartilaginous	Intrahepatic
Intracaudal	Intraileal
Intralesional	Iontophoresis
Intralingual	Irrigation
Intraluminal	Laryngeal
Intralymphatic	Nasal
Intramammary	Nasogastric
Intramedullary	Ophthalmic
Intrameningeal	Parenteral
Intramuscular	Percutaneous
Intranodal	Periarticular
Intraocular	Peridural
Intraomentum	Perineural
Intraovarian	Periodontal
Intrapericardial	Rectal
Intraperitoneal	Respiratory (Inhalation)
Intrapleural	Retrobulbar
Intraprostatic	Soft Tissue
Intrapulmonary	Subarachnoid
Intraruminal	Subconjunctival
Intrasinal	Subcutaneous
Intraspinal	Subgingival
Intrasynovial	Submucosal
Intratendinous	Subretinal
Intratesticular	Transendocardial
Intrathecal	Transmucosal
Intrathoractic	Transplacental
Intratubular	Transtracheal
Intratumor	Transtympanic
Intratympanic	Ureteral
Intrauterine	Urethral
Intravascular	Vaginal
Intravenous	
Intraventricular	
Intravesical	
Intravitreal	

We propose that manufacturers identify 5i drugs based upon the FDA route of administration list that we have provided. We are interested in comments on this proposal, including comments regarding other FDA routes of administration that could be used to identify 5i drugs that are not reflected on the provided list.

We believe that by utilizing the FDA route of administration, manufacturers will be readily able to identify products which are inhaled, infused, instilled, implanted, and injected as the information is readily available. However, manufacturers would need to determine if those products identified as 5i drugs are ''not generally dispensed through a retail community pharmacy''. Therefore, we also considered how to establish a standard by which manufacturers would determine when a drug is ''not generally dispensed through a retail community pharmacy.''

We considered adopting the Medicare Part B guidelines used to determine if a drug is to be classified as self-administered as a way to determine when a drug is ''not generally dispensed'' through a retail community pharmacy. In accordance with section 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, the Medicare Benefit Policy Manual, Chapter 15—Covered Medical and Other Services, § 50.2(C) provides guidance regarding the term ''usually.'' Specifically, it provides that the term is used to mean more than 50 percent of the time in determining when a drug is to be classified as self-administered. In light of this guidance, we believe that if a drug can be self administered, it is reasonable to assume that it is usually dispensed through a retail community pharmacy; however, for physician-administered drugs, we believe it is reasonable to conclude that the drug may be provided by physicians or other licensed practitioner in a variety of entities (such as clinics and physician's offices), and given the nature of the drugs, are usually not dispensed by a retail community pharmacy.

If we were to adopt a similar 50 percent methodology for determining when a drug is not generally dispensed through a retail community pharmacy, it would mean that a drug would be classified as ''not generally dispensed'' through a retail community pharmacy if more than 50 percent of the sales were to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer. We believe that if we were to adopt a 50 percent methodology, some 5i drugs which are self-administered and generally dispensed through retail community pharmacies would be included in the alternate 5i AMP calculation due to the breadth of the percentage allowed in this calculation methodology.

We also considered whether we could use the methodology commonly used by manufacturers to calculate the Department of Veterans Affairs (DVA) non-Federal Average Manufacturer Price (non-FAMP). This methodology is described in the draft ''Amended Master Agreement'',[2] between the Secretary of Veterans Affairs and the Manufacturer in section VII of this Agreement. Manufacturers, manufacturer associations, pharmacies and pharmacy associations have repeatedly referred to this draft ''Amended Master Agreement'' when requesting guidance from CMS on the issue of defining ''not generally dispensed''. According to the definition of Wholesaler found in the draft ''Amended Master Agreement,'' manufacturers are to consider a buyer to be a wholesaler when drugs with unit sales of 90 percent or greater are to retailers, other merchants, industrial, institutional or commercial users. Manufacturers are responsible for using this 90 percent principle as a guideline to determine when their sales are to wholesalers in their determination of non-FAMP. We considered whether it would be reasonable to apply the same principle to 5i drug determinations as to when a drug is ''not generally dispensed'' through a retail community pharmacy. We considered adopting a similar 90 percent principle because the definition of AMP, as specified in section 1927(k)(1)(B) of the Act, as revised by the Affordable Care Act, reflects sales to wholesalers for drugs distributed to retail community pharmacies (and retail community pharmacies that purchase drugs directly from the manufacturer). Therefore, for 5i drugs, our understanding of the 90 percent principle would be that if 90 percent or more of the manufacturer's sales for the respective drug were to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer, then the drug would be classified as ''not generally dispensed'' through a retail community pharmacy.

We believe providing a quantitative method to determine when a drug is ''not generally dispensed'' through a retail community pharmacy would be preferable to a more qualitative drug specific approach as it provides a more definitive meaning to the term ''not generally dispensed'' through a retail community pharmacy. Therefore, in this proposed rule, we propose at § 447.507(b)(1) to use the 90 percent principle to determine when a drug is not generally dispensed through a retail community pharmacy. However, we continue to have some concerns regarding whether the 90 percent threshold is reasonable because it might result in a portion of drugs eligible for

[2] While the Amended Master Agreement (9/7/00 draft) between the Secretary of Veterans Affairs and the Manufacturer Identified in Section VIII of this Agreement has not been finalized and is therefore not an official DVA document, it is our understanding that it is still utilized by those in the industry when determining non-FAMP.

the 5i alternate AMP calculation to be omitted from AMP because the percentage of sales required to classify a drug as ''not generally dispensed through a retail community pharmacy'' may be too high. Manufacturers that enter into and have in effect a Medicaid drug rebate agreement, as set forth in section 1927(a) of the Act, are responsible for reporting AMP on a monthly and quarterly basis. Therefore, we propose at § 447.507(b)(2) that the determination of a 5i drug's status as ''not generally dispensed'' through a retail community pharmacy will need to be evaluated on a monthly and quarterly basis. We invite comments on this approach, including comments indicating if we should consider other quantitative options (for example, 75 percent, or 50 percent) to identify if a 5i drug is ''not generally dispensed'' through a retail community pharmacy and reasons as to why those options would be appropriate. We also invite comments on whether manufacturers should evaluate the status of a 5i drug's status as ''not generally dispensed'' through a retail community pharmacy on a monthly or quarterly basis.

We further propose at § 447.504(d) that, in light of section 1927(k)(1)(B)(i)(IV) of the Act, AMP for these drugs will include all sales, rebates, discounts, or other financial transactions already proposed for inclusion in the determination of AMP as well as the sales, rebates, discounts, or other transactions concerning these drugs, that are provided to the following non-retail community pharmacy entities:

- Direct sales to physicians.
- Sales to pharmacy benefit managers, including their mail order pharmacy's purchases.
- Sales to HMOs, including MCOs.
- Sales, discounts, or rebates paid directly to insurers.
- Sales to hospitals.
- Sales to clinics and outpatient facilities.
- Sales to mail order pharmacies.
- Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.
- Sales to hospices.
- Sales to other manufacturers who conduct business as wholesalers or retail community pharmacies.

7. Further Clarification on the Calculation of AMP—§ 447.504(e)

a. Chargebacks and Other Discounts (§ 447.504(e)(1))

We propose that chargebacks must be included in the calculation of AMP, except for those chargebacks provided to any of the entities that are excluded from the determination of AMP. Inasmuch as we believe chargebacks are based on identified sales to a specific entity, a manufacturer cannot make assumptions regarding these chargebacks and must identify them to included or excluded AMP sales. Additionally, we propose that AMP is to include cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, incentives, administrative fees, service fees (other than bona fide service fees), distribution fees, and any other rebates, discounts or other financial transaction, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

b. Quarterly AMP (§ 447.504(e)(2))

Based on prior experience and on the MDR program submissions we believe that the quarterly AMP should be calculated as a weighted average of the monthly AMPs in the quarter. We believe that, based on our prior experience and the similarities of both calculations, this approach will minimize discrepancies between the monthly and the quarterly AMPs. Therefore, we propose that quarterly AMP is to be calculated as a weighted average of monthly AMPs in the quarter.

c. Manufacturer Adjustments (§ 447.504(e)(3))

To account for discounts, rebates or other price concessions that may not be available during the rebate reporting period, we propose that the manufacturer must adjust the AMP for the applicable rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that these discounts, rebates or arrangements are not excluded from the determination of AMP by statute or regulation.

D. Determination of Best Price (§ 447.505)

1. Definitions of Best Price and Providers

We are proposing re-codifying the terms ''best price'' and ''Providers'' under newly proposed § 447.505(a). Additionally, we are proposing to revise the definition of the term ''best price'' at newly proposed § 447.505(a) so that it is consistent with the definition of best price found in section 1927(c)(1)(C) of the Act.

2. Prices Included in Best Price

We believe that revising the definition of best price to be consistent with the definition provided in the statute provides sufficient detail as to which prices are to be included in the determination of best price. Therefore, we further propose the ''Prices included in best price,'' currently located in regulations at § 447.505(c)(1)–(11), be redesignated to § 447.505(b) and that it would be revised to remove the list of prices included in best price. Instead, the paragraph would read as follows: ''Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly.''

3. AMP Methodology Applied to Best Price

In order to provide consistency between the AMP and best price sections, where applicable, we are proposing to apply the same methodology to best price that we are applying to AMP. This will be accomplished by making the following revisions to the prices exempt from best price section. We propose the ''Prices excluded from best price,'' currently located in regulations at § 447.505(d)(1)–(13), be redesignated to § 447.505(c)(1)–(18). The current list of prices excluded from best price would be expanded to include three new price exclusions not currently identified in regulations. They are (1) manufacturer vouchers, (2) manufacturer-sponsored patient refund/rebate programs and (3) sales outside of the United States. These terms have been discussed earlier in the Determination of AMP section and the addition of them to the prices excluded from best price serves to align best price and AMP. We also propose to revise the phrasing of several of the existing prices listed in the ''prices excluded from best price'' section so they are consistent with the phrasing of the same items listed in the ''sales excluded from the determination of AMP'' section of the regulation. These changes do not alter the meaning or intention of the section, and applies the same treatment of sales, prices and discounts, where applicable, to best price that we are applying to AMP.

4. 340B Expanded List of Covered Entities Exempt From Best Price

In accordance with section 7101 of the Affordable Care Act, we are proposing to clarify how manufacturers are to treat orphan drugs sold to new covered entities described in sections 340B(a)(4)(M), (N) and (O) of the PHSA for best price. The Affordable Care Act expanded the list of entities eligible to enroll in the 340B drug pricing program to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Additionally, the Affordable Care Act amended the PHSA by excluding certain orphan drugs from being considered covered outpatient drugs for these newly covered entities. Section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309) excludes certain children's hospitals from this exclusion, effective as if included in the enactment of section 2302 of the HCERA of 2010. In accordance with sections 1927(a)(5)(B) and 1927(c) of the Act, we propose that manufacturers can exclude only drugs purchased under the 340B Drug Pricing program from their best price calculation where the covered entities meet the conditions set by PHSA. We believe there may be circumstances in which covered entities purchase drugs outside of the 340B program, such as instances when drugs are purchased for inpatient use, drugs that have both inpatient and outpatient uses, and when a covered entity purchases drugs outside the 340B program to dispense to its Medicaid patients. In order to better understand the purchasing practices of covered entities and the scope of our proposed policy on best price, we invite comments regarding other circumstances in which covered entities purchase drugs outside of the 340B program. We believe that this position is consistent with our reading of these provisions and as a result strengthens the integrity of the MDR program because covered entities are prohibited from diverting drugs purchased under 340B authority to anyone who is not a patient of the covered entity. These requirements are proposed in a new regulation at § 447.505(c)(2)(i) and (ii).

5. Medicare Coverage Gap Discount Program (The Discount Program)

The Affordable Care Act established the Discount Program under sections 1860D–43 and 1860D–14A of the Act. The Discount Program makes manufacturer discounts available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap.

In general, the discount on each applicable covered Part D drug is 50 percent of an amount that is equal to the negotiated price. In accordance with the Affordable Care Act, manufacturer discounts attributed to the Discount Program will be excluded from the determination of best price as defined in § 447.505(c)(6).

E. Authorized Generics Drugs (§ 447.506)

We propose to remove the definition of ''Authorized generic drugs'' from § 447.506(a), as discussed in section II.B.1 of this regulation. In § 447.506(a), we propose to define the term ''Primary manufacturer'' to mean a manufacturer that holds the NDA of the authorized generic drug. We also propose to define the term ''Secondary manufacturer of an authorized generic drug'' to mean a manufacturer that is authorized by the primary manufacturer to sell the drug, but does not hold the NDA. In § 447.506(b), we propose to revise the existing paragraph to specify that sales of an authorized generic drug must be included in the AMP calculation of the manufacturer holding the NDA, referred to in this discussion as the primary manufacturer, when such drugs are being sold directly to a wholesaler. In accordance with section 1927(k)(1)(C) of the Act, we propose in § 447.506(b) to require that the primary manufacturer of an authorized generic, include in its calculation of AMP all sales of its authorized generic drug product sold or licensed to a secondary manufacturer, including transfer prices and fees paid by the secondary manufacturer to the primary manufacturer, when the secondary manufacturer is acting as a wholesaler, as set forth in section 1927(k)(11) of the Act. Additionally, the primary manufacturer holding the NDA must also include those sales in its AMP calculation that it makes directly to wholesalers including other manufacturers acting as wholesalers.

In § 447.506(c), we propose to revise the existing paragraph to specify that a primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, when such drugs are being sold by the primary manufacturer holding the NDA.

Further, we propose to add a new § 447.506(d) to specify that the secondary manufacturer of an authorized generic drug must also provide a rebate based on its sales of authorized generic drugs, and must calculate AMP and best price consistent with the requirements specified at § 447.504 and § 447.505 respectively.

F. Exclusion From Best Price of Certain Sales at a Nominal Price (§ 447.508)

Currently, the existing regulations at § 447.508(a) defines nominal sales which should be excluded from a manufacturer's best price calculation only when made to 340B covered entities as defined in section 340B(a)(4) of the PHSA, ICFs/MR, State-owned or operated nursing facilities and safety net providers or facilities/entities which the Secretary determines to be eligible.

Previously, the Secretary did not exercise the authority to add other safety net providers for which sales at nominal prices are excluded from best price. Section 221 of the Omnibus Appropriations Act, 2009, Public Law 111–8, enacted on March 11, 2009, revised section 1927(c)(1)(D) of the Act by expanding the definition of nominal priced sales to include sales of covered outpatient drugs to two new categories of entities. The expansion allows public or nonprofit entities (as defined by the Internal Revenue Service (IRS)), or State-owned or operated facilities providing the same services to the same populations as 340B(a)(4) entities of the PHSA but not funded as such and in compliance with the prohibition on abortion services as set forth in section 1008 of the PHS Act or academic health care centers providing family planning services to be eligible for the nominal priced sales.

We propose to revise § 447.508(a) to include the additional entities to which manufacturers may have nominal price sales excluded from best price. To qualify for the exception, entities must meet the criteria set forth below for either of the two new categories:

- Category 1 criteria:

+ The entity is an exempt organization as defined by section 501(c)(3) of the Internal Revenue Code of 1986; and exempt from tax under section 501(a) of such Act, or is State-owned or operated; and,

+ Provides the same type of services to the same type of populations as a covered entity described in 340B(a)(4) of the PHS Act but does not receive funding under such section.

- Category 2 criteria: The entity is a public or nonprofit entity or an entity based at an institution of higher learning, whose primary purpose is to provide health care services to students of that institution, that provides a

service or services as described under section 1001(a) of the PHS Act, 42 U.S.C. 300.

The legislation further provides that nothing in section 1927(c)(1)(D) of the Act should be construed to alter any existing statutory or regulatory prohibition on services for Category 1 entities, including the prohibition set forth in section 1008 of the PHSA.

Because these additions appear to address those nominal price sales that are not related to a manufacturer's attempt to influence market share or for other marketing reasons, we are again choosing not to identify any further entities for which manufacturer nominally priced sales would be exempt from best price.

G. Medicaid Drug Rebates (§ 447.509)

1. Determination of Rebate Amount (§ 447.509(a))

Manufacturers that participate in the MDR program are required to pay rebates for covered outpatient drugs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Act. As described in the ''Background'' section above, the Affordable Care Act made several revisions to the statutory rebate formulas. In light of these revisions, we propose to incorporate the rebate formulas into Federal regulations.

We propose in § 447.509(a)(1) that the basic rebate, for each dosage form and strength of a single source drug or an innovator multiple source drug, will be equal to the total number of units of each dosage form and strength paid for under the State plan in the rebate period multiplied by the greater of the difference between the AMP and best price of the drug or the AMP multiplied by:

- 17.1 percent for a clotting factor for which a separate furnishing payment is made under section 1842(o)(5);
- 17.1 percent for a drug approved by the FDA exclusively for pediatric indications; or
- 23.1 percent for all other single source drugs and innovator multiple source drugs.

We note that all clotting factors would not qualify for the minimum rebate percentage of 17.1 percent of AMP. Only those clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act would qualify as defined under the definition of clotting factors. Similarly, all drugs with pediatric indications would not qualify for the minimum rebate percentage of 17.1 percent of AMP. Only those drugs approved by the FDA exclusively for pediatric indications, in accordance with our proposed definition in § 447.502, would qualify.

We propose in § 447.509(a)(2) that the additional rebate for single source and innovator multiple source drugs will be equal to the number of units for such dosage form and strength paid for under the State plan in the rebate period multiplied by the amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the CPI–U for the month before the month in which the rebate period begins exceeds such index.

We propose in § 447.509(a)(3) that the total rebate amount for single source drugs and innovator multiple source drugs will be equal to the basic rebate amount plus the additional rebate amount, if any. We also propose at § 447.509(a)(5) that in no case will the total rebate amount exceed 100 percent of the AMP of the drug.

2. Treatment of New Formulations (§ 447.509(a)(4))

The Affordable Care Act established a separate formula for calculating the unit rebate amount for a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. For such a line extension drug, the rebate amount will be the amount calculated under section 1927 of the Act or, if greater, the product of the AMP for the line extension drug, the highest additional rebate (calculated as a percentage of AMP) under section 1927 for any strength of the original single source or innovator multiple source drug, and the total number of units of each dosage form and strength of the line extension drug paid for under the State plan in the rebate period (as reported by the State). We propose to incorporate this calculation in § 447.509(a)(4).

The statute defines a line extension for purposes of the rebate calculation as a new formulation of a drug such as an extended release formulation. However, the statute did not provide further specificity as to how line extensions should be defined. Therefore, as previously described in the definition of a line extension, we will define line extension at § 447.502. CMS plans to define a line extension drug as a single source or innovator multiple source drug that is an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug. Single source or innovator multiple source drugs that receive exclusivity are not proposed to be excluded from the definition of a line extension drug. For the purpose of calculating the unit rebate amount under the Affordable Care Act, we propose that both the initial brand name drug and the line extension drug have to be an oral solid dosage form drug. We also propose to exclude a new strength of the initial brand name drug from the definition of a line extension drug. We have adopted this policy in order to capture all new formulations (including extended release formulations) and potential line extensions of single source or innovator multiple source drugs. Further, we believe this policy is consistent with our understanding of the line extension provisions in the Affordable Care Act. We invite comments from the public on this proposed policy.

We do not plan to exclude reformulations of existing products that incorporate abuse deterrent technologies from the definition of line extension drugs. The goal of these new formulations are to mitigate the risk of abuse—as opposed to the outright elimination of abuse—by preventing alternate routes of administration, or employing physical barriers that resist common methods of tampering, thus abuse deterrent formulations (ADFs) have the potential to decrease abuse of prescription drugs and improve patient and public safety. Some examples of abuse deterrent strategies that are under development include combination oral formulation products with an opioid agonist and opioid antagonist, formulations with other aversive characteristics, prodrugs, physically impenetrable formulations, and drug-device combinations with patient recognition capability. However, the statute does not exclude reformulated drugs incorporating abuse deterrent technologies from the definition of a line extension drug and thus we do not plan to exclude drugs with this labeling from the definition. The types of drugs that we are considering as line extension drugs include these reformulated products.

FDA draft guidance on the assessment of abuse potential of drugs can be found at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM198650.pdf.*

We are soliciting feedback from the industry, the public, and other

stakeholders regarding whether existing or future reformulated products incorporating an abuse deterrent technology should be subject to the additional rebate formula under the Affordable Care Act.

We have determined that we do not have the ability to identify the line extension of the initial brand name listed drug based on manufacturer rebate submissions. We consulted with the FDA to determine if the FDA currently keeps a list of line extension drugs as we have defined the term, and the FDA does not. Thus, we reviewed the drug information and data files publicly available at the FDA and propose to use the FDA's list of Chemical Types to identify the line extension drug as well as the initial brand name listed drug of the line extension drug.

The FDA classification is given to nonbiologic products during the review process and is finalized when the NDA is approved. This classification consists of Chemical Type classification, which classifies these drugs according to the type of change made to the initial brand name product. Chemical Type represents the newness of a drug formulation or a new indication for an existing drug formulation, as noted in *http://www.fda.gov/Drugs/informationondrugs/ucm079436.htm*. The FDA classifies all NDAs based on Chemical Type. One measure of innovation is the newness of the listed drug or the drug's active ingredient. The Chemical Type may identify the drug as new, or as related to the active ingredient of another drug that has already been approved.

Based on the analysis of the FDA's drug information and data files, we propose to use Chemical Types 2, 3, 4, and 6 on the FDA's list of Chemical Types below as an indicator for line extension drugs as shown in Table 4.

TABLE 4—NEW DRUG APPLICATION CHEMICAL TYPES

Number	Meaning
1	New molecular entity (NME).
2	New ester, new salt, or other noncovalent derivative.
3	New formulation.
4	New combination.
5	New manufacturer.
6	New indication.
7	Drug already marketed, but without an approved NDA.
8	OTC (over-the-counter) switch.

Chemical Type 2 (new ester, new salt, or other noncovalent derivative) represents the incorporation of different salts or esters, or other noncovalent derivatives (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance of an approved pharmaceutical ingredient into a marketed dosage form which represents a change to the listed drug (21 CFR 314.108(a)). We propose to identify this Chemical Type as a line extension because it describes a new version of the initial brand name listed drug.

Chemical Type 3 (new formulation of a previously approved drug) (not a new salt or new molecular entity) represents a change in the inactive ingredients (excipients) in a drug but no change in the amount of active ingredient. A new formulation may be a dosage form that contains the same active ingredient as was previously approved in a different dosage form as the initial brand name listed. Chemical Type 4 (new combination) represents a drug comprised of two or more components that are physically, chemically, or otherwise combined or mixed to produce a single drug product. We propose to identify this Chemical Type as a line extension because the new combination of the initial brand name listed drug of two or more active ingredients represents a new formulation of the initial brand name listed drugs that are combined to form one drug product.

Chemical Type 6 (new indication for an already marketed drug) represents a change in the description of use of an already marketed initial brand name listed drug in the prevention, treatment, or diagnosis of a recognized disease or condition. According to the National Institute for Health Care Management, research performed on drugs that are already on the market may reveal that they provide safe and effective treatments for diseases or conditions other than the indication(s) for which the product was originally approved. We propose to identify this Chemical Type as a line extension because there is an approval for a new indication that represents a change to the initial brand name listed drug.

Chemical Type 1 (new molecular entity) represents an active ingredient that has never before been marketed in the United States in any form. CMS proposes to use this Chemical Type to identify the initial brand name listed drug of a line extension.

Chemical Type 5 (new manufacturer) is assigned to an already marketed drug when it has: (1) A new manufacturer, or (2) a product that duplicates another manufacturer's already marketed drug product. We do not propose to consider this Chemical Type as a line extension because the change is a non drug-related change; rather, it is simply a transfer of the application from one manufacturer to another.

Chemical Type 7 (drug already marketed, but without an approved new drug application (NDA)) represents drugs that have not been approved by the FDA. We do not propose to consider this Chemical Type as a line extension because these drugs have not been approved by the FDA.

Chemical Type 8 (OTC (over-the-counter) switch) represents the process of transferring FDA-approved prescription medications to nonprescription, OTC status. We do not propose to consider this Chemical Type as a line extension because there is no new formulation of the initial brand name listed drug.

We plan to identify line extension drugs by using drug information that is publicly available on the FDA Web sites. As stated, CMS currently does not have the ability to identify whether a drug is a line extension and which drug is the initial brand name listed drug of the line extension drug based on manufacturers' MDRP submissions. Therefore, we plan to rely on drug information obtained from the FDA. In order for us to identify the line extension drugs using the FDA's drug information to calculate the additional rebate, there are essentially five criteria that we believe must be met. First, the line extension drug should be a single source drug or innovator multiple source drug. Manufacturers are already required to report to CMS if their nine-digit NDC drug is a single source drug, innovator multiple source drug, or non-innovator multiple source drug; therefore, we have the information to make this determination.

Second, the line extension drug has to be an oral solid dosage form of a single source drug or innovator multiple source drug in accordance with the definition of an oral solid dosage form previously provided.

Third, the line extension is identified based on Drugs@FDA's application file. Since we currently do not have the ability to identify whether the drug is the actual line extension of the initial brand name listed drug based on manufacturers' submissions, we propose to rely on the FDA's list of Chemical Types to identify which drug is a line extension drug, as described above. Because we do not approve new drugs or changes to a drug, using the Chemical Types would permit us to identify line extension drugs based on FDA data, since the FDA currently has an identifier for the Chemical Types in their Drugs@FDA's application file.

Fourth, the initial brand name listed drug of the line extension drug needs to be identified to calculate the Affordable Care Act unit rebate amount for the line extension drug. Again, as described above, we plan to use Chemical Type 1 to assist us in tracking back to the initial brand name listed drug of the line extension drug. Chemical Type 1 is assigned to an active ingredient that has not been marketed in the United States in any form; therefore, we have decided that this can be used as the initial brand name listed drug identifier. An active ingredient that has never been marketed in the United States would be approved by the FDA under a new NDA with no therapeutic equivalents, which would meet our definition of a single source drug. If there are therapeutic equivalents for the single source drug, then the drug category would change to an innovator multiple source drug in accordance with the rebate definition of an innovator multiple source drug. However, the innovator multiple source drug would retain the same NDA that was assigned to the single source drug that was first approved by the FDA. Additionally, the initial brand name listed drug has to be an oral solid dosage form per our definition of an oral solid dosage form.

Lastly, CMS currently collects drug product and pricing information by NDC, not by active ingredient. However, the FDA information is mainly available by active ingredient. Therefore, we need to identify the line extension drugs by NDC. In order for CMS to translate the active ingredient into NDC, a manual matching process has to be done to match the Drugs@FDA's application file against the FDA's Orange Book's product file: (1) To extract the Chemical Type and the application number, (2) to identify the oral solid dosage form, and (3) to obtain the FDA approval date for each drug. This file will then be matched with the FDA's NDC Directory's application and listing files to identify the NDC of each active ingredient to compile a master list of all initial brand name listed drugs and their line extension drugs by NDC. This master list will then be matched by NDC against the CMS' drug product file to identify which of CMS' NDCs are the initial brand name listed drugs and which are the line extension drugs.

Since NDCs enter and exit the MDRP frequently, we propose to update the master list based on the FDA's drug information on a quarterly basis and then match the master file against CMS' drug product file to identify new initial brand name listed drugs and new line extension drugs for the initial three quarters. Following these initial three updates, manufacturers will be responsible for identifying and reporting to CMS which of their NDCs is the initial brand name listed drug and which is the line extension drug. This is necessary to effectuate the line extension provisions of the Affordable Care Act. Additionally, as mentioned in the definition of a line extension drug, we propose that a new strength of the initial brand name listed drug would not qualify as a line extension drug. Furthermore, if we were to consider a new strength to be a line extension, it would be difficult to identify the first strength of the initial brand name listed drug because multiple strengths are often launched simultaneously and CMS would not be able to track back to the first strength of the initial brand name listed drug. We invite comments from the public on all aspects of this proposed policy.

We also do not plan to exclude a single source or innovator multiple source drug that receives 3-year exclusivity, pediatric exclusivity, or 7-year orphan drug exclusivity from the definition of a line extension drug. Drug manufacturers may separately obtain a 3-year exclusivity or a pediatric exclusivity. Drug manufacturers can reformulate a drug before it goes off patent by developing a new formulation such as a time-release version or by combining it with another existing drug, marketing it for another illness, or claiming a patent on an inactive ingredient. The 3-year exclusivity protection as indicated in sections 505(c)(3)(D)(iii), (c)(3)(D)(iv), (j)(5)(D)(iii), and (c)(5)(D)(iv) of the FFDCA, and at 21 CFR 314.108 is granted for a drug product that contains an active moiety that has been previously approved, when the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. This exclusivity requires conducting new clinical studies that are judged to be essential for approval of the change. Changes to a drug that qualify for this exclusivity are changes that we are considering for the definition of a line extension drug.

According to section 505A of FFDCA (Food and Drug Administration Modernization Act (FDAMA) and Best Pharmaceuticals for Children Act (BPCA), drug manufacturers can also apply for a pediatric exclusivity, which permits certain applicants to obtain an additional 6-month period of exclusivity on the use of a drug moiety in pediatric patients. We do not plan to exclude drugs that have this exclusivity from the definition of line extension drugs.

According to sections 526–527 of FFDCA and regulations at 21 CFR 316, drug manufacturers can apply for a 7-year orphan drug exclusivity. Orphan drug exclusivity promotes research and marketing for the development of drugs to treat rare diseases, defined as a disease affecting 200,000 or fewer patients in the United States, by granting a 7-year protection against competition for the designated orphan indication. We do not plan to exclude drugs that have this exclusivity from the definition of line extension drugs.

For the purpose of calculating the unit rebate amount (URA) for the line extension drug, the highest additional rebate as added by the Affordable Care Act for a line extension shall be referred to as the Alternative URA. We propose to interpret section 1927(c)(2) to provide that the URA determination is based on the greater of the Standard URA calculated under section 1927 of the Act without regard to the alternative rebate calculation provided in the Affordable Care Act, or the Alternative URA for the line extension drug under the Affordable Care Act. As previously stated, to effectuate the line extension provisions of the Affordable Care Act, we propose that both the initial brand name listed drug and the line extension drug are reported to CMS under the MDR program for the purpose of calculating the URA for a line extension drug.

Additionally, to calculate the Alternative URA, the line extension drug should be tracked back to the initial brand name listed drug. We recognize that there are multiple issues when it comes to tracking the line extension back to the initial brand name drug, such as when the line extension drug and the initial brand name listed drug are marketed by two different manufacturers or when the initial brand name listed drug has been terminated from the Medicaid drug rebate program. However, in accordance with the statute, manufacturers are responsible for calculating the Alternative URA for their line extension drugs.

We propose that when the initial brand name listed drug has been terminated that manufacturers should not be responsible for calculating the Alternative URA. The initial brand name listed drug must be active in the Medicaid drug rebate program to calculate the Alternative URA. We propose that we would calculate the URA for line extension drugs and will provide this amount to States on the quarterly rebate tape as in the current rebate process. However, in accordance with the current process, manufacturers are responsible for calculating and

making rebate payments to each State Medicaid Agency. Therefore, manufacturers are responsible for ensuring that all necessary product and pricing data, whether such information is for the initial brand name listed drug or the line extension drug, are exchanged between the manufacturer of the initial brand name listed drug and the manufacturer of the line extension drug to accurately calculate the URA for the line extension drug and provide rebates in accordance with the statute.

As provided in § 447.509(a)(5), section 2501(e) of the Affordable Care Act added section 1927(c)(2) of the Act to cap the URA at 100 percent of AMP for all brand name drugs. Therefore, this cap will also apply to the URA calculation for the line extension drugs as well.

Below are the proposed steps outlining how we plan to calculate the URA for a line extension drug. For clarification purposes, the highest additional rebate as added by the Affordable Care Act for a line extension shall be referred to as the ''Alternative URA'' and the URA calculation based on section 1927 of the Act (without regard to the alternative rebate calculation provided in the Affordable Care Act) shall be referred to as ''Standard URA.''

Step 1—Standard URA = Basic Rebate Amount + Additional Rebate Amount

Step 2—The Alternative URA is calculated as the product of the AMP of the line extension that is an oral solid dosage form and the highest additional rebate (calculated as a percentage of AMP) for any strength of the original drug.

Step 3—URA = The greater of (1) Standard URA or (2) the Alternative URA.

Step 4—Determine if the URA is greater than 100 percent of AMP.

a. If the URA is greater than 100 percent of AMP, then the URA = AMP.

b. If the URA is less than 100 percent of AMP, then use the calculated URA.

Below is an example of calculating the URA for a line extension drug.

Baseline AMP (line extension) = 100.00
AMP (line extension) = 300.00
Best Price (line extension) = 250.00
Baseline CPI–U = 170.00
CPI–U = 200.00

Step 1—Calculate Standard URA

Greater of

a. AMP × 23.1% = 300.00 × 23.1% = 69.30 or

b. AMP − Best Price = 300.00 − 250.00 = 50.00

The greater of the two results (69.30 or 50.00) is 69.30

Basic Rebate Amount for the line extension drug = 69.30

Additional Rebate Amount calculated under section 1927 of the Act Formula: If the [(Baseline AMP/Baseline CPI–U) × CPI–U] is less than the quarterly AMP, subtract [(Baseline AMP/Baseline CPI–U) × CPI] from the quarterly AMP to determine the additional URA. If the [(Baseline AMP/Baseline CPI–U) × CPI] is equal to or greater than the quarterly AMP, the additional URA is equal to zero.

[(Baseline AMP/Baseline CPI–U) × CPI–U] = 100/170 × 200 = 0.5882 × 200 = 117.65

117.65 is less than 300.00; then, 117.65 is subtracted from 300.00, 300.00 − 117.65 = 182.35

Additional Rebate Amount under section 1927 = 182.35

Standard URA = 69.30 + 182.35 = 251.65

Step 2—Calculate the Alternative URA

AMP (line extension) = 300.00

AMP (initial brand name listed drug) strength A = 280.00

AMP (initial brand name listed drug) strength B = 275.00

AMP (initial brand name listed drug) strength C = 270.00

Additional Rebate Amount (initial brand name listed drug) strength A = 200.00

Additional Rebate Amount (initial brand name listed drug) strength B = 125.00

Additional Rebate Amount (initial brand name listed drug) strength C = 110.00

Strength A additional rebate amount ratio = 200/280 = 0.7143

Strength B additional rebate amount ratio = 125/275 = 0.5636

Strength C additional rebate amount ratio = 110/270 = 0.4074

Highest additional rebate (calculated as a percentage of AMP) for any strength of the initial brand name listed drug = 0.7143

Alternative URA = Product of the AMP of the line extension that is an oral solid dosage form and the highest additional rebate (calculated as a percentage of AMP) for any strength of the original drug

Alternative URA = 300 × 0.7143 = 214.29

Step 3—URA of the line extension drug = the greater of

(1) Standard URA = 251.65 or

(2) Alternative URA = 214.29

URA of the line extension drug = 251.65

Step 4—Determine if the URA is greater than 100 percent of AMP.

AMP (line extension) = 300.00 = 100% × 300.00 = 300.00

URA = 251.65

URA is less than 100 percent of AMP; therefore, URA is equal to 251.65

3. Rebates for Drugs Dispensed Through Medicaid Managed Care Organizations (MCOs) (§ 447.509(b))

From the inception of the MDR program, section 1927(j)(1) of the Act exempted participating manufacturers from paying drug rebates for drugs dispensed to individuals enrolled in MCOs. The Affordable Care Act eliminated this exemption. Effective March 23, 2010, section 1927(b) of the Act, as amended by section 2501(c) of the Affordable Care Act requires manufacturers that participate in the drug rebate program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs. The requirement to collect rebates beginning March 23, 2010 is irrespective of any existing contracts States may have with MCOs. To comply with this section of the law and to assure that States fully collect these increased rebates, States must obtain utilization data from each Medicaid MCO in order for States to request quarterly rebates from manufacturers as well as report it in their quarterly utilization reports to CMS. This data reporting will also have other quality-related benefits for States and the Medicaid program in terms of providing timely information on drug utilization.

Section 2501(c) of the Affordable Care Act also amended section 1903(m)(2)(A) of the Act, effective March 23, 2010, by adding new conditions for Federal financial participation for MCO contracts including that:

- Any covered outpatient drug provided by the MCO is eligible for the rebates authorized under section 1927 of the Act;
- MCO capitation rates will be based on actual cost experience related to rebates and subject to Federal regulations at § 438.6 regarding actuarial soundness of capitation payments; and
- The MCO must report to the State information on the total number of units of each dosage form, strength and package size by NDC of each covered outpatient drug dispensed to Medicaid MCO enrollees and such other data that the Secretary determines necessary for the State to access the rebates authorized by this provision.

Section 2501(c) also made a conforming amendment to section 1927(j)(1) of the Act, effective March 23, 2010, to specify that certain covered outpatient drugs in this section are not subject to the rebate requirements if such drugs are both dispensed by health maintenance organizations (HMOs), including Medicaid MCOs that contract under section 1903(m), and are subject to discounts under section 340B of the Public Health Service Act.

In accordance with these revisions to sections 1927 and 1903 of the Act, we propose a new § 447.509(b). In § 447.509(b)(1), we propose to require participating manufacturers to pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for payment for such drugs. In § 447.509(b)(2), we propose that manufacturers are exempt from the requirement in paragraph (b)(1) if such drugs are dispensed by health maintenance organizations, including MCOs that contract under section 1903(m) of the Act, and subject to

discounts under section 340B of the PHS Act. In § 447.509(b)(3), we propose that a Medicaid MCO that is responsible for covered outpatient drugs dispensed to Medicaid beneficiaries must submit a report to the State within thirty days of the end of each quarter. We also propose the specific data that MCOs must include in such reports. It is expected that the States will ensure that the MCOs comply with providing timely utilization data to meet the State reporting requirements.

4. Federal Offset of Rebates (§ 447.509(c))

Section 2501(a)(2) of the Affordable Care Act added section 1927(b)(1)(C) of the Act, which provides that, effective January 1, 2010, the amount of the savings resulting from the increases in the rebate percentages described above will be remitted to the Federal government. These offset amounts are in addition to the amounts applied as a reduction under section 1927(b)(1)(B) of the Act.

We propose to calculate the offset as described below.

For single source or innovator multiple source drugs that are subject to a minimum rebate percentage of 23.1 percent of AMP:

- If the difference between AMP and best price is less than or equal to 15.1 percent of AMP, then we propose to offset the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).
- If the difference between AMP and best price is greater than 15.1 percent of AMP but less than 23.1 percent of AMP, then we propose to offset the difference between 23.1 percent of AMP and AMP minus best price.
- If the difference between AMP and best price is greater than or equal to 23.1 percent of AMP, then we propose to not take any offset amount.

For single source or innovator multiple source drugs that are blood clotting factors and drugs approved by the FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

- If the difference between AMP and best price is less than or equal to 15.1 percent of AMP, then we propose to offset the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).
- If the difference between AMP and best price is greater than 15.1 percent of AMP but less than 17.1 percent of AMP, then we propose to offset the difference between 17.1 percent of AMP and AMP minus best price.
- If the difference between AMP and best price is greater than or equal to 17.1 percent of AMP, then we propose to not take any offset amount.

In the September 28, 2010 State Medicaid Director (SMD) letter, #10–019, we stated that for a drug that is a line extension of a brand name drug that is an oral solid dosage form, we planned to apply the same offset calculation as described above to the basic rebate. Further, we planned to offset only the difference in the additional rebate of the reformulated drug based on the calculation methodology of the additional rebate for the drug preceding the requirements of the Affordable Care Act and the calculation of rebates for the reformulated drug, if greater, in accordance with the Affordable Care Act. If there is no difference in the additional rebate amount in accordance with the Affordable Care Act, then we do not plan to take any offset amount. (A copy of the SMD letter can be found at *http://www.cms.gov/smdl/downloads/SMD10019.pdf*.)

However, after further review of the offset provisions in section 2501 of the Affordable Care Act, we have decided to reconsider our instructions regarding the calculation of the offset provisions for line extension drugs to reflect the difference between the URA for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act. If there is no difference between the URA for the line extension drug based on the Affordable Care Act and URA calculation based on the applicable rebate percentage in section 1927 prior to the Affordable Care Act, then we do not plan to take any offset amount. If there is a difference then we will offset the amount of that difference.

For noninnovator multiple source drugs, we plan to offset an amount equal to 2 percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP) since these drugs are unaffected by best price.

For covered outpatient drugs that are dispensed to Medicaid MCO enrollees, we propose to offset the non-Federal share limited to the difference between the rebate percentages in effect outside of the MCO context on December 31, 2009 and the rebate percentages in effect on January 1, 2010, as described previously. Specifically, we planned for States to retain the non-Federal share of rebates below the 15.1 percent rebate percentage for single source or innovator multiple source drugs and 11 percent for noninnovator multiple source drugs as in effect on December 31, 2009. In addition, we planned for States to retain the non-Federal share of the amount above the revised minimum rebates for brand name drugs.

Additionally, we do not plan to offset the non-Federal share of any supplemental rebate States may receive above the increased Federal rebate percentages.

To ensure efficiency and uniformity, CMS plans to calculate a unit rebate offset amount (UROA) that will, on a quarterly basis, identify the amount of offset per unit of drug at the 9-digit NDC for States. The UROA will be provided to States in a manner similar to how States currently receive the URA every quarter. States will then match the UROA with the number of units of the drug for which they receive payment from a manufacturer to determine the Quarterly Rebate Offset amount (QROA) for that drug. All QROAs for all drugs of all manufacturers will then be added together to determine the Total QROA. This then will be the amount that States offset on the Quarterly Expenditure reports. Adjustments to the UROA will be treated as prior period adjustments (PPAs) and will be reported to the States the same way that URA PPAs are currently transmitted.

Please note that the offset provision would also apply to the Territories that participate in the MDR program.

H. Requirements for Manufacturers (§ 447.510)

In the Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs final rule published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments to delete references to § 447.504 ''Determination of AMP'' from § 447.510 ''Requirements for Manufacturers''. In this proposed rule, we are proposing conforming regulatory amendments to add regulatory text to § 447.510. Specifically, those references that will be added are at § 447.510(a)(1), § 447.510(c)(2)(i), and § 447.510(d)(2).

We are also proposing a conforming amendment to § 447.510(g) to clarify that the electronic format in which the product and pricing data is submitted to CMS must be submitted in a format designated by CMS.

1. Failure to Report Quarterly AMP (§ 447.510(a)(5))

In an effort to better ensure timely quarterly AMP reporting at the end of each rebate period, in accordance with the statute at section 1927(b), a manufacturer that fails to submit and certify a quarterly AMP to CMS for a

product by the 30th day after the end of each quarter will be reported to the OIG. We propose, in accordance with the statutory requirements at section 1927(b)(3)(C)(i), that manufacturer will be subject to a civil monetary penalty for each product not reported on the thirty-first day. Please see the OIG's Special Advisory Bulletin issued in September 2010 regarding reporting AMP timely, *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf*.

Additionally, we are considering adding regulatory guidance on suspension and termination for manufacturers that do not report quarterly AMP on a timely basis or are otherwise out of compliance with rebate requirements. We have considered a number of formal and informal administrative procedures similar to those set forth in 42 CFR part 498 or 42 CFR 430.18, which would permit an opportunity for reconsideration and administrative appeals. We are considering the appropriate terms and procedures for suspension and termination and, therefore, we invite comments from the public.

2. Reporting Revised Monthly and Quarterly AMP, Best Price, Customary Prompt Pay Discounts, or Nominal Prices (§ 447.510(b))

In this proposed rule, we propose to revise the 12-quarter rule filing limitation currently in place for manufacturers to report revisions to their quarterly AMP, best price, customary prompt pay discounts, or nominal prices. We initially established a time limit of 12 quarters for manufacturers to report revisions to their quarterly pricing data. The 12-quarter period established a time limit within which manufacturers are responsible for reporting revisions to pricing data in part to decrease associated administrative burdens on manufacturers and States. Despite the effective date of January 1, 2004 for the 12-quarter rule, we are still receiving requests from manufacturers to make revisions to the pricing data that fall outside of the 12-quarter period. Therefore, we propose that any request from manufacturers submitted to CMS to revise the monthly and quarterly AMP, best price, customary prompt pay discounts, or nominal prices that are outside of the 12-quarter filing deadline will be considered, only if it falls within one of the following categories:

- The change is a result of the drug category change or a market date change.
- The change is an initial submission for a product.
- The change is due to termination of a manufacturer from the MDR Program for failure to submit pricing data and must submit pricing data to reenter the program.
- The change is due to a technical correction (such as a keying error), that is, not based on any changes in sales transactions or pricing adjustments from such transactions.
- The change is to address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS, applicable law or regulations, or an OIG or DOJ investigation.

We propose that § 447.510(b)(1) be revised to clarify that a manufacturer is required to report to CMS any revisions to correct AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12-quarters from the quarter in which the data were due. The 12-quarter limit is meant to be a specific time limit for any revision. Any revision request, except for those falling within the exceptions noted above, must be made within this 12-quarter time period. We propose to add to § 447.510(b) that any revision request that falls outside of the 12-quarter time limit will not be considered by CMS, unless it falls under the above five criteria. We also propose to revise timeframe for reporting revised monthly AMP in § 447.510(d)(3) to clarify that the only exceptions to the 36-month limit for reporting monthly AMP would be considered by CMS if it falls under the same five criteria.

We are contemplating whether to allow manufacturers that have revisions to their pricing data beyond the 12-quarter limit that meet the five criteria above to revise their pricing data on a retroactive basis: (1) Without any time limits back to beginning of the program, 1991, or (2) with some time limits outside of the 12-quarter restrictions. In other words, we are considering whether we should impose a timeframe as to how far back we should allow manufacturers to make this revision. We invite public comments on suggestions as to how far back we should allow manufacturers to make revisions to their pricing data if their request meets one of the above five exceptions.

Additionally, to ensure that any revision to pricing data is consistent across the monthly and the quarterly AMP data, if a revision request is submitted for monthly AMP and AMP units, then a revision request is also required for quarterly AMP. In addition, if a revision request is submitted for quarterly AMP, then a revision request is also required for monthly AMP and AMP units.

3. Recalculations Including Good Cause

Separate from pricing data revision request, we are proposing an option for manufacturers to submit a recalculation request outside of the 12-quarter time limit based on good cause, which would permit a manufacturer to revise its methodology for calculating AMP and best price. Our regulations at § 447.510(b) specify that manufacturers have a 12-quarter time limit to report price revisions. Manufacturers are responsible for reporting any revisions to AMP or best price within the 12 quarter limit, which begins with the quarter in which the data was due. As is the case with all pricing data submitted under the MDR program, if a subsequent review of the manufacturers' pricing data by CMS, the OIG, or another authorized government agency determines or reveals that adjustments or revisions are necessary irrespective of the quarter, the manufacturer is responsible under the statute to comply with that determination. Based on questions from manufacturers often as a result of False Claims Act concerns, we have considered allowing manufacturers to submit recalculations of AMP and best price outside of the twelve quarter time limit due to good cause. We plan to establish a good cause option to allow manufacturers to submit their pricing data due to a recalculation of the methodology for calculating AMP and best price outside of the 12-quarter time limit to address underpayments and potential liability regarding those underpayments that may extend outside of that 12-quarter period. We are considering proposing a ''good cause'' option to extend the time limit for filing a recalculation request, similar to that used in Medicare. We invite comments from the public on this option.

4. Base Date AMP (§ 447.510(c)(1) to § 447.510 (c)(4))

In the 2007 AMP final rule, we allowed manufacturers to report a revised base date AMP to CMS within the first four full calendar quarters following the publication date of the final rule. To differentiate between the timeframe when manufacturers were allowed to report revised base date AMPs in accordance with the DRA-based definition of AMP and the timeframe described below, we propose to revise § 447.510(c)(1) and § 447.510(c)(2) by inserting ''DRA'' before base date AMP where it occurs. We also propose to remove the notation ''[OFR: insert publication date of the final rule]'' and replace it with ''July 17, 2007'' in § 447.510(c)(1).

The Affordable Care Act significantly revised the definition of AMP to mean for a covered outpatient drug (including those sold under section 505(c) of the FFDCA), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. To reflect the changes to AMP as set forth in the Affordable Care Act, we propose to allow manufacturers to recalculate base AMP in accordance with the definition of AMP in § 447.504 of this subpart. Base AMP is used in the calculation of the additional rebate described in section 1927(c)(2) of the Act. This additional rebate is defined as the difference between the current quarterly AMP reported to CMS and the base date AMP trended forward using the CPI–U. We propose this revision so that the additional rebate would not increase solely due to the changes in the definition of AMP. We propose giving manufacturers the option to report a recalculated base date AMP based on the Affordable Care Act. We propose to allow manufacturers the option to decide whether they will recalculate and report to CMS an Affordable Care Act base date AMP in light of the revised definition of AMP or continue to use their existing base AMP. We propose to give manufacturers this option because we are aware that some manufacturers may not have the actual data needed to recalculate their base date AMP or may find the administrative burden to be more costly than the savings gained. We propose to provide manufacturers with the option to report the recalculated Affordable Care Act base date AMP for a period of four full calendar quarters beginning with the first full quarter after the publication of the final rule.

5. Calculation of Monthly AMP (§ 447.510(d)(2))

Section 1927(e)(5) of the Act specifies that the Secretary is to implement a smoothing process for AMP, which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological under Medicare Part B. The Medicare Part B regulations at § 414.804(a)(3) specify that the ASP methodology for smoothing lagged price concessions requires that manufacturers calculate the total lagged price concessions for the previous 12-month period and convert the dollar amount to a percentage of sales over that same 12-month period. This percentage is then applied to the current quarter's sales to estimate the lagged price concessions for that quarter.

Therefore, we are proposing manufacturers would be required to use a 12-month rolling percentage to estimate the value of lagged price concessions in their calculations of the monthly and quarterly AMPs.

Specifically, we are proposing that a manufacturer's monthly AMP is to be calculated based on the weighted average of the prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units of the drug sold, excluding goods or any other items specifically excluded in the statute or regulations. The drug unit is the lowest identifiable amount (for example, tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams) as reported by the manufacturer.

Monthly AMP should be calculated consistent with this methodology, based on the best data available to the manufacturer at the time of submission.

In calculating monthly AMP, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. Following is an example of how manufacturers would calculate the monthly AMP by using a 12-month rolling percentage to estimate the lagged price concessions:

- Total lagged price concessions over the most recent 12-month period = $150,000.
- Total sales subject to AMP reporting for the most recent 12-month period = $600,000.
- $150,000/$600,000 = 0.25 (or 25 percent).
- The result (25 percent) is the percentage manufacturers subtract from their total sales for that month to estimate lagged price concessions for that month.
- Current month sales = $50,000.
- $50,000 × 25 percent (estimated percentage of lagged price concessions) = $12,500 estimated lagged price concessions for the current month.
- $50,000 − $12,500 = $37,500 (net total sales after subtracting estimated lagged price concessions for the current month).
- Units sold during current month = 10,000 units.
- $37,500/10,000 units = $3.75 AMP.

The only differences between the proposed AMP smoothing process methodology and the ASP smoothing process methodology is that the ASP smoothing process is applied on a quarterly basis whereas the AMP smoothing process will be applied on a monthly basis and by statutory definition, the ASP calculation includes more sales than in the AMP calculation. We believe this process will result in more stable AMP calculations on a month to month basis, because the estimated lagged price concessions will increase as sales increase, and likewise as sales decrease. In addition, it meets the statutory requirement that the AMP smoothing process be similar to the smoothing process used in determining the ASP.

6. Manufacturer Reported AMP Units (§ 447.510(d)(6))

Section 2503(b) of the Affordable Care Act requires manufacturers to submit to CMS on a monthly basis the total number of units that are used to calculate the monthly AMP for each covered outpatient drug no later than 30 days after the last day of each prior month. We propose that the manufacturer report monthly AMP units as the number of units that are used to calculate the monthly AMP to be reported to CMS. Additionally, in order to be consistent and to implement the rebate and FUL provisions, the monthly units should be of the unit type that is reported as part of the product data and the unit type used in the quarterly and monthly AMP calculation for each NDC to ensure consistency in the calculation as well as the reporting of the monthly and quarterly AMP and the AMP units.

7. Failure To Report Monthly AMP and AMP Units (§ 447.510(d)(7))

Currently a manufacturer must submit a monthly AMP to CMS no later than 30 days after the last day of the prior month. Under the Affordable Care Act, a manufacturer will be required to submit the total number of units that are used to calculate the monthly AMP no later than 30 days after the last day of the prior month. To ensure that each manufacturer is reporting timely to CMS, a manufacturer that fails to submit and certify monthly AMP and the AMP Units for a product to CMS by the 30th day after the end of each month will be reported to the OIG. We propose, in accordance with the statutory requirements at section 1927(b)(3)(C)(i), that the manufacturer will be subject to civil monetary penalty for each product not reported on the thirty-first day. Please see the OIG's Special Advisory Bulletin issued in September 2010 regarding reporting AMP timely, *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin_AMP_ASP.pdf*.

Additionally, we are considering adding regulatory guidance on suspension and termination for manufacturers that do not report monthly AMP and AMP Units on a timely basis. As noted previously, we have considered a number of formal and informal administrative procedures similar to those set forth in 42 CFR part 498 or 42 CFR 430.18. Therefore, we invite comments on these procedures from the public.

I. Requirements for States (§ 447.511)

Section 1927(b)(2)(A) of the Act specifies that States are required to report to each manufacturer, not later than 60 days after the end of each rebate period, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed, and to promptly transmit a copy of such report to the Secretary. Effective March 23, 2010, the Affordable Care Act amended section 1927(b)(2)(A) of the Act to require that the State include in those reports, the information reported by each Medicaid MCO.

We propose a new § 447.511 to clarify the requirements for States. In § 447.511(a), we propose to list the data that the State must provide to participating drug manufacturers. We further propose that States must submit this data within 60 days after the end of each quarter.

In § 447.511(b), we propose that the States report drug utilization data as defined in § 447.511(a) to CMS on a quarterly basis.

In § 447.511(c), we propose that a State that has participating Medicaid MCOs, which includes covered outpatient drugs in its capitated arrangements with the MCOs, report data listed in §§ 447.511(a) for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is responsible for coverage of such drugs under section 1903 of the Act. We further propose that this data be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

With the proposed change in the definition of ''State'' to include the territories, we recognize that these requirements would ultimately be applicable to the territories. We are also aware that it will take the territories time in order to upgrade their computer systems and come into compliance with the MDR program requirements. Therefore, we are proposing that the requirements discussed in this section would not be effective for the territories until one year after the first day of the first full quarter after the publication of the final rule.

J. Drugs: Aggregate Upper Limits of Payment (§ 447.512)

In the ''Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs'' final rule that we published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments to remove references to § 447.514 ''Upper limits for multiple source drugs'' from § 447.512 ''Drugs: Aggregate upper limits of payment''. We are proposing regulatory amendments to add those references back into the regulatory text of § 447.512.

Currently, § 447.512(b) establishes guidelines for payment levels that the agency has determined to be appropriate. At § 447.512(b)(1), we propose to replace the term ''EAC'' with the term ''AAC'' as we have previously proposed to replace ''estimated acquisition cost'' with ''actual acquisition cost''. Further, we propose to add the word ''professional'' to the description of dispensing fee in this section.

We are proposing these changes in terminology in part because we believe that using the AAC in determining the drug ingredient component of the reimbursement formula will be more reflective of actual prices paid, as opposed to unreliable published compendia pricing.

Currently, States usually determine EAC for single source drugs and drugs other than multiple source drugs for which either a specific Federal Upper Limit (FUL) or State maximum allowable cost (SMAC) has been established by paying the lower of:

- A percentage decrease applied to a commercially published reference price such as average wholesale price (AWP) or a percentage increase to wholesale acquisition cost (WAC), or
- The pharmacy's usual and customary charge to the public.

Using a commercially published reference price as the basis for Medicaid pharmacy reimbursement has been problematic for both the States and the Federal government. Several reports issued by the OIG have shown that AWP is often a significantly inflated price, and not necessarily reflective of a pharmacy's actual purchase price for a drug. (OIG Audit reports—A–06–00–00023, A–06–01–00053, A–06–02–00041).[3]

Further, AWP raises other concerns when used as a basis for payment, as evidenced by litigation relating to its use. See *New England Carpenters Health Benefits Fund* v. *First DataBank,* 602 F.Supp.2d 277, 279 (D.Mass. 2009) (in which the Court stated that ''despite its name, AWP is not an average of prices charged by wholesalers to providers (such as pharmacies and doctors) and it does not necessarily bear any relationship to any prices actually charged in the marketplace.'')

At this time the commercial compendium, First DataBank, Inc. has reported that it is scheduled to cease the publication of AWP as of September 2011. While other drug pricing compendia may publish both AWPs and WACs, we have concerns, based on the previously referenced OIG reports, that these prices will not be based on actual costs or reflect actual prices that providers pay for these drugs.

Certain States, in order to calculate more accurate payment rates, have already begun to base some of their drug prices on survey data based on pharmacy invoice prices.[4] We believe that these surveys of pharmacy providers will assist States in determining valid reference prices from which to develop drug ingredient reimbursement. Section 447.518 of this proposed regulation provides further discussion about how States can develop and justify their AAC.

K. Upper Limits for Multiple Source Drugs (§ 447.514)

Section 2503(a) of the Affordable Care Act revises the definition of ''multiple source drug'' established in section 1927(k)(7)(A)(i) of the Act to mean, for a rebate period, a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent (under the FDA's most recent publication of the Orange Book), is pharmaceutically and bioequivalent, as determined by the FDA; and is sold or marketed in the United States during the period. We propose this definition be included in § 447.502 ''Definitions.'' In accordance with these statutory requirements, we also propose that at least two

[3] *http://oig.hhs.gov/oas/reports/region6/60000023.htm. http://oig.hhs.gov/oas/reports/region6/60100053.htm. http://oig.hhs.gov/oas/reports/region6/60200041.htm.*

[4] Alabama-10–008, effective date September 22, 2010 (Alabama AAC Survey information available at *http://al.mslc.com/Faqs.aspx*) and Oregon-10–13, effective date January 1, 2011 (Oregon AAC Survey information available at *http://or.mslc.com/AACList.aspx* or *http://or.mslc.com/uploadedFiles/Oregon/OR%20Communications%20Plan.pdf*).

therapeutically equivalent (''A'' rated) formulations must be listed in the FDA's Orange Book in order for the drug to be defined as a multiple source drug.

Also, section 2503(a) of the Affordable Care Act revised section 1927(e) of the Act to change the requirement for a FUL to be established for each multiple source drug for which the FDA has rated two or more products therapeutically and pharmaceutically equivalent, to three or more products, regardless of other formulations. In accordance with this statutory requirement, we are proposing in § 447.514(a)(1) that a FUL be established for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. We propose that the FUL will be calculated, in accordance with section 1927(e)(4) of the Act, using only therapeutically and pharmaceutically equivalent drugs. Any other formulations of the drug listed in the FDA Orange Book that are not therapeutically and pharmaceutically equivalent to the reference listed drug, for example, ''B'' rated drugs, will not be used in the calculation of the FUL.

For purposes of applying this rule, we consider drug products to be therapeutically equivalent if they are identified as A-rated in the current edition of FDA's Orange book. Per the FDA's Orange Book, drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration. In general, with limitations that may apply to particular patients, the FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.[5]

''B'' rated drugs are drugs that FDA does not consider therapeutically equivalent to other pharmaceutically equivalent products. Per the FDA Orange Book, drug products designated with a ''B'' code fall under one of three main policies:

- The drug products contain active ingredients or are manufactured in dosage forms that have been identified by FDA as having documented bioequivalence problems or a significant potential for such problems and for which no adequate studies demonstrating bioequivalence have been submitted to FDA; or
- The quality standards are inadequate or the FDA has an insufficient basis to determine therapeutic equivalence; or
- The drug products are under regulatory review.[6]

Therefore, we propose that any alternative formulations not therapeutically equivalent to the reference listed product in FDA's Orange Book will not be subject to the FUL. We propose that the FUL will only be applied to those drugs that are therapeutically equivalent to the reference listed drug, that is, ''A'' rated drugs that are pharmaceutically equivalent to the reference listed drug; however, we are inviting comments on the issue of the FUL being applied to drugs that are not therapeutically equivalent to the reference listed drug.

In accordance with section 2503(a) of the Affordable Care Act, we are proposing that the FUL will be calculated as no less than 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products. We plan to determine the weighted average on the basis of manufacturer submitted utilization of the most recently reported monthly AMPs for all therapeutically equivalent innovator (I) and non-innovator (N) multiple source drug products that, by definition elsewhere in this proposed rule, are available for purchase by retail community pharmacies on a nationwide basis.

In computing the FUL, we would use the monthly AMP and the monthly utilization data submitted by the manufacturer. Using the monthly AMP data will provide for the timeliest pricing data and allow revisions to the FUL list on a monthly basis. In addition, the statute requires us to use the recently reported monthly AMPs to calculate the FUL. It will also permit us to update the FULs on a timely basis in accordance with the provisions of section 1927(f)(1)(B) of the Act.

The currently reported AMP is based on the nine-digit NDC and is specific to the product code, combining all package sizes of the drug into the same computation of AMP. Inasmuch as this computation is used to determine the AMP that is currently reported by manufacturers, we propose to use this AMP for the FUL calculation.

Section 2503(a) of the Affordable Care Act redefines AMP, effective October 1, 2010. Due to this change in the determination of AMP, and the requirement that the monthly AMP under this calculation first be reported for October 2010 data, CMS received these revised monthly AMPs and utilization data beginning in November 2010. While the law required manufacturers to change their calculation of AMP effective October 1, 2010, we did not issue FULs based on this data. Further, we decided to not use data submitted before December 15, 2010 to calculate the FULs, as there was some concern within the industry that manufacturers may have based their AMP calculation on prior AMP regulations that were in effect until December 15, 2010.

In the interim, CMS has been reviewing monthly pricing data submitted and continues to work towards increasing labeler compliance of reporting data timely. When establishing a FUL, we propose to disregard the AMP of an NDC which has been terminated. We note that we have published four sets of draft FUL files on our Web site. We invited comments from stakeholders and we have posted several of those comments and our responses to those comments at *http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits-.html*.

In calculating the FUL, we propose to eliminate covered outpatient drugs designated as single source (S) drugs from the FUL calculation because the FUL in the statute, is based on the weighted average of AMPs for multiple source drugs, and, single source drugs are, by definition, not multiple source drugs, and should be reported according to the statute. We note here that there should be no instances of an (S) drug in a FUL group, as labelers should be reporting drugs that are therapeutically equivalent drug products as (I) drugs, and statutory provisions require us to use only multiple source drugs when calculating the FUL. We propose to rely on manufacturer submitted data in determining if a drug product is used in the calculation of the FUL, that is, if it is an (I) or an (N) drug. CMS has issued guidance previously, and more recently, requested drug labelers to review the drug category for which their NDC is reported, and if they determine that an incorrect drug category has been reported to CMS for a product, they are required to request a drug category change for the product. We have also recently reminded labelers that changing a drug category from (S) to (I)

[5] *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.*

[6] *Id.,* vii.

has no prior approval requirement from CMS, and that these changes can and should be made timely by the labeler via the Drug Data Reporting for Medicaid system. See Manufacturer Releases No. 80 and No. 82 (issued on January 5, 2010 and November 1, 2010, respectively). Accordingly, we propose to include pharmaceutically and therapeutically equivalent innovator multiple source and non-innovator multiple source drugs when calculating the weighted average of monthly AMPs.

In light of our experience with the implementation of section 1927 of the Act, we believe that when a drug product has at least one other FDA-approved, pharmaceutically and therapeutically equivalent drug product, the drug is generally sold or marketed on a nationwide basis. Further, we believe that when a drug product has at least two FDA-approved, pharmaceutically and therapeutically equivalent drug products, that all retail community pharmacies would be able to purchase at least one of the drug products through a pharmaceutical market channel of distribution, including, but not limited to, a national, regional, or specialty drug wholesaler, chain warehouse, group purchasing organization, or directly from the drug manufacturer. We do not believe it is necessary that each retail community pharmacy have the ability to purchase every supplier's pharmaceutically and therapeutically equivalent drug in order for the Secretary to calculate the FUL for pharmaceutically and therapeutically equivalent multiple source drug products, provided the retail community pharmacy is able to purchase at least one of the drug products. We invite comments on the issue of national availability in the context of the FUL requirements and request comments regarding specific instances where such drug products are not available for purchase by retail community pharmacies on a nationwide basis. Further, as noted previously, we will not be using the AMP of a terminated NDC to set the FUL beginning with the first day of the month after the termination date reported by the manufacturer to CMS, and a weighted average, using the monthly AMP unit data, will be used to calculate the FUL.

We further propose to establish the upper limit reimbursement at 175 percent of the weighted average of monthly AMPs in the aggregate.

We analyzed the FUL and determined that the weighted AMP multiplied by 175 percent including (I) and (N) drugs would be an adequate reimbursement methodology, per the below chart that shows the analysis of the fiscal year 2009 estimated aggregate expenditures, comparing reimbursement using the DRA AMP-based FUL methodology to the pre-DRA FUL methodology, weighted AMP FUL, weighted AMP multiplied by 175 percent, and Indiana's State Maximum Allowable Cost (IN's SMAC). Utilization data provided to CMS by States were used to calculate the total number of units reimbursed for each drug group and was multiplied by the DRA AMP-based FUL, the pre-DRA FUL, the weighted AMP FUL, the weighted AMP multiplied by 175 percent FUL, and IN's SMAC to get the aggregate limit for each drug group based on each formula used to calculate the FUL. We chose IN's SMAC as one of the formulas in our comparative analysis because IN's SMAC, in accordance with its State plan, is developed by using pharmacy invoices, and is equal to the average AAC per drug adjusted by a multiplier of at least 1.0. IN's Office of Medicaid Policy and Planning reviews the SMAC rates on an ongoing basis, and adjusts the rates as necessary to reflect prevailing market conditions and ensure reasonable access by providers to drugs at or below the applicable SMAC rate. Currently, IN adjusts their average AAC using a multiplier of 1.2. There are approximately 550 drug groups reflected in this estimated analysis. Because utilization data are reported on a quarterly basis while the DRA AMP-based FUL is generated on a monthly basis, the estimated aggregate limit is calculated for each month using the quarterly utilization data averaged out by the 3 months. This calculation was done for all four quarters of fiscal year 2009, which was then aggregated to get the fiscal year 2009 estimated aggregate expenditure for each FUL formula. Each bar represents the aggregate expenditure while the percentage amount represents the comparison to the DRA AMP-based FUL.

The estimated aggregate is calculated with the availability of at least three therapeutically equivalent drug products.

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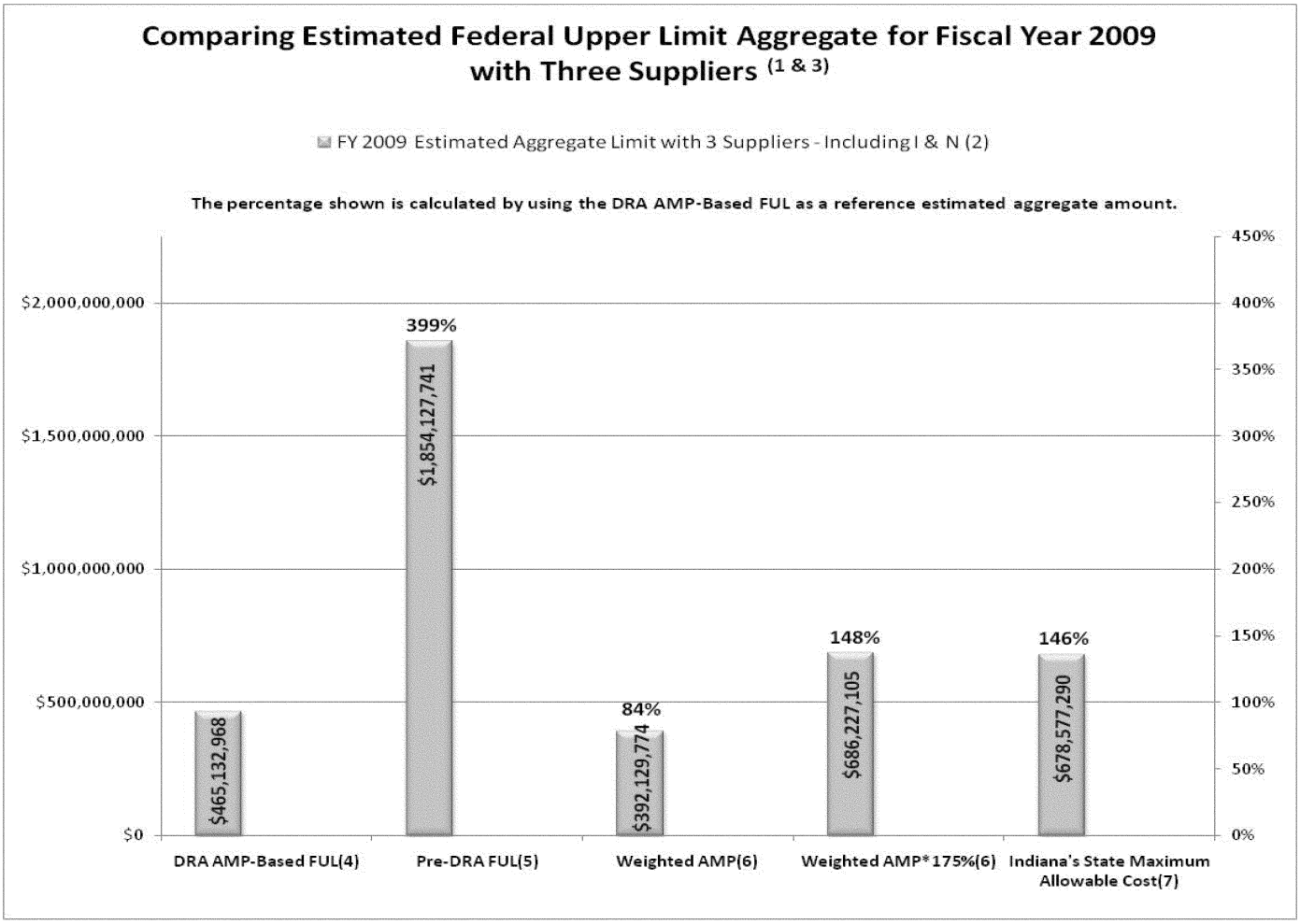

Footnotes:

1. Each FUL group is established based on the DRA criteria that if all formulations of a multiple source drug are identified as A-rated in the FDA's most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), then there must be at least 2 A-rated versions of the drug.
2. I is for innovator multiple source drug and N is for noninnovator multiple source drug.
3. Calculations excluded drug products that were not therapeutically equivalent, had NDCs with AMP not reported, and NDCs with zero utilization. Additionally, calculation of each formula is based on the availability of three or more suppliers at the NDC-9 level and two different product codes are considered as two different suppliers.
4 DRA AMP-based FUL is based on the DRA criteria to calculate FUL, which included the availability of two suppliers and included a 40% outlier.
5. Pre-DRA FUL is based on FUL issued by CMS on September 25, 2009.
6. States' utilization data are used to calculate weighted AMP (WAMP) and the estimated aggregate limit: FY 1Q09 = 3Q08 Utilization, FY 2Q09 = 4Q08 Utilization, FY 3Q 2Q09 = 1Q09 Utilization, and FY 4Q09 = 2Q09 Utilization. An NDC is excluded if there is no utilization on that NDC.
7. Indiana State Maximum Allowable Cost effective as of October 23, 2009 was obtained from Indiana Pharmacy website, http://www.indianamedicaid.com/ihcp/PharmacyServices/list.asp. Please note that when making the determination for their State MAC, IN does not use innovator multiple source drugs.

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In a recent report issued by the Government Accountability Office (GAO) ''Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act'' (GAO–11–141R), the GAO found that Affordable Care Act FULs were higher than the undiscounted average retail pharmacy acquisition costs for 34 of the 40 drugs in the sample and was 35 percent higher than the sum total of the undiscounted pharmacy acquisition costs for these drugs, which would have also lowered the Medicaid expenditures on these drugs by 60 percent.

Furthermore, the GAO stated that the Affordable Care Act FULs could further exceed the retail pharmacy acquisition costs if the GAO was to take into consideration factors that were not used in the analysis of this report. The GAO stated that the acquisition cost data the GAO used do not include rebates paid by manufacturers to retail pharmacies. If included, any applicable rebates would have reduced the average retail acquisition costs for the drugs in the

sample; thus, the Affordable Care Act FULs would exceed the retail pharmacy acquisition costs by more than 35 percent. Additionally, if the Affordable Care Act FULs were to be calculated using the new AMPs based on the revised definition under the Affordable Care Act, then the Affordable Care Act FULs would have exceeded the retail pharmacy acquisition costs by even greater than 35 percent.

Therefore, based in part on the findings from the GAO report, we believe that calculating the Affordable Care Act FULs at weighted AMP times 175 percent would be a more than adequate reimbursement to the pharmacies.

The Affordable Care Act's revisions to section 1927(e)(5) of the Act allow but do not require the Secretary to calculate the FUL above the 175 percent of the weighted average of AMPs. Based on the data described above, we have decided to calculate the FUL at 175 percent. Using any percentage greater than 175 percent would further inflate the aggregate expenditures depicted on our chart. As provided in the chart above, calculating the FUL as 175 percent of the weighted AMP, including multiple source drugs, that is, I and N drugs, yields a reimbursement that is just slightly higher than Indiana's SMAC which is based on actual pharmacy acquisition data and is consistent with the GAO's findings that these levels are generally in excess of the actual acquisition cost of the drug. Because it is virtually impossible to price each drug at its actual acquisition cost to each pharmacy and reflect the changes in the marketplace at the same time they occur, the upper limit reimbursement continues to be established in the aggregate. States maintain their right to adjust reimbursement on a drug by drug basis to the extent that the State's reimbursement remains under the aggregate upper limit.

Thus, using a factor of 175 percent of weighted monthly AMPs should yield adequate reimbursement for pharmacy providers, while achieving cost savings for the Medicaid program compared to pre-DRA FULs.

L. FULs Smoothing Process

As discussed previously, section 2503(a) of the Affordable Care Act amended the FUL provision at section 1927(e)(5) of the Act to specify that the Secretary shall implement a smoothing process for AMPs which shall be similar to the smoothing process used in determining the ASP of a drug or biological under Medicare Part B. In order to ensure that the smoothing process being utilized by manufacturers is uniform and consistent with statutory requirements, as was discussed in Manufacturer Release #83, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. This guidance is restated in the preamble language of this proposed rule and would be codified in proposed regulatory text at § 447.510(d)(2).

We also considered whether to implement a further smoothing process applicable to the FUL calculation. While the statute requires us to use the most recently reported monthly AMPs to calculate the FUL, it did not address smoothing the FULs themselves. However, after reviewing the first months of the draft FULs, which we posted on our Web site, we note that there is some variability in the FULs from one month to the next. Therefore, we looked at various approaches for smoothing the FULs, as follows. We considered:

- Using the mean of the most recently reported monthly AMPs over a specific period of time; for example, three months, to minimize the variability of the monthly AMPs before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- Using the median of the most recently reported monthly AMPs over a specific period of time; for example, three months, before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- Weighting the most recently reported monthly AMPs over a specific period of time; for example, three months, to minimize the variability of the monthly AMPs before weighting the monthly AMPs and multiplying the result by 175 percent to calculate the FUL;
- After calculating the FUL as the weighted average of monthly AMPs in a FUL product group, calculate the mean of the FULs for each product group over a specific period of time; for example, three months, to smooth the FUL if there is variability in the calculated FUL from month to month;
- Excluding outlier monthly weighted AMPs that are less than a certain percentage of the next highest monthly AMP for therapeutically and pharmaceutically equivalent products;
- Excluding a monthly AMP if the percent change is greater than a certain percentage when compared to the last manufacturer reported and certified monthly AMP;
- Increasing the calculated FUL by a certain percentage if the FUL is less than a certain percentage from the last FUL;
- Calculating the FUL using only monthly weighted AMPs within a FUL Product Group that have a certain percentage of the market share based on the monthly AMP units reported to us by drug manufacturers.
- Using the mean of the monthly weighted average of AMPs for an entire FUL Product Group over a specific period of time; for example, three months; and/or,
- Excluding monthly AMPs that are higher or lower than the standard deviation of the mean of all the monthly AMPs in a specific FUL Product Group.

Smoothing the pricing data using one of these methodologies would prevent some month-to-month fluctuations in the FULs. However, implementing any of the smoothing methods would have limitations. For example, it could require that for the entire averaging period, all manufacturers have timely reported monthly AMP and AMP units or that we look at alternatives to that. Further, it would require us to look at how to add newly available generic drugs or other changes in circumstances that affect these FULs. We are concerned that this could skew a resultant FUL so that it would be less representative of the price at which the pharmacy could purchase that drug. For example, it could cause a FUL for a particular FUL group to be lower than if we use only one month of AMP data in the calculation depending on the reported and certified monthly AMP and AMP units over the averaging period. As such, it may not capture price increases in a drug or reflect changes in price caused by a shortage of the drug. Conversely, it could overstate the price of drugs where more manufacturers are coming into the marketplace and the price of the drug was decreasing over time.

After careful consideration, we have decided not to propose a specific methodology to smooth the FULs at this time. Because AMPs are based on prices paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, they are subject to some fluctuations and variances in the generic drug market, which may result in fluctuations in the AMP-based FUL from month to month. Furthermore, these changes may be present even if we decide to implement a smoothing process over and above the smoothing process that manufacturers are presently using for AMP calculations. As previously mentioned, price changes

can occur as a result of product shortages, manufacturing disruptions, seasonal supply and demand, and products with a short shelf life. We are inviting comments on this issue, including the benefit of such a process, the options we considered, options we have not considered, and whether a smoothing process is necessary.

M. State Plan Requirements, Findings, and Assurances (§ 447.518)

In the Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs final rule published in the November 15, 2010 **Federal Register** (75 FR 69591), we made conforming amendments which deleted references to § 447.514 ''Upper limits for multiple source drugs'' from § 447.518 ''State plan requirements, findings and assurances''. We are proposing conforming regulatory amendments to those references and are adding them in the regulatory text of § 447.518.

In addition, to conform with the change from ''estimated acquisition cost'' to ''actual acquisition cost'', we propose in § 447.518(c) to require all States to provide data to adequately support proposed changes in reimbursement using AAC. This supporting data could include, but is not limited to, a national survey, to create a database of actual acquisition costs that States may use as a basis for determining State-specific rates. Additionally, a State survey of retail pharmacy providers or other reliable data which reflects the pharmacy provider's price to acquire a drug could be used as a basis to support proposed changes in reimbursement. We believe that surveying pharmacy providers for acquisition costs or using other reliable data, based on actual sales transactions, as a base from which to develop an appropriate ingredient cost reimbursement is reasonable. Alternatively, the use of an AMP, which is based on actual sales data and reported and certified by drug manufacturers, could be considered as a reimbursement metric. The State can also determine the relationship of the AMP to factors such as the wholesaler markup, which covers the cost of distribution and other service charges by the wholesaler, to determine a reasonable reimbursement that would appropriately compensate pharmacies for these costs.

We are inviting comments on the practicality of requiring each State to conduct a survey, the frequency of such a survey, and how closely we would expect the State to conform to the survey results in the reimbursement rates they propose in their SPA, including the use of acquisition cost averaging, AMPs as a basis for reimbursement, including the application of an appropriate markup factor or other methods of determining the ingredient cost.

Although we considered various alternatives for how AAC will apply in the case of reimbursement for covered outpatient drugs purchased under other Federal drug programs such as the 340B Drug Pricing Program and the Federal Supply Schedule (FSS) we are not proposing specific methodologies. Through these programs, certain Federal grantees and others can purchase drugs at significant discounts, and these drugs will then be reimbursed through the State Medicaid program for Medicaid beneficiaries. Under current HRSA policy, participating covered entities are permitted to dispense drugs purchased outside of 340B authority for their Medicaid patients, often referred to as the ''Medicaid carve out'' option. In accordance with section 340B(a)(5) of the PHS Act and section 1927(a)(5)(C) of the Act, a covered entity is not permitted to seek Medicaid payment for a drug that is subject to discounts under the 340B Drug Pricing Program and a Medicaid rebate in order to protect drug manufacturers from paying a Medicaid rebate on drugs that are already subject to a Federal discount. This ''duplicate discount'' prohibition in the Medicaid statute only applies to drugs purchased through the 340B Drug Pricing Program and does not apply to drugs carved out for Medicaid patients and billed to the Medicaid program.

In a recent OIG report, ''State Medicaid Policies and Oversight Activities Related to 340B–Purchased Drugs'', OEI–05–00321, the OIG reported that many State Medicaid agencies have written policies that direct covered entities to bill at cost for the ingredient cost of 340B purchased drugs or relied on HRSA's 1993 guidance directing covered entities to bill States at AAC (although that guidance is no longer in effect and was superseded by subsequent HRSA guidance directing covered entities to refer to States' policies). We believe that paying 340B providers at cost for these 340B drugs would meet the AAC requirements but seek further comments on what other methodologies would meet the AAC requirements.

IHS, tribal and urban Indian organization pharmacies may purchase drugs through the FSS or the 340B program and are oftentimes paid the Medicaid reimbursement rates established in State plans. In turn, States are reimbursed at 100 percent Federal medical assistance percentage for services provided in IHS and tribal pharmacies. While we have considered alternatives for payment methodologies for IHS, tribal and urban Indian pharmacies, we are proposing no specific methodologies and invite public comment on Medicaid payment levels for these facilities. In addition, pursuant to E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), the CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

We propose that States that do not have specific methodologies develop such methodologies for these providers consistent with our proposed shift from EAC to AAC. In addition, we propose to add a new requirement at § 447.518(a) that the State plan must describe the agency's payment methodology for drugs dispensed by a covered entity participating in the 340B Drug Pricing Program or by a contract pharmacy under contract with a participating covered entity.

In addition, States would be required to submit a SPA through the formal review process, as well as comply with all Federal requirements including consultation with tribal governments and IHS, tribal and urban Indian programs pursuant to section 5006 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), when submitting a request to change their professional dispensing fee. As is true for the drug ingredient reimbursement, we do not intend to mandate a specific formula or methodology which the States must use to determine their dispensing fee, however, as is consistent with current policy, States would still be required to substantiate how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries. Where the professional dispensing fee might differ because of unique circumstances for 340B covered entities or IHS and tribal pharmacies, the State should look at these circumstances to determine if a different professional dispensing fee is warranted for these entities. One component of the reimbursement formula should not be revised without appropriately evaluating the other part.

With the proposed change in the definition of ''State'' to include the territories, we acknowledge that these same requirements could ultimately be applicable to the territories. Since the territories that participate in the

Medicaid Program are already required to submit changes to their State Plans through the State Plan Amendment process, we are proposing that the requirements discussed in this section would be effective for the territories in the same manner in which they would be effective for the 50 States and the District of Columbia.

N. Optional Coverage of Investigational Drugs and Other Drugs Not Subject To Rebate (§ 447.522)

Investigational drugs, also referred to as experimental drugs, do not fall within the definition of covered outpatient drugs set forth in section 1927(k) of the Act; therefore, these drugs are not subject to rebate. However, Medicaid coverage may be provided under section 1905(a)(12) of the Act at the State's option, and FFP is available to the extent it is consistent with section 1903(i) of the Act and § 440.120.

There are a number of other items that may also be covered as prescribed drugs or products under section 1905(a)(12) of the Act, such as whole blood products.

We propose to add § 447.522 to clarify that States providing coverage of investigational drugs may only pay for and receive FFP for these drugs when they are billed for in accordance with the FDA final rules 21 CFR Part 312 and 316, as amended by the final rules published in the August 13, 2009 **Federal Register** (''Charging for Investigational Drugs Under and Investigational New Drug Application'' (74 FR 40872) and ''Expanded Access to Investigational Drugs for Treatment Use'' (74 FR 40900)). These regulations clarify the circumstances under which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of expanded access for treatment, and clarify what costs can be recovered.

We are also adding a provision to allow for the coverage of other non-covered outpatient drugs.

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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICR's Regarding Medicaid Drug Rebates (§ 447.509)

As discussed earlier in the preamble, section 2501(c) of the Affordable Care Act amended section 1903(m) of the Act by specifying new conditions for MCO contracts, including that covered outpatient drugs dispensed to individuals eligible for medical assistance under Title XIX of the Act who are enrolled with a Medicaid MCO shall be subject to the same rebate required by the rebate agreement authorized under section 1927 of the Act. Proposed § 447.509(b) adds requirements for States to collect necessary drug utilization data from Medicaid MCOs in order to include MCO data in the quarterly rebate requests.

We estimate that these requirements would affect the 51 State Medicaid Programs, as well as the territories. The burden associated with the inclusion of Medicaid MCOs in the Drug Rebate Program is the time and effort it would take for the State Medicaid Program to gather the drug utilization information from the Medicaid MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to manufacturers. Our current reporting hour burden, specific to the invoice and State utilization data reporting within the MDR Program, for the current State Medicaid Programs is 2,346 hours per quarter or 9,384 hours annually, at a total estimated cost of $302,165.

As referenced in § 447.509(b) and § 447.511, we believe the collection of drug utilization data from MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to the manufacturers will add a total 678 hours per quarter or 2,712 hours annually to the current reporting burden for the States (which include the 50 States, District of Columbia, and the territories). Therefore, the total new reporting burden, as a result of this proposed rule requesting additional requirements to collect drug utilization data from MCOs, will be 2,712 hours annually at a total estimated cost of $98,744.

The aforementioned burden estimates will be submitted for OMB review and approval as a revision to the information collection request currently approved under OMB control number 0938–0582.

Proposed § 447.509(c) would also require States to remit to the Federal government the amount of the savings resulting from the increases in the rebate percentages. The reporting process is similar to the current reporting process for drug expenditures and rebates onto the CMS–64 Form. In addition to reporting onto the CMS–64 Form the quarterly amount for prescribed drug expenditures, Federal rebates, and rebates under State side bar agreements, States will report the total quarterly rebate offset amount that they are remitting to the Federal government for the fee-for-service rebates they currently receive from drug manufacturers and for the MCO rebates they will receive from drug manufacturers. The information collection requirements and burden associated with CMS–64 are already approved by OMB through April 30, 2014, and have been assigned OMB control number 0938–0067. This proposed rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS–64.

B. ICR's Regarding Requirements for Manufacturers (§ 447.510)

Manufacturers must report, electronically, product and quarterly pricing information to CMS not later than 30 days after the end of the rebate period. Monthly pricing and units are due no later than 30 days after the end of the month. In addition, customary prompt pay discounts and nominal prices must be reported quarterly. The proposed rule would significantly revise the definitions of AMP and best price and, therefore, would require the manufacturers to reconfigure their pricing systems to correctly calculate AMP and best price. In addition, manufacturers must submit the total number of units that are used to calculate the monthly AMP. Therefore, the burden associated with these new requirements is the time and effort it would take for a drug manufacturer to reconfigure its pricing systems to correctly calculate AMP and best price before it can submit the required data to CMS. We estimate that these requirements would affect the approximately 600 drug manufacturers in the Medicaid Rebate Program. We believe the changes to the AMP and best price definitions will require 240 hours

per manufacturer, for a one-time total of 144,000 burden hours with a one-time total estimated burden cost of $8,640,000. Once the pricing systems have been reconfigured, there should be no additional burden in time or effort than that which already exists.

Manufacturers will be required to submit the FDA application number issued by FDA when the product is approved. If the product does not currently have an FDA application number, the manufacturer must submit evidence demonstrating that the product is otherwise a covered outpatient drug. CMS shall refer to this evidence of demonstration as covered outpatient drug status, or COD status.

This information should not be difficult for the manufacturer to determine since the manufacturer should already know the FDA application number of the product when it was approved by FDA, or the reason it qualifies as a covered outpatient drug, if there is no application number.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number and the COD status will require a one-time total of 3,000 hours at a one-time total estimated burden cost of $180,000.

Manufacturers will also be required to identify drugs that are approved by the FDA exclusively for pediatric indications. These drugs will be referred by CMS as ''Exclusively Pediatric'' drugs. This information should not be difficult for manufacturers to determine and therefore would not add any significant hourly burden since the exclusively for pediatric indications will be provided by the FDA upon approval of these drugs.

Additionally, manufacturers will need to consider certain requirements when it comes to the calculation of their AMP for inhalation, infusion, instilled, implanted, and injectable drugs (5i), when not generally dispensed through retail community pharmacies. Using the methodology proposed earlier in this rule, a manufacturer would be required to identify and determine the AMP of these drugs. It is our estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the initial reporting of the 5i drugs is the time and the effort it would take for each drug manufacturer to identify these drugs and then to determine which of the 5i drugs are not generally dispensed through a retail community pharmacy by using the methodology proposed earlier in this rule. However, it is our understanding that each drug manufacturer should have some knowledge as to which drug is a 5i based on the approval information the manufacturer received from the FDA as well as the FDA Route of Administration list that CMS has identified. Once the manufacturer has established its initial list of 5i drugs, it would then be required on both a monthly, as well as quarterly basis, to determine which of those drugs are not generally dispensed through a retail community pharmacy. Therefore, we believe that the new reporting requirements will require a one-time total of 1,500 burden hours for manufacturers to identify the 5i drugs at a one-time total estimated burden cost of $90,000. In addition, on both a monthly and quarterly basis (12 months, plus 4 quarters, for a total of 16 times per year) the manufacturer will be required to determine whether the percentage of sales for the 5i drugs has met the threshold to be considered not generally dispensed through a retail community pharmacy. Specifically, we estimate that it will add 20 hours per response with 16 responses per year for each manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy. This equates to a total estimate of 320 additional hours annually per manufacturer. The total annual burden hours for the 600 drug manufacturers participating in the Medicaid Rebate Program is estimated to be 192,000 hours with a total cost of $11,520,000.

Furthermore, manufacturers participating in the rebate program that have reformulated drugs are now required to calculate an alternative rebate calculation for certain drugs. In order to calculate the alternative rebate calculation for a line extension drug of a brand name in an oral solid dosage form, the line extension drug and the initial brand name listed drug need to be identified. Although CMS will be identifying both the initial brand name listed drug and the line extension drug for the initial three quarters for manufacturers, they will be responsible for identifying the initial brand name listed drug and the line extension drug after the initial three quarters. Manufacturers are responsible for calculating the unit rebate amount for the line extension drug.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the initial brand name listed drug and the line extension drug is the time and the effort it would take for each drug manufacturer to identify these drugs. However, it is our understanding that each drug manufacturer should have some knowledge on which drug is the line extension based on the approval information that the manufacturer received from the FDA as well as the Chemical Type that CMS has identified as a line extension drug and the initial brand name listed drug. Therefore, we believe that the new reporting requirements to identify the initial brand name listed drug and the line extension drug would add 20 additional hours per quarter, per manufacturer; or 48,000 total hours annually to the drug manufacturers at a total estimated cost of $2,880,000.

Finally, a manufacturer is required to retain records for 10 years from the date the manufacturer reports data to CMS for that rebate period. While this requirement is subject to the PRA, we believe this is a usual and customary business practice as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

The aforementioned burden estimates will be submitted for OMB review and approval as a revision to the information collection request currently approved under OMB control number 0938–0578.

C. ICR's Regarding Requirements for States (§ 447.511)

The definition of the term ''States'' would be revised to include the territories: The Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, in addition to the 50 States and the District of Columbia. The territories will be able to receive manufacturer rebates through the MDR program in the same manner that the 50 States and the District of Columbia are currently receiving rebates.

In order for territories to be able to begin collecting rebates from the manufacturers, the territories will be required to come into compliance with the MDR program because the systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors in order to ensure that their systems are in place to begin to collect rebates from manufacturers.

We are unsure what the time, effort and cost would be for this compliance process to be completed and seek comments specific to this issue.

States will have to report the total MCO rebates they receive from manufacturers onto the MBES CMS–64 Form and submit this data to CMS on a quarterly basis. The information collection requirements and burden associated with CMS–64 are already approved by OMB through April 30, 2014, and have been assigned OMB control number 0938–0067. This proposed rule does not impose any new or revised burden or reporting or recordkeeping requirements concerning CMS–64.

TABLE 5—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 447.509(b), § 447.511	* 0938–0582	56	224	12.1	2,712	36.41	98,744	0	98,744
§ 447.510	* 0938–0578	600	600	240	144,000	60	8,640,000	0	8,640,000
§ 447.510	* 0938–0578	600	600	5	3,000	60	180,000	0	180,000
§ 447.510	* 0938–0578	600	600	2.5	1,500	60	90,000	0	90,000
§ 447.510	* 0938–0578	600	9600	20	192,000	60	11,520,000	0	11,520,000
§ 447.510	* 0938–0578	600	2400	20	48,000	60	2,880,000	0	2,880,000
Total		3,056	14,024		391,212		23,408,744		23,408,744

* The data contained in the table reflects the burden associated with the proposed revisions to the information collection requests approved under the OMB control numbers listed. The table does not display the currently approved burden for the listed OMB control numbers.

We have submitted a copy of this proposed rule to the OMB for its review of information collection and recordkeeping. These requirements are not effective until they have been approved by the OMB.

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–2345–P] Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Economic Analyses

A. Regulatory Impact Analysis

1. 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 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. Accordingly, the rule has been reviewed by the Office of Management and Budget.

We solicit comment on the entire Economic Analyses section.

2. Statement of Need

This proposed rule would implement changes to section 1927 of the Act as set forth in section 221 of Division F, Title II, of the Omnibus Appropriations Act, 2009 (Pub. L. 111–8, enacted on March 11, 2009). This includes changes to, (1) section 1927 of the Act as set forth in sections 2501, 2503, and 3301(d)(2) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148, enacted on March 23, 2010), (2) section 1927 of the Act as set forth in sections 1101(c) and 1206 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152, enacted on March 30, 2010), and (3) section 1927 of the Act as set forth in section 202 of the Education Jobs and Medicaid Funding Act (Pub. L. 111–226, enacted on August 10, 2010). It also proposes to codify other requirements in section 1927 of the Act pertaining to the Medicaid drug rebate program and revise certain regulatory provisions presently codified at 42 CFR part 447, subpart I and make other changes.

3. Overall Impacts

Overall, we estimate this rule would save approximately $17.7 billion for Federal Fiscal Years (FFYs) 2010 through 2014, reflecting $13.7 billion in Federal savings and $4.0 billion in State savings, as shown in the Table 6. These impact estimates represent the increased percentages of rebates on generic and brand name drugs, the treatment of new formulations, the change in the maximum rebate amounts, the extension of rebate collection for Medicaid managed care organizations, and provides for adequate pharmacy reimbursement. Lastly, we estimate costs to MCOs, drug manufacturers, and States in the amount of $81.4 million for FFYs 2010 through 2014 which includes administrative and infrastructure expenses necessary to implement the required systems changes.

[7] Except as noted below, savings estimates were developed by the Office of the Actuary (OACT) and the Center for Medicaid, CHIP and Survey & Certification (CMCS) at CMS and are consistent with the President's FY 2012 budget baseline.

(* The estimates for section 2503 were developed by CMS. An alternative methodology discussed below produces a 5-year cost to States and Federal government of $1.7 billion explained in the alternatives considered section of the Regulatory Impact Analysis).)

Continued

TABLE 6—STATE AND FEDERAL SAVINGS (−) OR COSTS (+) (FFYS 2010–2014)
[In $millions] [7]

Affordable Care Act section and provision		2010	2011	2012	2013	2014	Total 2010–2014
Section 2501(a)(1)—Increase minimum rebate percentages for brand name drugs.	Federal	−$350	−$730	−$765	−$810	−$865	−$3,520
	State	0	0	0	0	0	0
Section 2501(a)(2)—Recapture of total savings	Federal	Included with affected provisions					
	State						
Section 2501(b)—Increase rebate percentages for generic drugs.	Federal	−30	−50	−55	−55	−65	−255
	State	0	0	−0	0	0	0
Section 2501(c)—Extension of collection of rebates for MCOs.	Federal	−580	−720	−720	−770	−820	−3,610
	State	−280	−490	−560	−580	−620	−2,530
Section 2501(d)—Rebates new formulation drugs	Federal	−160	−345	−360	−380	−400	−1,645
	State	0	0	0	0	0	0
Section 2501(e)—Maximum rebate amount	Federal	30	40	40	40	50	200
	State	20	30	30	30	30	140
Section 2503—Providing adequate pharmacy *	Federal	0	−351	−702	−702	−702	−2,457
	State	0	−234	−468	−468	−468	−1,638
Interactions **	Federal	−310	−420	−440	−510	−700	−2,380
	State	0	0	0	0	−5	−5
Total Impact	Federal	−1,400	−2,576	−3,002	−3,187	−3,502	−13,667
	State	−260	−694	−998	−1,018	−1,063	−4,033
Total Federal & State Impacts		−1,660	−3,270	−4,000	−4,205	−4,565	−17,700

TABLE 7—COSTS TO MCOS, DRUG MANUFACTURERS, AND STATES
[FFYs 2010–2014]

Provision(s)	Regulation section(s)	(In $millions)					Total
		2010	2011	2012	2013	2014	(FFYs 2010–2014)
Drug Rebates for Medicaid MCOs	§ 447.509(b), § 447.511	$0.1	$0.1	$0.1	$0.1	$0.1	$0.49
Requirements for manufacturers	§ 447.510	23.3	14.4	14.4	14.4	14.4	80.91
Total Costs		23.4	14.5	14.5	14.5	14.5	81.4

4. Detailed Economic Analysis

All savings estimates provided were developed by the Office of the Actuary (OACT) and the Center for Medicaid, CHIP and Survey & Certification (CMCS) at CMS. We note that the Congressional Budget Office (CBO), in its estimates of the budgetary effects of these provisions of the Affordable Care Act, reached similar aggregate estimates with a $600 million difference between CMS and CBO total estimates. The report can be seen at the following link (*http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf*). CBO reached an estimated savings of $13.1 billion in Federal outlay reduction for FFY 2010–2014 compared to CMS' estimates of $13.7 billion for that same time period.[8] Savings estimates for sections 2501 and 2503 of the Affordable Care Act reflect increased rebate percentages for generic and brand name drugs, treatment of new formulations, revised FULs, and extended collection of rebates to MCOs. As well as a cost estimate for provision of section 2501(e) of Affordable Care Act for maximum rebate amount. The following analysis describes the methodology used to reflect each provision's savings estimates.

The estimates for section 2501(a)(1) of the Affordable Care Act were derived from baseline Medicaid prescription drug rebates developed for the mid-session review (MSR) of the FY 2010 budget. Data from the MDR system was used to estimate the share of rebates attributable to single source and innovator multiple source drugs. Using this data, we developed a model to estimate the effect of raising the minimum rebate by fitting a distribution to data on brand drug rebates as a percent of AMP with and without the 15.1 percent minimum. The distribution was then used to calculate the mean rebate percentage taking into account the new minimums specified in section 2501(a) of the Affordable Care Act. These percentages were applied to baseline brand drug rebates to estimate potential savings from the provision. A behavioral offset of 40 percent was applied to the potential savings to account for actions on the part of manufacturers to minimize the impact of the higher rebate payments (for example, by raising prices).

The estimate for section 2501(a)(2) of the Affordable Care Act represents the State share of savings projected for subsections (a)(1),(b), and (d) of section 2501 and is included in the Federal savings of those subsections.

The impact of section 2501(b) of the Affordable Care Act was estimated using MDR data to estimate the share of baseline Medicaid drug rebates attributable to non-innovator, multiple source drugs. Increasing the rebate from 11 percent to 13 percent of AMP results in additional rebates of 2 percent of AMP, or about 18 percent (2/11) of projected generic drug rebates.

For section 2501(c) of the Affordable Care Act, current projections of Medicaid prescription drug spending and managed care premiums were developed as part of the MSR 2010 Medicaid baseline. The estimated impact represents two different effects of this section. First, current prescription drug spending by Medicaid

(** These are interactions among drug provisions and the interaction of drug provisions with Medicaid expansion.)

[8] *http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf.*

managed care plans would receive additional rebates. Estimates for (1) the portion of managed care plan expenditures going to rebates and (2) the level of additional rebates that could be obtained by the managed care plans were developed to calculate this impact.

Second, it is anticipated that some fee-for-service prescription drug spending that is currently carved out of Medicaid managed care plans would be included in future managed care contracts. To develop this estimate, estimates were made for (1) the increased efficiency of managed care plans in managing prescription drug use, and (2) the increased administrative costs by including additional expenditures under managed care plans. It was also assumed that 10 percent of current fee-for-service drug spending would eventually shift to Medicaid managed care plans.

About 75 percent of the savings to the Federal government from this section are estimated to come from the impact of additional rebates for managed care plan expenditures on prescription drugs, and about 25 percent are estimates to come from the impact of moving fee-for-service prescription drug spending into managed care plans.

The impact for section 2501(d) of the Affordable Care Act utilized MDR data and focused on new formulations that are extended-release forms of the initial brand name listed drug. The analysis concluded that by calculating the additional rebate, based on the initial brand name listed drug, Medicaid rebates would increase by about 5 percent. A behavioral offset of 15 percent was applied to these potential savings.

The estimates for section 2501(e) of the Affordable Act were derived from an analysis of MDR data for single source and innovator multiple source drugs for which the unit rebate amount exceeds the AMP. The amount of rebates in excess of AMP was found to account for approximately one percent of total Medicaid rebates.

The estimate for FULs under section 2503 was developed by calculating the FUL based on weighted AMP times 175 percent, including (I) innovator and (N) non-innovator drugs, for the purpose of savings and providing adequate reimbursement to pharmacy providers.

a. Anticipated Effects on Drug Manufacturers

As previously indicated in the Collection of Information there are approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate program. The rule would require all drug manufacturers to provide an increased rebate percentage for generic and brand name drugs.

The burden associated with the drug program is for labelers to gather and report existing sales and product information on an additional monthly basis and an expanded quarterly basis. As mentioned previously there are approximately 600 drug manufacturers who will have to provide reporting drug information to CMS. We believe each manufacturer will spend a one-time annual burden of approximately 144,000 total hours in complying with these requirements. The estimated one-time cost to labelers is $8.6 million. This information is required for the new base AMP and the new best price. This is based on the Bureau of Labor Statistics (BLS) average rate of $60.00 an hour for a computer systems analyst.

Manufacturers also will be required to submit the FDA application number issued by FDA when the product is approved. If the product does not currently have an FDA application number, the manufacturer must provide a demonstration that product is a covered outpatient drug, or a COD status. We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number or the COD status will require a total one-time burden of 3,000 hours at an estimated cost of $180,000. This is based on the BLS average rate of $60.00 an hour for a computer systems analyst.

In addition, we believe that it will take time for manufacturers to identify the drugs that fall into 5i drugs category. We estimate they will spend a one-time total of 1,500 burden hours to identify these drugs. This translates to a one-time cost for manufacturers to identify the 5i drugs of $90,000, utilizing the average BLS wage rate of $60 an hour for this function. Furthermore, we believe that it will require all manufacturers to spend 192,000 total hours annually in identifying which drugs fall into the 5i category. The estimated cost to the labelers for this addition is $11.5 million. This is also based on the average BLS wage rate of $60 an hour for this function. More information on manufacturer requirements can be found in § 447.510 of this proposed rule.

Lastly, we believe that the initial identification of the initial brand name listed drug and the line extension would also add an additional 48,000 annual hours to identify which drugs with the extension qualify. The estimated additional cost to labelers for this addition is also $2.9 million. This figure is also based on the average BLS wage rate of $60 an hour for this function. Additional information can be found in section § 447.510 of this proposed rule.

b. Anticipated Effects on Retail Community Pharmacies

Retail community pharmacies would be affected by this regulation, as the law will result in FULs that are closer to the acquisition cost of the drug. In a 2009 OIG report titled ''A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices,'' the OIG found that for the fourth quarter of FY 2007 the pre-DRA FUL reimbursement was more than double the average pharmacy acquisition cost for 46 of the 50 highest- expenditure FUL drugs. The Affordable Care Act FULs would generally reduce those limits in comparison to the pre-DRA highly inflated FULs and, thereby, reduce Medicaid payment for drugs subject to the limits. However, we note that since States had the option to reimburse at their SMAC, instead of the pre-DRA FUL, the actual reimbursement to the pharmacies under the Affordable Care Act FUL may be more compared to that SMAC reimbursement. An example of this is exemplified in comparing the pre-DRA FUL, the Affordable Care Act FUL and Indiana's SMAC, as explained the preamble of § 447.514 of this proposed rule.

However, other than the comparison chart provided in § 447.514 of this proposed rule, we have not analyzed how each State's MAC program would impact the total savings under the new Affordable Care Act FUL methodology. Therefore, we invite public comments on this impact. The Federal savings in section 2503 of the Affordable Care Act reflect this change in reimbursement for retail community pharmacies. Although there are savings to the Medicaid program largely realized because of lower payment to pharmacies, pharmacies may receive a higher reimbursement under the Affordable Care Act FUL than they would when compared to what States currently reimburse pharmacies.

c. Anticipated Effects on State Medicaid Programs

States share in the savings from this rule. As noted in the Table 6, we

estimate a 5-year State savings of over $4.0 billion. We also note States would be impacted by the provisions of this regulation that offset the States' share of the increased rebate amounts under the Affordable Care Act. State administrative costs associated with this regulation are minor; as States currently pay based on a FUL, have already determined their drug reimbursement rates, and currently collect claims information on physician administered drugs.

The States will have added reporting data for the MCOs to CMS and we believe that this will require a total of 2,712 hours annually costing the States $98,744.

Also, as a result of the increased rebate amounts under the national rebate agreement, manufacturers may reduce rebates they pay to States through supplemental rebate agreements. While this potential loss of supplemental rebates is not a direct consequence of this proposed rule, we recognize that this may occur.

The interactions of the drug provisions with the Medicaid expansion in the Affordable Care Act will provide States a savings of $5 million in FFY 2014. More information can be found in § 447.509(c) and § 447.511 of this proposed rule.

d. Anticipated Effects on U.S. Territories

The definition of the term ''States'' would be revised to include the territories: The Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, in addition to the 50 States and the District of Columbia. The territories will be able to receive manufacturer rebates through the MDR program in the same manner that the 50 States and the District of Columbia are currently receiving rebates.

In order for territories to be able to begin collecting rebates from the manufacturers, the territories will be required to come into compliance with the MDR program because the systems that the territories currently have are not setup for the MDR program. As a result, these territories will likely have to utilize contractors in order to ensure that their systems are in place to begin to collect rebates from manufacturers. We do not have cost estimates for this compliance process to be completed and solicit comment specific to this issue.

5. Alternatives Considered

We considered a number of different policies and approaches during the development of this proposed rule.

As mentioned in the Determination of AMP § 447.504, the goal of the Affordable Care Act is to capture the AMP for those drugs that would be difficult for manufacturers to calculate an AMP based on only retail community pharmacy sales. Therefore, to eliminate any problems that may result from a manufacturer not able to determine an AMP for a particular drug, Congress amended the Affordable Care Act to include inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through retail community pharmacies. We considered whether we need to define and determine which drugs constitute the five aforementioned. Also, we looked at Medicare Part B drugs and considered using their list to define these drugs. Though, when speaking with our counterparts in Medicare Part B, the ASP NDC–HCPCS covered drugs that are usually not self administered were not all inclusive. In addition to using the Medicare Part B list, we also considered whether CMS or manufacturers would be responsible for defining which drugs would fall into this category. Additionally, we considered using the FDAs dosage forms and route of administrations to assist manufacturers in determining which drugs meet this requirement.

We propose to use a multistep process to identify if the drug is not generally dispensed. To recap, first manufacturers would identify which drugs would fall within the parameters of the five aforementioned drugs. Then, they would need to determine if the drug is ''not generally dispensed'' through a retail community pharmacy. (See § 447.504 to learn more about the alternatives considered in developing AMP policy.)

With regard to the offset of the increased rebate percentages, we did consider offsetting the non-Federal share of the entire difference between the minimum rebate percentages in effect on December 31, 2009 and the new minimum rebate percentages in effect under Affordable Care Act, regardless of whether States received a rebate amount based on the difference between AMP and best price. However, after careful consideration of the provision in 2501 of the Affordable Care Act, we propose to calculate the offset amount to reflect rebates based on the difference between AMP and best price.

We also considered a different interpretation when calculating the offset for line extension drugs. However, we believe that the new alternative rebate calculation is more aligned than the statute.

We also considered determining whether there would be a cost or savings in implementing the Affordable Care Act FUL by comparing simulations of the DRA FUL and new Affordable Care Act FUL, using price, utilization, and reimbursement data from the MDR system combined with generic group codes from First Data Bank. The difference in savings from these simulations (expressed as a percent of total Medicaid drug spending) was applied to projected Medicaid prescription drug spending developed for the mid-session review of the FY 2010 Budget, resulting in a five-year Federal and State cost of $1.7 billion for the Affordable Care Act FULs compared to the DRA FULs. However, this alternative does not take into account a State's ability to choose to reimburse at the SMACs, which may be lower than the FUL for a drug. As a result, this alternative/methodology yields a cost to the States and Federal government, when in actuality it should reflect a savings as many States have implemented their own SMAC and reimburse below the FUL. In addition, the DRA FUL was never implemented and therefore this alternative is based on unpublished FULs and not representative of actual reimbursement.

We solicit comment on the Alternatives Considered section.

6. Accounting Statement and Table

As required by OMB's Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the Table 8 we have prepared an accounting statement showing the classification of the transfers and costs associated with the provisions of this proposed rule. Table 9 provides our best estimate of the decreases in Medicaid payments and increase in drug rebates under sections 2501(a), 2501(b), 2501(c), 2501(d), 2501(e), and 2503 of the Affordable Care Act. All transfers to the Federal and State Medicaid program are from retail pharmacies and drug manufacturers. Lastly, we present the costs to MCOs, Drug Manufacturers, and States.

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS, FROM FFYS 2010 TO 2014

[In $millions]

Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	−$2,667.5	−$2,704.8	
From/To	Reduction in transfers from the Federal Government to State Governments.			
Category	TRANSFERS			
Annualized Monetized Transfers	Year Dollar	Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	−$780.0	−$795.1	
From/To	Reduction in transfers from the State Governments to Retail Pharmacies and increased transfers from Drug Manufacturers to State Governments.			
Category	COSTS			
Annualized Monetized Transfers	Year Dollar	Units Discount Rate		Period Covered
	2011	7%	3%	FFYs 2010–2014
	Primary Estimate	$16.5	$16.4	
	Costs to MCOs, Drug Manufacturers, and States.			

7. Conclusion

We estimate savings from this regulation of $17.7 billion over 5 years, $13.7 billion to the Federal government and $4.0 billion to the States. Most of these savings result from the increased rebate percentages on brand name drugs and the offsets of the total savings of the increased rebate percentage, treatment of new formulations, and from the collection of rebates from enrollees of MCOs. Lastly, we estimate costs to MCOs, drug manufacturers, and States of $81.4 million for FFYs 2010 through 2014.

While the effects of this regulation are substantial, they are a result of changes in the law.

B. Regulatory Flexibility Act Analysis

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. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, three types of small businesses are potentially impacted by this proposed rule. These include small retail community pharmacies, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small Medicaid managed care organizations (MCOs). More detailed analysis on the impact of these entities is provided in the Detailed Economic Analysis section (V.A.4) above. 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 Small Business Administration's (SBA) definition of a small business (having revenues of less than $7.0 million to $34.5 million in any one year).

TABLE 9—IMPACT ON SMALL ENTITIES

Small entity type	Number of entities	Impact (FFYs 2010–2014)
Pharmaceutical Manufacturers in Medicaid Drug Rebate Program	600	Decrease in revenue of $5.4 billion as a result of higher rebates over 5 years.
Small Retail Community Pharmacies	17,069	Minimal impact.
Small Rural Hospitals	700	Minimal impact.
Small (HMOs/MCOs) Health Maintenance Organizations/Managed care organizations	*118	Decrease in revenue of $6.1 billion over 5 years.

(* Figure may reflect overestimation relative to overall MCOs.)

For purposes of the RFA, most of the retail pharmacies are considered small businesses according to the SBA's size standards with total revenues of $25.5 million or less in any 1 year (*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*). The latest 2007 SBA estimates that there are approximately 17,069 small pharmacies. These pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the payment limits, thus reducing Medicaid payments to pharmacies for generic drugs. The revision to the FULs would generally reduce those limits and, thereby reduce Medicaid payments for drugs that are subject to the payment limits. The savings for section 2503 of the Affordable Care Act reflect this statutory change. Beginning September 2011, the publication of AWP by First Databank would in all likelihood cease; therefore, CMS proposes to replace the term ''estimated acquisition cost'' with Actual Acquisition Cost (AAC) and require States to begin paying pharmacy providers based on the AAC of the drug. Additionally States will reimburse providers with a comparable dispensing fee as mentioned in § 447.502 of this proposed rule. There will be a savings for States and the Federal government for reimbursing pharmacists at AAC because of the highly inflated prices that the Medicaid programs are currently reimbursing providers.

According to the SBA size standards, drug manufacturers are considered small businesses if they have fewer than 750 employees (*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*). Approximately 600 drug manufacturers currently participate in the Medicaid Drug Rebate Program. We believe most manufacturers are small businesses. We anticipate this rule would have an impact on small drug manufacturers. We believe there will be an impact on these entities and solicit comments on this analysis.

The rule would require all drug manufacturers participating in the Medicaid Drug Rebate program to increase the rebate percentages that they are currently paying. Manufacturers are required by the Affordable Care Act to pay the increased percentages. The savings for sections 2501(a)(1), 2501(b) and 2501(d) reflect this statutory change.

According to the SBA's size standards, an HMO, of which we have included MCOs, is considered a small business if it has revenues of $10 million or less in any one year (*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*). The SBA estimates that there are approximately 118 small HMO/MCO Medical centers that meet this threshold. Because of limited data available, we are unable to quantify how many MCOs fall within the HMO standard and meet the $10 million threshold. We do contend that only a small portion of the small MCOs meet this standard. We request any information that may help us better estimate the portion of MCOs that meet the SBA standard. The small Medicaid MCOs may be affected by this rule if manufacturers reduce rebate payments to them to any extent that these rebates are paid to the States but these costs would likely be mitigated because it is likely that the MCOs rates would be adjusted.

Therefore, the Secretary has determined that this proposed rule would have a significant economic impact on a substantial number of small entities. We offer an analysis of the alternatives considered in section V.A.5 of this proposed rule. The analysis above, together with the remainder of this preamble, constitutes the initial regulatory flexibility analysis. We solicit comment on the RFA analysis.

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 and has fewer than 100 beds. There are approximately 700 small rural hospitals that meet this definition. We do not expect this rule to have a significant impact on small rural hospitals although States are now required to furnish rebates from MCOs including NDCs for physician administered drugs. The national cost of this provision would be estimated at $580 million for FY 2010. However, the impact on these entities would be minimal because there would be no other requirement except for providing NDC numbers for physician administered drugs. Therefore, the Secretary has determined that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals. At this time, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries. We request any information that may help us better assess those effects before we make final decisions.

C. Unfunded Mandates Reform Act Analysis

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 of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. We expect this proposed rule would impose additional costs to manufacturers, whereas it would likely increase savings for States and the Federal government. A detailed discussion on costs is offered below. We believe the rule would not impose additional costs to States and local governments. This proposed rule will have tribal implications, and in accordance with E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

There would be additional costs for drug manufacturers. This occurs as a result of the increased rebate percentages for generic and brand name drugs, and the treatment of new formulation drugs which for manufacturers, total over $11.2 billion dollars over the next 5 years.

VI. Federalism Analysis

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. This proposed rule does not impose substantial direct requirement costs on State or local governments, preempts State law, or otherwise has Federalism implications.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare &

Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Secs.

447.500 Basis and purpose.
447.502 Definitions.
447.504 Determination of Average Manufacturer Price.
447.505 Determination of best price.
447.506 Authorized generic drugs.
447.507 Identification of 5i drugs.
447.508 Exclusion from best price of certain sales at a nominal price.
447.509 Medicaid drug rebates.
447.510 Requirements for manufacturers.
447.511 Requirements for States.
447.512 Drugs: Aggregate upper limits of payment.
447.514 Upper limits for multiple source drugs.
447.516 Upper limits for drugs furnished as part of services.
447.518 State plan requirements, findings, and assurances.
447.520 FFP: Conditions relating to physician-administered drugs.
447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

Subpart I—Payment for Drugs

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and best prices and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(4) Implements section 1903(m)(2)(A)(xiii) of the Act, in part, and section 1927(b) of the Act with regard to rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid Managed Care Organizations (MCOs).

(5) Implements section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

5i drug means an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

Bona fide service fee means a fee paid by a manufacturer to wholesalers or retail community pharmacies; that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

(1) The discounts in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs in the bundle.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the CMS and posted on the CMS Web site.

Consumer Price Index—Urban (CPI–U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Covered outpatient drug means of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA where the manufacturer has obtained a NDA and also under section 505(j) of the FFDCA where the manufacturer has obtained an ANDA;

(ii) Was commercially sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a ''new drug'' (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or 304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for

an opportunity for a hearing under section 505(e) of the FFDCA. This provision specifies a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended or suggested in its labeling;

(iv) Is a biologic product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biologic product, or insulin provided as part of or incident to and in the same setting as, any of the following services (and for which payment is made as part of that service instead of as a direct reimbursement for the drug):

(i) Inpatient Services;

(ii) Hospice Services;

(iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;

(iv) Physician services;

(v) Outpatient hospital services;

(vi) Nursing facility and services provided by an intermediate care facility for the mentally retarded;

(vii) Other laboratory and x-ray services; or

(viii) Renal dialysis.

(3) A covered outpatient drug does not include:

(i) Any drug product, prescription or OTC, for which an NDC number is not required by the FDA;

(ii) Any drug product that is not listed electronically with the FDA;

(iii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;

(iv) Any drug product or biological used for a medical indication which is not a medically accepted indication; or

(v) Over-the-counter products that are not drugs.

Customary prompt pay discount means any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

Innovator multiple source drug means a multiple source drug marketed under a new drug application (NDA) approved by the FDA, including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologic license application (BLA), product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA). For purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness.

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Line extension means a single source or innovator multiple source drug that is in an oral solid dosage form that has been approved by the FDA as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug, such as a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug.

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) For authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent as reported in the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857 or successor publications and Web sites;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his or her designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means—

(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;

(2) A multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meet the definition of covered outpatient drug; or

(5) Any noninnovator drug that is not therapeutically equivalent.

(6) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives a new NDA or ANDA approval from the FDA, the manufacturer must change the reporting of the product's drug category to correlate with the new product application type and furnish the appropriate information.

Oral solid dosage form means capsules, tablets, or similar drugs products intended for oral use as defined in accordance with the FDA regulation at 21 CFR 206.3 that defines solid oral dosage form.

Over-the-counter drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be

purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group, meaning from birth through 16 years of age, or a subset of this group, as specified in the ''Indications and Usage'' section of the FDA approved labeling.

Professional dispensing fee means the professional fee which—

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an NDA approved by the FDA and has an approved NDA number issued by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application (BLA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). For purposes of the MDR program, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness.

States means the 50 States, the District of Columbia and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America Samoa).

United States means the 50 States, the District of Columbia, and the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and America Samoa).

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

§ 447.504 Determination of Average Manufacturer Price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Average Manufacturer Price (AMP) means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Average unit price means a manufacturer's sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

Net sales means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, and a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) *Sales, nominal price sales, discounts, rebates, payments, or other transactions included in AMP.* Except for those sales, nominal price sales, rebates, discounts and other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales and associated discounts, rebates, payments, or other transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.

(3) Sales, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies.

(4) Sales, discounts, rebates (other than rebates under section 1927 of the Act or as otherwise specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to entities that conduct business as wholesalers or retail community pharmacies, which includes but is not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers.

(c) *Sales, nominal price sales, rebates, discounts, or other transactions excluded from AMP.* AMP excludes the following sales, nominal sales, rebates, discounts, or other transactions:

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA).

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(4) Sales outside the United States.

(5) Direct and indirect sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(8) Sales to mail order pharmacies.

(9) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, and mental health centers).

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but not limited to inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs (such as medication compliance programs and patient education programs), including bona fide service fees paid to Group Purchasing Organizations.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D–14A of the Act.

(18) Sales to PBMs, including their mail order pharmacy's purchases.

(19) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Direct sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(26) Manufacturer vouchers.

(27) Prices negotiated under Manufacturer-sponsored drug discount card programs.

(28) Goods provided free of charge under Manufacturer-sponsored patient refund/rebate programs.

(29) Goods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs.

(d) *Sales and associated discounts, rebates, payments, or other transactions included in AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs) not generally dispensed through a retail community pharmacy.* AMP for 5i covered outpatient drugs indentified in accordance with § 447.507 of this subpart shall include sales and associated discounts, rebates, payments or other financial transactions to all entities as specified in paragraph (b) of this section, as well as the following sales and associated discounts, rebates, payments or other transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers where the PBM is not acting as an insurer, including its mail order pharmacy purchases.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales, discounts, or rebates paid directly to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

(6) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, mental health centers).

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(9) Sales to hospices.

(10) Sales to other manufacturers who conduct business as a wholesaler or retail community pharmacy.

(e) Further clarification of AMP calculation.

(1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees, and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

§ 447.505 Determination of best price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

Provider means a hospital, HMO, including an MCO, or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(b) *Prices included in best price.* Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly.

(c) *Prices excluded from best price.* Best price excludes the following:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, or the PHS.

(2) Prices to 340B covered entities.

(i) Prices charged under the 340B drug pricing program to a covered entity described in section 1927(a)(5)(B) of the Act; and

(ii) Any inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA.

(3) Any prices charged under the FSS of the GSA.

(4) Any prices provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D–14A of the Act.

(7) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(8) Prices negotiated under manufacturer-sponsored drug discount card programs.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(10) Goods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs.

(11) Goods provided free of charge under Manufacturer-sponsored patient refund or rebate programs.

(12) Manufacturer vouchers.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that it only covers these costs.

(15) Nominal prices to certain entities as set forth in § 447.508 of this subpart.

(16) Bona fide service fees paid by manufacturers to wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy, including but not limited to inventory management fees, product stocking allowances, and fees associated with administrative agreements and patient care programs (such as medication compliance programs and patient education programs), including bona fide service fees paid to Group Purchasing Organizations.

(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.

(18) Sales outside the United States.

(d) *Further clarification of best price.*

(1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees, distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Primary manufacturer means a manufacturer that holds the NDA of the authorized generic drug.

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.

(b) *Inclusion of authorized generic drugs in AMP by a primary manufacturer.* The primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler, or when the primary manufacturer holding the NDA sells directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price by a primary manufacturer.* A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding the NDA.

(d) *Inclusion of authorized generic in AMP and best price by a secondary manufacturer.* The secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in § 447.504 and § 447.505 of this subpart.

§ 447.507 Identification of 5i drugs.

A manufacturer must identify each covered outpatient drug that is a 5i drug that is not generally dispensed through a retail community pharmacy.

(a) *Identification of a 5i drug.* A manufacturer must use the list of FDA's Routes of Administration posted on the CMS Web site to identify each covered outpatient drug that qualifies as a 5i drug.

(b) *Not generally dispensed through a retail community pharmacy.* A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 90 percent or more of the sales of the 5i drug, during the reporting period, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly and quarterly basis.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity as described in section 340B(a)(4) of the PHSA.

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter.

(3) A State-owned or operated nursing facility providing services as set forth in § 440.150 of this chapter.

(4) A public or non-profit entity or facility at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, and provide family planning services described under section of 1001(a) of PHSA, 42 U.S.C. 300.

(5) An entity that—

(i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and

(ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but is not in receipt of grant funds under that Act.

(b) *Nonapplication.* This restriction does not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

(c) *Rule of construction.* Nothing in this subpart is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates.

(a) *Determination of rebate amount.*

(1) *Basic rebate for single source drugs and innovator multiple source drugs.* The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of—

(i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) The greater of—

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages—

(*1*) For a clotting factor, 17.1 percent;

(*2*) For a drug approved by the FDA exclusively for pediatric indications, 17.1 percent; or

(*3*) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) *Additional rebate for single source and innovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of—

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period; and

(ii) The amount, if any, by which—

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) *Total rebate.* The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) *Treatment of new formulations.*

(i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation is the amount computed under paragraphs (a)(1) through (a)(3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) The term ''line extension'' means, with respect to a drug, a new formulation of the drug, such as an extended release product.

(iii) *Identification of line extension drugs.*

(A) The FDA's list of Chemical Types, listed in FDA Drugs in FDA's database, is used to identify the line extension drug and the initial brand name listed drug.

(B) Chemical Type 2, new ester, new salt, or other noncovalent derivative; Chemical Type 3, new formulation; Chemical Type 4, new combination; and Chemical Type 6, new indication are determined to be line extension drugs.

(C) Chemical Type 1, new molecular entity, represents the initial brand name listed drug.

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the drug.

(6) *Rebate for noninnovator multiple source drugs.* The amount of the rebate for each dosage form and strength of a noninnovator multiple source drug will be equal to the product of—

(i) The total number of units of such dosage form and strength for which payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(b) *Rebates for drugs dispensed through Medicaid managed care organizations (MCOs).*

(1) Manufacturers participating in the Medicaid drug rebate program will pay rebates for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act.

(ii) Discounted under section 340B of the PHSA.

(3) Within 30 days of the end of each quarter, a Medicaid MCO that contractually provides covered outpatient drugs dispensed to Medicaid beneficiaries must report to the State the following data:

(i) MCO identifier.

(ii) National Drug Code.

(iii) Period covered.

(iv) Product FDA list name.

(v) Total units.

(vi) Total number of prescriptions.

(vii) Amount reimbursed.

(c) *Federal offset of rebates.* States must remit to the Federal government the amount of the savings resulting from the increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by the FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting

factors and drugs approved by the FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the URA calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For noninnovator multiple source drugs, the offset amount is equal to 2 percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP).

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include the following:

(1) AMP, calculated in accordance with § 447.504 of this subpart.

(2) Best price, calculated in accordance with § 447.505 of this subpart.

(3) Customary prompt pay discounts, which are reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(5) A manufacturer that fails to submit a quarterly AMP to CMS for a product by the thirtieth day after the end of each rebate period will be subject to civil monetary penalties for each product not reported on the thirty-first day of $10,000 per day per drug.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.*

(1) A manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction, that is, not based on any changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS or court order, or pursuant to an internal investigation, or an OIG or DOJ investigation.

(2) A manufacturer may report revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period in excess of 12 quarters from the quarter in which the data were due based on the approval of CMS for good cause.

(3) A manufacturer must report revisions to AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.*

(1) *Reporting period.* A manufacturer may report a revised DRA base date AMP to CMS within the first four full calendar quarters following July 17, 2007.

(2) *Recalculation of the DRA base date AMP.*

(i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart.

(ii) A manufacturer may choose to recalculate the DRA base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the DRA base date AMP.

(3) *Reporting a revised Affordable Care Act base date AMP.* A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first four full calendar quarters following [publication date of the final rule].

(4) *Recalculation of the Affordable Care Act base date AMP.*

(i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart.

(ii) A manufacturer may choose to recalculate the Affordable Care Act base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the Affordable Care Act base date AMP.

(d) *Monthly AMP.*

(1) *Definition.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP is calculated based on § 447.504 of this subpart, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due, except as allowed in paragraph (b)(1) of this section.

(4) *Exception.* A manufacturer must report revisions to monthly AMP within the 36-month time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(6) *Monthly AMP units.* A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP

to CMS not later than 30 days after the last day of each month.

(7) *Failure to report product information, monthly AMP and AMP units.* A manufacturer that fails to submit a monthly AMP and the total number of units that are used to calculate that monthly AMP to CMS for a product by the thirtieth day after the last day of each month will be subject to civil monetary penalty for each product not reported on the thirty-first day of $10,000 per drug per day.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO).

(2) The manufacturer's chief financial officer (CFO).

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (e)(1) through (e)(3) of this section.

(f) *Recordkeeping requirements.*

(1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations.

(ii) The 10-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the 10-year period if all of the following circumstances exist:

(i) The records are the subject of an audit, or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format designated by CMS.

§ 447.511 Requirements for States.

(a) *Invoices submitted to participating drug manufacturers.* Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data:

(1) The State code.

(2) National Drug Code.

(3) Period covered.

(4) Product FDA list name.

(5) Unit rebate amount.

(6) Units reimbursed.

(7) Rebate amount claimed.

(8) Number of prescriptions.

(9) Medicaid amount reimbursed.

(10) Non-Medicaid amount reimbursed.

(11) Total amount reimbursed.

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers.

(c) *State that has participating Medicaid Managed Care Organizations (MCO).* A State that has participating Medicaid Managed Care Organizations (MCO), which includes covered outpatient drugs in its contracts with the MCOs, must report data described in paragraph (a) of this section for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is required under contract for coverage of such drugs under section 1903 of the Act. This data must be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for ''other drugs'' set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the following:

(1) AAC plus a professional dispensing fee established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.

(2) The agency must decide what certification form and procedure are used.

(3) A check off box on a form is not acceptable but a notation like ''brand necessary'' is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.*

(1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs available for purchase by retail community pharmacies on a nationwide basis that the FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in its most current edition of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or in successor publications). Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those therapeutically equivalent drug products

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, prior to the application of any Federal or State drug rebate considerations, payment levels determined by applying for each drug entity a professional dispensing fee established by the State agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMP using manufacturer submitted utilization data.

(c) *Ensuring a drug is for sale nationally.* To assure that a multiple source drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the termination date reported by the manufacturer to CMS.

(2) The monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL.

(d) The FUL will be applied as an aggregate upper limit.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings, and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(1) A covered entity described in section 1927(a)(5)(B) of the Act.

(2) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(3) An Indian Health Service, tribal and urban Indian pharmacy.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart.

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in § 447.512 and § 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

(d) *Data requirements.* When proposing changes to the ingredient cost reimbursement or professional dispensing fee reimbursement, States must provide adequate data, including, but not limited to, a State or national survey of retail pharmacy providers or other reliable data which reflects the pharmacy's actual or average acquisition cost as a base to support any proposed change in ingredient cost reimbursement. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers to secure rebates.

(2) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(b) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers to secure rebates.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

§ 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

(a) Medicaid coverage of investigational drugs may be provided at State option under section 1905(a)(12) of the Act when such drug has been indicated by the FDA for human trials.

(b) A State agency electing to provide coverage of an investigational drug must include in its State plan a description of the coverage and payment for such drug.

(c) The State plan must indicate that any payments for investigational drugs will be reimbursed in accordance with the FDA final rules at 21 CFR parts 312 and 316 if they are to be eligible to receive FFP for these drugs.

(d) Medicaid coverage of other drugs may be provided at State option under section 1905(a)(12) of the Act provided that they are not covered outpatient drugs or fail to be listed electronically with the FDA.

(e) Investigational drugs and other drugs are not subject to the rebate requirements of section 1927 of the Act provided they do not meet the definition of a covered outpatient drug as set forth in section 1927(k) of the Act.

Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.

Dated: March 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 16, 2011.

Kathleen Sebelius,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on January 26, 2012.

[FR Doc. 2012–2014 Filed 1–27–12; 11:15 am]

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FEDERAL REGISTER

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Part III

The President

Executive Order 13598—Assignment of Functions Relating to Certain Promotion and Appointment Actions in the Armed Forces

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Presidential Documents

Title 3—

The President

Executive Order 13598 of January 27, 2012

Assignment of Functions Relating to Certain Promotion and Appointment Actions in the Armed Forces

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

Section 1. *Assignment of Functions to the Secretary of Defense.* The Secretary of Defense shall perform the functions of the President under the following provisions of title 10, United States Code:

(a) the first sentence of section 14111(a) with respect to reports relating to the grades of brigadier general or above, or rear admiral (lower half) or above;

(b) sections 629(c)(2) and 14310(c)(2) with respect to extending officer promotion eligibility periods; and

(c) section 6222(c)(2) with respect to appointments of members of the Marine Band and members of the Marine Drum and Bugle Corps to grades not above the grade of captain.

Sec. 2. *Reassignment of Functions Assigned.* The Secretary of Defense may reassign the functions assigned to him by sections 1(a) and (b)of this order only to civilian officers within the Office of the Secretary of Defense (as defined in section 131(b) of title 10, United States Code) who hold a position for which the President makes an appointment by and with the advice and consent of the Senate. The Secretary of Defense may not reassign the function assigned to him by section 1(c) of this order.

Sec. 3. *General Provisions.* (a) Nothing in this order shall be construed to limit or otherwise affect the authority of the President as Commander in Chief of the Armed Forces of the United States, or under the Constitution and laws of the United States to nominate or to make or terminate appointments.

(b) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
January 27, 2012.

[FR Doc. 2012–2557
Filed 2–1–12; 11:15 am]
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This is the final list of public bills from the first session of the 112th Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

H.R. 1540/P.L. 112–81

National Defense Authorization Act for Fiscal Year 2012 (Dec. 31, 2011; 125 Stat. 1298)

H.R. 515/P.L. 112–82

Belarus Democracy and Human Rights Act of 2011 (Jan. 3, 2012; 125 Stat. 1863)

H.R. 789/P.L. 112–83

To designate the facility of the United States Postal Service located at 20 Main Street in Little Ferry, New Jersey, as the "Sergeant Matthew J. Fenton Post Office". (Jan. 3, 2012; 125 Stat. 1869)

H.R. 1059/P.L. 112–84

To protect the safety of judges by extending the authority of the Judicial Conference to redact sensitive information contained in their financial disclosure reports, and for other purposes. (Jan. 3, 2012; 125 Stat. 1870)

H.R. 1264/P.L. 112–85

To designate the property between the United States Federal Courthouse and the Ed Jones Building located at 109 South Highland Avenue in Jackson, Tennessee, as the "M.D. Anderson Plaza" and to authorize the placement of a historical/identification marker on the grounds recognizing the achievements and philanthropy of M.S. Anderson. (Jan. 3, 2012; 125 Stat. 1871)

H.R. 1801/P.L. 112–86

Risk-Based Security Screening for Members of the Armed Forces Act (Jan. 3, 2012; 125 Stat. 1874)

H.R. 1892/P.L. 112–87

Intelligence Authorization Act for Fiscal Year 2012 (Jan. 3, 2012; 125 Stat. 1876)

H.R. 2056/P.L. 112–88

To instruct the Inspector General of the Federal Deposit Insurance Corporation to study the impact of insured depository institution failures, and for other purposes. (Jan. 3, 2012; 125 Stat. 1899)

H.R. 2422/P.L. 112–89

To designate the facility of the United States Postal Service located at 45 Bay Street, Suite 2, in Staten Island, New York, as the "Sergeant Angel Mendez Post Office". (Jan. 3, 2012; 125 Stat. 1903)

H.R. 2845/P.L. 112–90

Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011 (Jan. 3, 2012; 125 Stat. 1904)

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