DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 149

RIN 0991–AB64

Early Retiree Reinsurance Program

AGENCY: Office of the Secretary, HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) implements the Early Retiree Reinsurance Program, which was established by section 1102 of the Patient Protection and Affordable Care Act (the Affordable Care Act). The Congress appropriated funding of $5 billion for the temporary program. Section 1102(a)(1) requires the Secretary to establish this temporary program not later than 90 days after enactment of the statute, which is June 21, 2010. The program ends no later than January 1, 2014. The program provides reimbursement to participating employment-based plans for a portion of the cost of health benefits for early retirees and their spouses, surviving spouses and dependents. The Secretary will reimburse plans for certain claims between $15,000 and $90,000 (with those amounts being indexed for plan years starting on or after October 1, 2011). The purpose of the reimbursement is to make health benefits more affordable for plan participants and sponsors so that health benefits are accessible to more Americans than they would otherwise be without this program.

DATES: *Effective Date:* These regulations are effective on June 1, 2010.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on June 4, 2010.

ADDRESSES: In commenting, please refer to file code DHHS–9996–IFC. 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).

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions on the home page.
- *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: DHHS–9996–IFC, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *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: DHHS–9996–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *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) 786–9994 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.

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: James Slade, (410) 786–1073, for information regarding the Purpose and Basis, Requirements for Eligible Employment-Based Plans, Use of Reimbursement Amounts, Appeals, and Disclosure of Data Inaccuracies.

David Mlawsky, (410) 786–6851, for information regarding the Definitions, Reinsurance Amounts, Reimbursement Methods, Including Provision of Necessary Information, and Change of Ownership Requirements.

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 electronic comments received before the close of the comment period on the following public 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 be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445–G, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1–800–743–3951.

I. Background

A. Overview of the Early Retiree Reinsurance Program Enacted as Part of the Patient Protection and Affordable Care Act

On March 21, 2010, the Congress passed the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), which was signed into law on March 23, 2010. Included in this health insurance reform law is a provision that establishes the temporary Early Retiree Reinsurance Program. This provision addresses the recent erosion in the number of employers providing health coverage to early retirees. People in the early retiree age group often face difficulties obtaining insurance in the individual market because of advanced age or chronic conditions that make coverage unaffordable and inaccessible. The Early Retiree Reinsurance Program provides needed financial help for employer-based plans to continue to provide valuable coverage to plan participants, and provides financial relief to plan participants.

The Early Retiree Reinsurance Program provides reimbursement to participating sponsors for a portion of the costs of providing health coverage to early retirees (and eligible spouses, surviving spouses, and dependents of such retirees). Section 1102(a)(2)(B) of

the Affordable Care Act defines "employment-based plan" to include a group benefits plan providing health benefits that is maintained by private employers, State or local governments, employee organizations, voluntary employees' beneficiary association, a committee or board of individuals appointed to administer such plan, or a multiemployer plan (as defined by Employee Retirement Income Security Act or ERISA). Section 1102 does not differentiate between health benefits provided by self-funded plans or through the purchase of insurance.

Section 1102(a)(1) requires the Secretary of HHS (the Secretary) to establish the program within 90 days of enactment of the law, which is June 21, 2010. We expect this program to be established by June 1, 2010. By law, the program will expire on January 1, 2014. Funding for the program is limited to $5 billion.

II. Provisions of the Interim Final Rule

This regulation establishes 45 CFR part 149, "Requirements for the Early Retiree Reinsurance Program." This part implements section 1102 of the Affordable Care Act, which requires the Secretary to provide reimbursement to sponsors with certified plans for a portion of the cost of health benefits for early retirees and their spouses, surviving spouses and dependents, provided funds remain available. In part 149, we established new subparts A through H. These new subparts set forth the framework for implementing the Early Retiree Reinsurance Program effective June 1, 2010 through January 1, 2014. We are implementing the statutory requirements of the program as follows:

A. General Provisions (Subpart A)

1. Purpose and Basis (§ 149.1)

In this section, we provide the statutory authority for promulgating the regulation.

2. Definitions (§ 149.2)

Section 1102(a) of the Affordable Care Act (also referred to as the "statute") provides definitions for three specific terms. One of these terms is the term "employment-based plan", which the statute defines as a "group benefits plan providing health benefits" that satisfies certain conditions. The statute at section 1102(a)(1) also specifies that under the program, the Secretary shall provide reimbursement to participating employment-based plans. However, a plan typically constitutes merely an arrangement to provide benefits, as opposed to a discrete entity to which payments can be directly made or sent. Thus, the regulation interprets this provision to require reimbursement under the program to a "sponsor," and defines sponsor as that term is defined in regulations promulgated for the Retiree Drug Subsidy (RDS) Program at 42 CFR 423.882. That definition defines sponsor as a plan sponsor as defined in section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B), except that, in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer. By defining the term sponsor in the regulation, and by specifying that sponsors are the entities that apply for and get reimbursed under the program, we believe we are achieving two important objectives: (1) We are ensuring that program reimbursements can be made to actual existing entities, and (2) We are promoting consistency with the RDS Program. This second objective is critical, as we believe that many of the entities that will apply for the Early Retiree Reinsurance Program are entities that participate in the RDS Program, as these two programs have many similarities. Thus, the common use of terms across the two programs will minimize confusion, and we believe will help to maximize program participation.

Although we drafted the regulation to specify that a sponsor is the entity that would be directly paid under the program, there is still a need to use the term "employment-based plan" in the regulation. This is because the statute envisions that the entity receiving reimbursement have a benefits arrangement (that is, a plan) in place that satisfies certain criteria (for example, implements programs and procedures to generate cost-savings with respect to participants with chronic and high-cost conditions.) The statute provides a definition of "employment-based plan" as constituting a "group benefits plan" that has certain characteristics. Those characteristics (for example, must be maintained by one or more employers, can include a multiemployer plan as defined in section 3(37) of ERISA) borrow components of the ERISA definition of a "group health plan". For that reason, we define "employment-based plan" as meaning a "group health plan" as defined in the RDS regulations at 42 CFR 423.882 that provides health benefits to early retirees, but excludes Federal governmental plans. (Unlike the RDS statutory provisions, the Early Retiree Reinsurance Program's statutory provisions do not expressly include Federal plans). The RDS regulatory definition of "group health plan" largely tracks the ERISA definition. For reasons previously stated, we believe it is beneficial to use the same or similar terminology, and have the same or similar requirements for the RDS Program and the Early Retiree Reinsurance Program, when appropriate. Because the RDS program requires a sponsor to have a benefits arrangement that constitutes a group health plan, we believe the benefits arrangement must be in place for purposes of the Early Retiree Reinsurance Program (that is, an employment-based plan), should also be a group health plan (that is, an employment-based plan, defined generally as group health plan). Generally, the regulation uses the term "sponsor" when referring to the entity that applies for and receives reimbursement under the program, and uses the term "employment-based plan" when discussing the health benefits arrangement the sponsor must offer.

In addition to introducing the definition of "sponsor", the regulation also defines other terms that are not defined in the statute, including the term "authorized representative." We define this term to mean an individual with legal authority to sign and bind a sponsor to the terms of a contract or agreement. This term is important in the regulatory provision relating to the program application and the plan sponsor agreement. The regulation requires an authorized representative to sign a plan sponsor agreement as part of the program application.

We use the term "benefit option" in the regulation when discussing the fact that there is only one cost threshold and cost limit per early retiree per plan, regardless of how many benefit options within that plan the early retiree is enrolled in, in a given plan year. We define "benefit option" as a particular benefit design, category of benefits, or cost-sharing arrangement offered within an employment-based plan.

The statute at section 1102(b) requires that an employment-based plan be certified by the Secretary, and submit an application for the program, before the plan can participate in the program. As stated above, under this regulation, the entity that participates in (that is, applies for) the program, is the plan sponsor. We will not approve an application unless the sponsor, and the employment-based plan, meet their respective requirements under the statute and the regulation. Therefore, we define the term "certified" as meaning that the sponsor and its employment-

based plan or plans meet the requirements of this part and the sponsor's application to participate in the program has been approved by the Secretary. All elements of this requirement must be satisfied before a sponsor can participate in the program.

The statute at section 1102(b)(2) requires employment-based plans to have programs and procedures in place to generate cost savings for participants with chronic and high-cost conditions. We define the term "chronic and high-cost condition" to mean a condition for which $15,000 or more in health benefit claims are likely to be incurred during a plan year by any one participant. Sponsors participating in this program are likely to be sponsors that have offered the applicable plan in previous years. Sponsors, therefore, will recognize which conditions are likely to result in $15,000 in claims in a plan year for one participant. While we expect that the employment-based plans will have programs and procedures in place that have generated or have the potential to generate savings for participants with these conditions, which may vary across plans, geographic regions and due to other factors, we do not expect plans to have programs and procedures in place for all conditions for which claims are likely to exceed $15,000 in a plan year for a plan participant. To require that plans have programs and procedures in place to address all chronic and high-cost conditions could exclude many sponsors from participating in the program and could be overly restrictive. We expect sponsors to take a reasonable approach when identifying such conditions and selecting programs and procedures to lower the cost of care, as well as improve the quality of care, for such conditions.

We define "claim" or "medical claim" in order to lay out in more detail what is required on the claim to be reimbursed under this program, and to note that the terms "claim" or "medical claim" include medical, surgical, hospital, prescription drug and other types of claims as determined by the Secretary. The statute at section 1102(a)(2)(A) defines "health benefits" as medical, surgical, hospital, prescription drug, and such other benefits as shall be determined by the Secretary whether self-funded, or delivered through the purchase of insurance or otherwise. The regulatory definition of "health benefit" clarifies that such benefits include benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body. (As discussed below, health benefits do not include benefits specified at 45 CFR 146.145(c)(2) through (4)). Therefore, per the Secretary's authority to determine benefits for which claims may be submitted, the terms "claim" or "medical claim" include claims for the benefits set out in the definition of "health benefit." This list of benefits, for which the Secretary has the authority to determine are appropriate under the program, is not exhaustive.

The statute at section 1102(a)(2)(C) defines "early retirees" as individuals who are age 55 and older but are not eligible for coverage under Medicare, and who are not active employees of an employer maintaining, or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan. We have incorporated this definition into the regulation, and we clarified that spouses, surviving spouses, and dependents are also included in the definition of early retiree. This definition accommodates the language in section 1102(a)(1) of the statute, which states that reimbursement under the program is made to cover a portion of the costs of providing health coverage to early retirees and to the eligible spouses, surviving spouses, and dependents of such retirees. This definition accommodates the language in section 1102(a)(1) in such a way that reimbursement can be made under the program for the health benefit costs of eligible spouses, surviving spouses, and dependents of such retirees, even if they are under the age of 55, and/or are eligible for Medicare. We believe the statute can reasonably be interpreted to provide reimbursement for the health benefit costs of such individuals. This interpretation will provide additional assistance to sponsors, which will encourage them to continue to offer coverage to the spouses, surviving spouses, and dependents of early retirees.

The regulatory definition of early retiree also clarifies that the determination of whether an individual is not an active employee is made by the sponsor in accordance with the rules of its plan. However, an individual is presumed to be an active employee if, under the Medicare Secondary Payer (MSP) rules in 42 CFR 411.104 and related Centers for Medicare & Medicaid Services' (CMS) guidance, the person is considered to be receiving coverage by reason of current employment status. The presumption would apply whether or not the MSP rules actually apply to the sponsor. We also clarify that a sponsor may treat a person receiving coverage under its employment-based plan as a dependent in accordance with the rules of its plan, regardless of whether that person constitutes a dependent for Federal or state tax purposes. These two clarifications are also found in the RDS regulation in the definition of "qualifying covered retiree," under which, as that term implies, an individual must be a retiree. As previously stated, we believe that regulatory terminology and concepts should be the same or similar between the RDS Program and the Early Retiree Reinsurance Program when appropriate, and we believe it is appropriate when determining whether an individual is a retiree under each program. Finally, in the regulatory definition of "early retiree," we also clarify that for purposes of this definition, the phrase "an employer maintaining or currently contributing to the employment-based plan or any employer that has made substantial contributions to fund such plan," which is also found in the statutory definition of "early retiree," means a plan sponsor. Under ERISA (and the RDS Program regulation), a plan sponsor is an entity (such as an employer) that establishes or maintains a group health plan. Thus, because this part of the statutory definition of early retiree in the Affordable Care Act speaks to the relationship between the sponsor (for example, the employer) and the employment-based plan, we believe this clarification is appropriate.

Section 149.610 of this regulation permits the Secretary to reopen and revise a reimbursement determination upon the Secretary's own motion or upon the request of a sponsor within 1 year of the reimbursement determination for any reason, within 4 years of the reimbursement determination for good cause, or at any time in instances of fraud or similar fault. These three standards are the same regulatory standards that apply with respect to CMS' ability to reopen or revise an initial or reconsidered determination under the RDS Program, at 42 CFR 423.890(d). The RDS regulatory provision provides examples of what constitutes "good cause," and again, because of the similarity between that program and the Early Retiree Reinsurance Program, we believe those examples would be appropriate for the latter. Therefore, similar to the RDS regulation, this regulation provides the following examples of good cause: (1) New and material evidence exists that was not readily available at the time the reimbursement determination was made, (2) A clerical error in the computation of the reimbursement determination was made, or (3) The

evidence that was considered in making the reimbursement determination clearly shows on its face that an error was made. For example, if a sponsor receives a post-point-of-sale price concession that was not known at the time a reimbursement determination was made, good cause may be found and the reimbursement determination may be reopened and revised.

The statute at section 1102(a)(2)(A) defines "health benefits" as medical, surgical, hospital, prescription drug, and such other benefits as shall be determined by the Secretary, whether self-funded, or delivered through the purchase of insurance or otherwise. We clarify in the regulatory definition that such benefits include benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body. This is not an exhaustive list. We also specify that health benefits do not include certain benefits designated as excepted benefits under the regulations implementing the health insurance portability provisions of the Health Insurance Portability and Accountability Act (HIPAA). Those provisions impose certain requirements on group health plans and group health insurance issuers, but do not apply those requirements to certain arrangements that typically are not part of a major medical plan (that is, excepted benefits). For example, long-term care benefits are excepted benefits. In the context of the Early Retiree Reinsurance Program, we do not believe it would be appropriate to consider health benefits as including benefits provided under such arrangements, as we believe the best read of the statutory phrase "medical, surgical, hospital, [and] prescription drug" means such major medical benefits.

In order to aid stakeholders in understanding when the Secretary will make reimbursement to a sponsor, we define the term "incurred" to mean the point in time when the sponsor, health insurance issuer, group health plan or plan participant, or a combination of these or similar stakeholders, become responsible for payment of the claim. In short, the Secretary will not pay a sponsor until a claim has been incurred and paid, as the statute at section 1102(c)(1)(B) specifies that claims "shall be based on the actual amount expended."

We define a "negotiated price concession" as any direct or indirect remuneration that would serve to decrease the costs incurred under the employment-based plan. We set out examples of what negotiated price concessions are, which include discounts, rebates, coupons, and goods in kind. The list at § 149.2, "Definitions," describing what may constitute a negotiated price concession is not an exhaustive list.

Because the statute does not use the terms "early retiree" and "plan participant" interchangeably, we define the term "plan participant" to include all enrollees in a plan, including an early and other retiree, an early and other retiree's spouse, surviving spouse, and dependent, and an active employee and an active employee's spouse and dependent.

The statute at section 1102(c)(1)(B) specifies that claims submitted under the program "shall be based on the actual amount expended by the participating employment-based plan involved within the plan year" for the health benefits provided to early retirees and eligible spouses, surviving spouses, and dependents. This regulation includes a definition of plan year, and defines plan year as the year that is designated as the plan year in the plan document of an employment-based plan, except that if the plan document does not designate a plan year, if the plan year is not a 12-month plan year, or if there is no plan document, the plan year is: (1) The deductible or limit year used under the plan, (2) the policy year, if the plan does not impose deductibles or limits on a 12-month basis: (3) the sponsor's taxable year, if the plan does not impose deductibles or limits on a 12-month basis, and either the plan is not insured or the insurance policy is not renewed on a 12-month basis, or (4) the calendar year, in any other case. We define this term in such a way to give deference to the plan year the sponsor has already established for other purposes. However, we balance that deference with our belief that the intent of the statute is to calculate reimbursement amounts, and to apply the cost threshold and cost limit, to periods of time that are 12 months in duration. We believe most sponsors' plan years are in fact 12 months in duration.

The term "post point-of-sale negotiated price concession" is defined because not all negotiated price concessions occur at or before the point of sale. The statute requires negotiated price concessions to be excluded from the calculation of reimbursement, which causes reimbursement to be based on the actual amounts paid, not an inflated amount that may not reflect a price concession. When post point-of-sale negotiated price concessions occur they may cause data submitted for reimbursement to become inaccurate, resulting in ultimately, an inaccurate reimbursement. Once these price concessions are accounted for, a sponsor's reimbursement determination may be reopened and revised.

For purposes of brevity, we defined the term "program" to mean the Early Retiree Reinsurance Program.

We define the term "Secretary" to mean the Secretary of the Department of Health & Human Services or the Secretary's designee. We include the Secretary's designee in the definition because the Secretary will not actually be performing the tasks set out in this regulation, but will designate an individual or entity to act on the Secretary's behalf.

The term "sponsor agreement" is based on the definition of the term in the RDS regulation. The sponsor agreement is basically used to ensure that the sponsor and Department are bound to comply with the details of the program that appear in the regulation and in other guidance, and to address any other points that must be addressed in order to implement this program.

B. Requirements for Eligible Employment-Based Plans (Subpart B)

1. General Requirement (§ 149.30)

In this section, we provide the requirements that allow a sponsor to be eligible to participate in the Early Retiree Reinsurance Program.

2. Requirements to Participate (§ 149.35)

Section 1102(b)(2)(A) of the Affordable Care Act requires that an employment-based plan implement programs and procedures to generate cost-savings with respect to participants with chronic and high-cost conditions. We interpret this to mean that a plan must have in place programs and procedures that have generated or have the potential to generate cost-savings for these participants in order to participate in the Early Retiree Reinsurance Program, not necessarily that the sponsor has to ensure that new programs and procedures are put in place just to participate in this program.

Proper management and treatment of chronic and high-cost conditions may be promoted by generating cost-savings for plan participants with these conditions because plan participants may be more apt to seek out proper and timely treatment and management before a condition becomes critical if treatment and management are financially manageable. As an example of a program and procedure to generate cost savings for a participant with a chronic condition, a sponsor may determine that diabetes, if not managed

properly, is likely to lead to claims in excess of $15,000 for a plan year for one plan participant. The sponsor may ensure implementation of a diabetes management program that includes aggressive monitoring and behavioral counseling to prevent complications and unnecessary hospitalization. With respect to generating cost savings for a high-cost condition, a sponsor may determine that cancer is a high-cost condition for which it should generate cost savings. The sponsor may ensure that its plan covers all or a large portion of the participant's coinsurances or copayments, and/or it could eliminate or reduce the plan's deductible for treatment and visits related to the condition. Sponsors may choose other chronic and high-cost conditions to address, but upon audit the sponsor must be able to demonstrate that its programs and procedures have generated or had the potential to generate cost savings, consistent with the representations the sponsor made in its program application.

We considered various options of how best to implement this provision and developed several options. The first option was to further identify which specific conditions meet the chronic condition definition and which specific conditions meet the high-cost condition definition and identify these specific conditions in sub-regulatory guidance to be issued at the time of, or immediately after, the issuance of this regulation. Issues that arose with this option consisted of:

(1) How best to define the terms "chronic and high-cost conditions", which would likely involve a significant amount of data analysis. Chronic and high-cost conditions can vary significantly across geographic regions, age ranges, and due to other factors. We do not think that specifying the chronic and high-cost conditions to be addressed could effectively occur within the 90 days allowed for establishment of this program; and

(2) Our belief that the Congress intends this to be an inclusive program, not a program that excludes potential sponsors merely because they did not develop programs to address the specific conditions we might identify in our guidance. Had the Congress narrowly defined the types of plans for which sponsors might be reimbursed, we might have thought that this program is not an inclusive program. Instead Congress defined the term "employment-based plan" broadly in the statute at section 1102 (a)(2)(B). It defines the term as a "group benefits plan providing health benefits" as a plan that "is * * * maintained by one or more current or former employers (including without limitation any State or local government or political subdivision thereof), employee organization, a voluntary employees' beneficiary association, or a committee or board of individuals appointed to administer such plan; or * * * a multiemployer plan * * * " Therefore the scope of sponsors eligible to receive this reimbursement is extremely broad, which shows intent on behalf of Congress to be inclusive.

The inclusive nature of the program is particularly important because this program will involve plans with plan years that began before the effective date of the program, as will be discussed below. This means that a plan may not have a program in place to address certain chronic and high-cost conditions that we may have identified after the plan year has started, which would then exclude the sponsor from participation in the program. In such cases, sponsors would, in effect, be penalized if we identified specific conditions. As stated above, chronic and high-cost conditions can vary significantly across geographic regions, age ranges, and due to other factors, so we expect that sponsors might focus cost-saving programs and procedures on conditions that effect enrollees in their plan or plans. Our intent is that the regulation takes into account these differences.

The approach we decided to take was to define the term "chronic and high-cost condition" as specified in § 149.2—Definitions. "Chronic and high-cost condition" means a condition for which $15,000 or more in applicable claims are likely to be incurred during a plan year by one participant. Therefore, a sponsor must have programs and procedures in place that generate or have the potential to generate cost savings for plan participants with conditions that are likely to generate $15,000 in claims for a plan year, in order to participate in this program. We do not require that a sponsor have programs and procedures in place to address all conditions that may result in claims exceeding $15,000 for one participant in a plan year. The sponsor must take a reasonable approach to identifying which conditions it must address. We believe this is a reasonable interpretation of the statute because it will promote cost savings for participants with chronic and high-cost conditions, but due to the approaches' flexibility (that is, the fact that sponsors may choose programs and procedures that meet this requirement that are applicable to their enrollees) will serve to allow as many of the types of sponsors referenced in the definition of "employment-based plan" as possible to become certified to participate in the program. Of course, this requirement does not supersede requirements in other Federal laws that may apply to programs and procedures for chronic and high-cost conditions, such as the Americans with Disabilities Act.

In order to administer this program and to audit the program as required by section 1102(d), we are requiring the sponsor to make records available for these purposes. For example, when a sponsor is audited, the auditors may request a copy of the sponsor's (or the sponsor's health insurance issuer or group health plan's, as applicable) policies and procedures to detect fraud, waste and abuse, and data to substantiate the effectiveness of the policies and procedures. Under this provision, the sponsor is required to ensure that the applicable policies and procedures are produced.

We also require that the sponsor have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan (as defined in 45 CFR 149.2), as applicable, requiring the health insurance issuer or employment-based plan to disclose information on behalf of the sponsor to the Secretary. This requirement in part exists to accommodate the HIPAA Privacy Rule at 45 CFR part 160 and subparts A and E of part 164 ("Privacy Rule"). This rule applies to "covered entities," which include group health plans (that is, employment-based plans) and health insurance issuers, as defined in 45 CFR 160.103. Third party administrators would be business associates, as defined in 45 CFR 160.103, of group health plans. Sponsors would not become covered entities by sponsoring a plan. Sponsors typically do not perform administrative activities for their group health plans and therefore do not have access to the claims information or similar protected health information (PHI) we require in this regulation to support program reimbursement. Much of the data that we would need to support program reimbursements, as outlined above, would be PHI held by group health plans, health insurance issuers, or third party administrators on behalf of group health plans. The requirement for health insurance issuers and employment-based plans to disclose information to the Secretary encompasses information created or held by Business Associates on behalf of the health insurance issuer or group health plan.

We believe that we have the authority to require the disclosure of the PHI in accordance with section 1102(c)(1)(A), which states that a participating plan "shall submit claims for reimbursement

to the Secretary which shall contain documentation of the actual costs of the items and services for which each claim is being submitted." Additionally, section 1102(d) requires the Secretary to conduct audits of claims data submitted by, or on behalf of, sponsors participating in the program, to ensure that such plans are in compliance with the statute, and this simply cannot be done without mandating disclosure of PHI. Thus, covered entities can comply with the mandate (without first obtaining specific authorization from individuals) pursuant to "the required by law" provisions of the Privacy Rule (45 CFR 164.512(a)).

As noted above, typically group health plans and health insurance issuers or third party administrators acting on behalf of group health plans, have PHI that the Secretary requires for the submission of claims data for reimbursement under the program pursuant to the regulations. In these situations, it may be unlawful, under the Privacy Rule, for PHI to be shared with the sponsors. This regulation does not authorize disclosure of PHI to sponsors. Therefore, for purposes of this subpart, the sponsor must have a written agreement with the group health plan (that is, the employment-based plan) or health insurance issuer, as applicable, regarding disclosure of records, and the plan or issuer must disclose to us, on the sponsor's behalf, the information, data, documents, and records necessary for the sponsor to comply with this program, part, and guidance, at a time and in a manner specified by the Secretary. Sponsors of self-funded plans with legal access to such data will be able to either provide this data to us themselves or have a group health plan or insurer provide the data to us on their behalf.

Section 1102 (c)(6) of the Affordable Care Act requires the Secretary to establish procedures to protect against fraud, waste and abuse. In order to implement this provision, the Secretary will, for example, check the exclusions lists developed by the HHS' Office of the Inspector General and the U.S. General Services Administration before allowing an entity to participate, or play a role, in the program, and will take other steps such as verifying the identities of the early retirees for whom claims are being submitted. The Secretary may also verify the identities of the individuals associated with the sponsor and health insurance issuer, or group health plan, as applicable, and will examine claims before reimbursement is made, to ensure, among other things, that instances of fraud, waste and abuse are minimized. Furthermore, the Secretary will perform audits per section 1102(d) of the Affordable Care Act. To aid the Secretary in detecting and reducing fraud, waste and abuse, we are requiring that sponsors ensure that there are policies and procedures in place to detect and reduce fraud, waste and abuse. While the policies and procedures may be maintained by the sponsor's health insurance issuer or group health plan, the sponsor will have to attest that these policies and procedures are in place in the application. The sponsor must comply with requests from the Secretary to produce the policies and procedures and any documents or data to substantiate the implementation, and the effectiveness, of the procedures. We believe we meet the requirements of the statute by taking actions to detect and reduce fraud, waste, and abuse, by requiring sponsors to have such policies and procedures in place, and by requiring a sponsor to produce the policies and procedures upon request (such as for the purposes of an audit). If it is found that a sponsor committed fraud, waste or abuse, or allowed fraud, waste, and abuse to occur under its plan or plans, the Secretary may recoup from the sponsor some or all of the reimbursements paid under the program, and/or may revoke a sponsor's certification to participate in the program. Of course, there are other laws relating to fraud, waste, and abuse, with which sponsors and their health insurance issuers or group health plans must comply.

3. Application (§ 149.40)

Section 1102(b)(1)(B) requires the sponsor to submit "an application for participation in the program, at such time, in such manner, and containing such information as the Secretary shall require." In order to implement this provision, a sponsor must submit one application per plan, and identify the plan year cycle for which the sponsor is applying (that is, starting month and day, and ending month and day; no year is required). One application must be filed for each plan. Filing a different application for each plan will aid in tracking the plan as this program progresses to ensure proper reimbursement and compliance with program requirements.

In order to verify the accuracy of the information contained in the application, the application will have to be signed by an authorized representative of the applicant and the authorized representative will have to certify that the information contained in the application is true and accurate to the best of the authorized representative's knowledge and belief, among other certifications. We use the term applicant in this section to refer to any sponsor that has filed an application that has not yet been certified under the program. The term applicant is used to clarify that the applicant is not entitled to the privileges of a certified sponsor, such as the ability to submit a reimbursement request or appeal a reimbursement determination. Before a sponsor may submit claims and make a reimbursement request, the sponsor's application must be approved by the Secretary. Applications will be processed in the order in which they are received. Because funding for this program is limited, we expect more requests for reimbursement than there are funds to pay the requests. Therefore we expect an applicant to perform its due diligence when applying, which should result in the submission of a complete application upon the first submission. Because it is important that applicants submit complete applications the first time, we will be providing assistance. If an application is incomplete, it will be denied and the applicant will have to submit a new application, which will be processed based on when the new application is received. If we were to allow an applicant to cure defects in the application, it would likely result in an extended application process, which would hinder the efficient implementation of this program. We must be prepared to exercise our authority under section 1102(f) to stop accepting applications based on the availability of the $5 billion appropriated for the program. It is therefore of paramount importance to applicants that they submit complete applications upon their first submission, otherwise there may not be an opportunity to submit a new and complete application.

An application for a given plan does not have to be submitted each year. To require a separate application for a plan each year would only complicate the process and would place unneeded burden on applicants and the Secretary. The application will request the plan year cycles (that is, the start month and day and the end month and day; no year required), which for our purposes will provide the information we need to calculate reimbursement based on reimbursement requests. We do not think that an annual application approval is required. Once a plan is certified, the application approved, and the sponsor continues to meet the requirements of the statute, this part,

and applicable guidance, the plan and sponsor will continue to be certified and the application approved.

We set out in § 149.40 what we believe we will need in order to approve an application. The application must include the applicant's Tax Identification Number, the applicant's name and address, and contact information for the applicant. To ensure compliance with the requirements of the statute, an applicant must provide a summary in its application of how it will use the reimbursement to meet the requirements of the program, including how it will use the reimbursement to reduce plan participant or sponsor costs, or any combination of these costs, and its plans to implement programs and procedures to generate savings for plan participants with chronic and high-cost conditions. Because the statute requires that the funds dispersed under this program not be used as general revenue, we are requiring sponsors to maintain the level of effort in contributing to support their applicable plan or plans. Otherwise, sponsors might circumvent the prohibition on using the program funds as general revenue by using, dollar for dollar, sponsors' funds not otherwise used for health benefits due to the program reimbursement, as general revenue. We expect that sponsors will use the reimbursement to pay for increases in, for example, the sponsor's premium, or increases in other health benefit costs (or to reduce plan participants' costs). Therefore the sponsor's summary of how it will use the program's reimbursement must also explain how the reimbursement will be applied to maintain the sponsor's level of effort in contributing to support the applicable plan. We do not expect a sponsor to explain every detail of their programs and procedures and use of program funds but to give us an idea of how it will meet these requirements. We understand that these submissions may vary because applicants' situations with respect to their plans may vary widely. For example, reimbursements received in the first year that a sponsor participates may be applied the second year of participation because many plans will have already been negotiated, agreed to, and implemented upon the effective date of this regulation. Other sponsors may have more flexibility to use these reimbursements immediately to lower costs.

We will also require applicants to project their reimbursement amounts for the first two plan-year cycles in the application so that we can project total reimbursement amounts. To help us with our funding projections, we will need sponsors to identify specific projected reimbursement amounts for each of the two plan-year cycles. This assessment will help us determine if and when we should stop accepting applications due to funding limitations. We will also require applicants to identify all benefit options under the employment-based plan that any early retiree, for whom the applicant may receive program reimbursement, may be claimed. This is necessary for us to track where funds are being spent and to otherwise manage the program. We will also require sponsors to attest that there are fraud, waste and abuse policies and procedures in place.

As is required in the RDS program, as a condition of participation, the sponsor will be required to sign a plan sponsor agreement, which will include certain assurances made by the sponsor. Included in this agreement will be a provision stating that reimbursement is based on information and data submitted by the sponsor and if the information and data are found to be inaccurate, incomplete or otherwise incorrect, the Secretary may reopen and revise a reimbursement determination, including recouping reimbursement from the sponsor. The sponsor will be required to specifically agree to comply with the terms and conditions for participation in the program, and acknowledge that information in the application is being provided for the purpose of obtaining federal funds. This list of application requirements is not exhaustive. Due to the compressed timeline for implementing this program, we may need to request additional information in the application.

Finally, we allow the Secretary to reopen a determination under which an application had been approved or denied so that if it is later determined that a sponsor committed fraud or otherwise was untruthful in the application, the Secretary can revisit the determination.

4. Consequences of Non-Compliance, Fraud or Similar Fault (§ 149.41)

To clarify the actions the Secretary may take in instances when non-compliance, fraud, waste, and abuse, or similar fault are found, we include a regulation that states that failure to comply with the requirements of this part, or if fraud, waste, and abuse, or similar fault are found, the Secretary may recoup or withhold funds, terminate or deny an application, or take any combination of these actions. We include termination of an application because, depending upon the specific situation involved, if it is found that a sponsor committed fraud or otherwise was untruthful in the application, the determination to approve an application can be revised under § 149.40. We believe it is important to set out what actions the Secretary may take so that sponsors are aware of the ramifications of non-compliance, fraud, waste and abuse, or similar fault. This regulation does not, of course, supersede other Federal laws or consequences of non-compliance fraud, waste and abuse, or similar fault.

5. Funding Limitation (§ 149.45)

Section 1102(f) authorizes the Secretary to stop accepting applications based on the availability of funds. We clarify that a reimbursement request made on behalf of a certified plan may also be denied, in whole or in part, due to limitation of funds. Determinations based on funding limitations are final, binding and cannot be appealed, because any appeal, even if a sponsor is successful, would not result in reimbursement to a sponsor. Once the program funds are exhausted there will be no funds to reimburse a sponsor that may have been successful upon appeal.

C. Reinsurance Amounts (Subpart C)

1. Amount of Reimbursement (§ 149.100)

The statute at section 1102(c) requires the Secretary, upon receipt of a valid claim for health benefits, to make reimbursement in an amount of 80 percent of the portion of the health benefit costs (net of negotiated price concessions) attributable to the claims that exceed $15,000, but are below $90,000. We interpret the statute to mean that cumulative health benefits incurred in a given plan year and paid for a given early retiree, as defined in § 149.2, that fall between those amounts will receive reimbursement, rather than reimbursement being made only for discrete health benefit items or services whose reimbursement total falls between those amounts. This interpretation will get much needed program funds to plan sponsors more quickly. The statute also specifies that in determining the amount of claims, the costs paid by the early retiree (or his or her spouse, surviving spouse, or dependent) in the form of deductibles, copayments, or coinsurance shall be included in the amounts paid by the participating employment-based plan. As an initial matter, we clarify in the regulation that reimbursement will be made under the program only for claims that are incurred during the applicable plan year, and paid.

The regulation refers to the $15,000 lower limit and the $90,000 ceiling as

the "cost threshold" and "cost limit", respectively, and indicates that reimbursement under the program is calculated by first determining the costs for health benefits net of negotiated price concessions, within the applicable plan year for each early retiree, and then subtracting amounts below the cost threshold and above the cost limit within the applicable plan year for each early retiree. We also clarify that for purposes of determining the amounts below the cost threshold and above the cost limit for any given early retiree, all costs for health benefits paid by the plan or by the early retiree for all benefit options the early retiree is enrolled in with respect to a given certified employment-based plan for a given plan year, will be combined. We make this clarification because the statute, at section 1102(c)(3), specifies that "a claim submitted by a participating employment-based plan shall not be less than $15,000 nor greater than $90,000" (emphasis added). For example, an early retiree is simultaneously enrolled in two different benefit options within one group health plan—Option 1 as a retiree, and Option 2 as a spouse of a retiree. For purposes of determining when the early retiree satisfies the cost threshold, all claims incurred and paid for that early retiree by both benefit options within the applicable plan year, will be counted. The claims for that early retiree under each benefit option will not be separately counted. For purposes of determining if and when the early enrollee has satisfied the cost limit, the same principle applies. In other words, within one employment-based plan for a given plan year, there is one threshold limit, and one cost limit, per early retiree.

We also indicate that the reimbursement formula specified in the regulation applies to insured plans as well as self-funded plans, and that with respect to insured plans, costs for health benefits means costs the insurer and the early retiree pay for health benefits net of negotiated price concessions the insurer receives for health benefits. Thus, for insured plans, the amount of premium the sponsor pays (and the amount of premium contribution the early retiree pays) is irrelevant for purposes of calculating reimbursement under the program. We believe this is the correct interpretation because section 1102(c)(1)(A) states that claims for reimbursement must "contain documentation of actual costs of items and services * * *." Premiums are not costs for items and services.

2. Transition (§ 149.105)

The program becomes effective June 1, 2010. We carefully considered whether to allow sponsors to participate in the program for plan years that ended before the program's effective date, but decided that such an approach would seem inconsistent with the program's effective date. We also considered whether to permit sponsors to participate only for plan years that start on or after the program's effective date, but decided that such an approach would arbitrarily favor sponsors with plan years that start soon after June 1, 2010. Therefore, we decided to allow sponsors to apply for plan years that start before June 1, 2010, provided they end after that date (for example, calendar year 2010 plans).[1] This raised the question of how claims incurred during such a plan year, but before June 1, 2010, would be dealt with under the program. Under one approach considered, any such claims would count toward the cost threshold, and any such claims exceeding the threshold, but below the cost limit, would be eligible for program reimbursement. We did not adopt that approach, as it arguably would unfairly favor sponsors with plan years that started significantly before the program's effective date, especially in light of the program's limited funding.

We decided upon the following approach. For claims incurred before June 1, 2010, the amount of such claims up to $15,000 count toward the cost threshold and the cost limit. The amount of claims incurred before June 1, 2010 that exceed $15,000 are not eligible for reimbursement and do not count toward the cost limit. The reinsurance amount to be paid is based solely on claims incurred on and after June 1, 2010, and that fall between the cost threshold and cost limit for the plan year. As an example, for a plan with a plan year that began July 1, 2009, with an end date of June 30, 2010, with an early retiree for which it has spent $120,000 in health benefit claims before June 1, 2010, and it then spends another $30,000 in health benefit claims on the early retiree between June 1, 2010 and June 30, 2010, the sponsor would receive credit for $15,000 in claims incurred before June 1 and receive reimbursement of 80 percent of the $30,000 (for the claims incurred after June 1, 2010), or $24,000. We believe this is a reasonable approach because it provides as much relief as possible as soon as possible to sponsors, while giving meaning to the effective date of the program. A sponsor should therefore not submit claims above the $15,000 cost threshold that were incurred before June 1, 2010, for reimbursement, as submission of such claims is outside the scope of the regulation. Also, to submit these claims for reimbursement will make the reimbursement process more complex than it needs to be.

[1] Sponsors can also apply for plan years that start after June 1, 2010.

3. Negotiated Price Concessions (§ 149.110) and Cost Threshold and Cost Limit (§ 149.115)

Section 1102(c)(1)(B) states that any negotiated price concessions obtained by an employment-based plan with respect to a health benefit must be reflected in claims submitted for program reimbursement. We recognize that sponsors and insurers sometimes do not receive certain negotiated price concessions until after payment is made, and in many cases, after the plan year during which the claim is incurred and paid, has ended. For example, this is typically the case with prescription drug rebates. Thus, we specify in the regulation that sponsors must disclose such "post-point-of-sale" negotiated price concessions, in a form and manner to be specified by the Secretary. We expect to specify the form and manner of such disclosures in future guidance. This will ensure that sponsors ultimately submit accurate claims data, and thus ultimately receive accurate reimbursement.

Finally, the statute indicates that the $15,000 and $90,000 figures shall be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of $1,000) for the year involved. We specify in the regulations that for plan years starting on or after October 1, 2011, the figures will be so adjusted.

D. Use of Reimbursements (Subpart D)

Use of Reimbursements (§ 149.200)

Section 1102(c)(4) requires that the reimbursement "shall be used to lower costs for the plan. Such payments may be used to reduce premium costs for an entity" receiving a reimbursement or to reduce premium contributions, co-payments, deductibles, co-insurance, or other out-of-pocket costs for plan participants. We encourage sponsors to use their reimbursement under the program for both of the following purposes: (1) To reduce the sponsor's health benefit premiums or health benefit costs, and (2) To reduce health benefit premium contributions, co-payments, deductibles, coinsurance, or

other out-of-pocket costs, or any combination of these costs, for plan participants. We expect that sponsors will continue to provide at least the same level of contribution to support the applicable plan, as it did before this program. For example, for a sponsor that pays a premium to an insurer, if the premium increases, program funds may be used to pay the sponsor's share of the premium increase from year to year, which reduces the sponsor's premium costs. Section 1102(c)(4) sets forth the requirements for use of reimbursements under this section and envisions a role for the Secretary in developing a mechanism to monitor the appropriate use of such reimbursements. Additional information about this mechanism will be disseminated as it is developed.

The statute does not appear to use the terms "early retiree" and "plan participants" interchangeably. Therefore, we interpret this provision to mean that a sponsor may only receive program funds for claims of early retirees or their spouses, surviving spouses or dependents, but the funds may be used to lower health benefit costs for all participants in the plan, including retirees, and their spouses and dependents, and active employees and their spouses and dependents. At § 149.200 (b), we clarify the statutory prohibition on using the funds as general revenue of the sponsor.

E. Reimbursement Methods (Subpart E)

1. General Reimbursement Rules (§ 149.300), Timing (§ 149.310), Reimbursement Conditioned Upon Available Funds (§ 149.315), Universe of Claims That Must Be Submitted (§ 149.320), Requirements for Eligibility of Claims (§ 149.325), and Content of Claims (§ 149.330)

Section 1102(c)(1) of the Affordable Care Act states that a participating employment-based plan shall submit claims for reimbursement to the Secretary which shall contain documentation of the actual costs of the items and services for which each claim is being submitted. As noted above, we define "claim" as documentation specifying the health benefit provided, the provider or supplier, the incurred date, the individual for whom the health benefit was provided, the date and amount of payment net any known negotiated price concessions, and the employment-based plan and benefit option under which the health benefit was provided. The terms "claim" or "medical claim" include medical, surgical, hospital, prescription drug and other such claims as determined by the Secretary. We clarify in the regulation that claims for benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body, may be filed. This clarification is not an exhaustive list of claims that the Secretary may determine are appropriate.

The regulation also specifies that claims cannot be submitted for a given plan year until the application that is associated with the claim and that references the applicable plan year cycle has been approved. With respect to a given early retiree, claims cannot be submitted until the early retiree's total paid costs for health benefits incurred for the plan year exceed the applicable cost threshold. Once that threshold has been reached, claims can be submitted, but they must include all claims below the applicable cost threshold for the plan year in order to verify that the cost threshold has been met. Claims must be submitted based on the amounts actually paid, which may include the amounts paid by the early retiree. Once the cumulative claims of an early retiree, as defined in § 149.2, exceed $90,000 for a plan year, a sponsor should not submit claims above this claims limit for that early retiree because no reimbursement will be paid on these claims.

2. Documentation of the Actual Cost of Medical Claims Involved (§ 149.335), Rule for Insured Plans (§ 149.340), and Use of Information Provided (§ 149.345)

All claims submissions must include a list of early retirees for whom claims are being submitted. Both the documentation of actual costs of claims and the list of early retirees must be submitted in a form and manner to be specified by the Secretary. Claims submissions will be processed on a first-in, first-out basis until program funding is expended.

We also specify that with respect to insured plans, the claims and the list of early retirees can be submitted directly to the Secretary by the insurer.

In order for a sponsor to receive credit for the cost-sharing amounts paid by the early retiree or the early retiree's spouse, surviving spouse or dependent, the sponsor must provide prima facie evidence that the early retiree or the early retiree's spouse, surviving spouse or dependent, paid his or her portion of the costs. Such evidence may include an actual payment receipt. If a sponsor cannot provide prima facie evidence, it may receive credit under the program only for the portion of the claim the sponsor actually paid.

There may be instances when a sponsor contracts with, for example, a staff-model health maintenance organization, that either has its own provider(s) on-staff or pays providers a capitated payment to care for plan participants. In these instances, claims might not ordinarily be produced. However, in order for the Secretary to calculate reimbursement under this program for such sponsors, the sponsor will be required to ensure that the insurer submit the information required in a claim as specified in § 149.330 and § 149. 335. The information submitted by the insurer must be reasonable in light of the specific market that the insurer is serving.

3. Maintenance of Records (§ 149.350)

The regulations also specify how the Secretary may use the information collected for purposes of the program, and the records maintenance requirements that apply to the sponsor. The specified records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred, or longer if otherwise required by law. The sponsor must require its health insurance issuer or employment-based health plan, as applicable, to maintain and produce upon request records to satisfy the maintenance of records requirements.

F. Appeals (Subpart F)

1. Appeals (§ 149.500)

Section 1102(c)(6) of the Affordable Care Act requires the Secretary to establish an appeals process to permit sponsors to appeal a determination made by the Secretary with respect to claims submitted under the program. Due to the limited funding and temporary nature of the program, we have established a one-step appeal process. A sponsor may appeal directly to the Secretary within 15 calendar days of receipt of the determination at issue. Section 149.500 sets out what we consider to be an adverse reimbursement determination, which is a determination relating to the amount of reimbursement paid under the program.

2. Content of Request for Appeal (§ 149.510)

The request for appeal must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider. Essentially the sponsor must provide the Secretary with its issues and arguments and any supporting documentation that it has to support its

arguments. The Secretary may accept subsequent supporting documentation if, for example, the sponsor did not have time during the 15-day window to perform a comprehensive data analysis of the issue. It would be helpful in the request for appeal if the sponsor notes that further information will be provided to support the request for appeal and a date by which the information will be received by the Secretary.

3. Review of Appeals (§ 149.520)

The regulation sets out generally the process the Secretary will use when reviewing the appeal and clarifies that the Secretary's decision will be final and binding, unless fraud or similar fault are involved. The Secretary will not accept oral argument or oral testimony, either in person or on the telephone.

If all or part of a reimbursement request is denied based on the unavailability of funds, the sponsor may not appeal because an appeal would serve no purpose. If funds are exhausted, there will be no funds to reimburse a sponsor if it is found that the sponsor should otherwise be eligible for reimbursement. Allowing an appeal when funds are exhausted only serves to add burden to sponsors that have received an adverse determination, because, if we allow such an appeal, an aggrieved sponsor may feel that it must appeal in order to exhaust its remedies and to protect its interests. Once the funds for the program are exhausted, there is no interest for the sponsor to protect because there will be no chance of reimbursement, even upon a successful appeal. It will also serve to increase the Secretary's burden because the Secretary will have to process and respond to each of these appeals, when there would be no possibility of a reimbursement adjustment in favor of the sponsor.

The Secretary will inform the sponsor and the applicable HHS designee of the Secretary's decision. Because time is of the essence with respect to funding, we do not specify how the Secretary will inform these stakeholders of the decision because it may be in writing, via electronic means or orally. The response process will be further reviewed to ensure that stakeholders receive appropriate notice of a decision. Of course, we do specify that if the sponsor requests a written response, the Secretary will provide a written response.

G. Disclosure of Data Inaccuracies (Subpart G)

1. Sponsor's Duty To Report Data Inaccuracies (§ 149.600)

Claims submitted for reimbursement may change after the 15-day appeal-request period has expired. For example, if a provider reverses a claim after the appeal-request period has expired, data would need to be updated to reflect the reversal. However, in order to make accurate reimbursements (reopen and revise reimbursement determinations that have already been made), sponsors are required to submit accurate data for reimbursement purposes. We understand that claims may be reversed or otherwise altered and that data that was accurate when submitted for reimbursement under the program may become inaccurate. Furthermore, reimbursement under this program is based on claims that are net of negotiated price concessions. Because negotiated price concessions include post-point-of-sale price concessions, data submitted for reimbursement may become inaccurate once the price concessions are finalized for a given plan year.

We do not believe it is necessary to require a sponsor to submit a formal appeal under § 149.500 to the Secretary merely because data changes due to the natural course of business. Also, we realize that certain changes in data due to the normal course of business might not become evident to a sponsor within 15 days after a reimbursement determination. Therefore, we are establishing a process that will give sponsors the ability to update us on any data inaccuracies and will allow us to reopen and revise a reimbursement determination as necessary, based on the updated data. We believe this would be the most efficient way to administer this program, particularly because of the limited nature of the program funds and the uncertain length of time that an appeal to the Secretary may involve.

2. Secretary's Authority To Reopen and Revise Reimbursement Determination Amounts (§ 149.610)

While the details of this process will be developed in sub-regulatory guidance, we state that the Secretary may reopen and revise a reimbursement determination upon its own motion or upon the request of a sponsor, within 1 year of a reimbursement determination, for any reason, within 4 years of a reimbursement determination for good cause, or at any time in instances fraud or similar fault. We define the term "good cause" in § 149.2, and discuss in the regulation what we believe is not good cause for revising the reimbursement. This regulation tracks the language in the RDS and Part D reconciliation reopening regulations at § 423.890 and § 423.346, respectively.

We specify in this section that the Secretary may reopen and revise a reimbursement determination on the Secretary's own motion. If the Secretary becomes aware that a reimbursement determination was made based upon inaccurate data, this will allow the Secretary to reopen and revise the reimbursement determination without the sponsor having to make a request. Reimbursement determinations may be reopened and revised to pay out more funds to a sponsor assuming such funds exist or to recoup funds that were already paid, or to withhold funds from a future reimbursement to offset a sponsor's liability.

H. Change of Ownership Requirements (Subpart H)

1. Change of Ownership Requirements (§ 149.700)

We include in this regulation requirements for a sponsor to provide the Secretary with advance notice of any change of ownership of the sponsor. Complying with this requirement is critically important, as it helps to ensure that program reimbursement is being made only to legitimate entities, and only to such entities that are actually complying with the requirements of the program. The requirements mirror the change of ownership requirements that are found in the RDS regulation, which we believe are appropriate for the Early Retiree Reinsurance Program, in light of the fact that we expect many sponsors to participate in both programs. Complying with the change of ownership requirements is especially critical with respect to the Early Retiree Reinsurance Program, in light of the program's limited funding.

The regulations define a change of ownership as any of the following:

(1) The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable state law.

(2) Transfer of all or substantially all of the assets of the sponsor to another party.

(3) The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor

surviving, does not ordinarily constitute change of ownership.

A sponsor that has a sponsor agreement in effect and is considering or negotiating a change in ownership must notify the Secretary at least 60 days before the anticipated effective date of the change. When there is a change of ownership that results in a transfer of the liability for health benefit costs, the existing sponsor agreement is automatically assigned to the new owner. This requirement is necessary because there may be obligations under the plan sponsor agreement that do not surface until some time after the change of ownership. The Secretary must ensure that there is a party to the plan sponsor agreement that can satisfy those obligations, which may include the return of program reimbursement. The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes, regulations, and guidance, and to the terms and conditions of the sponsor agreement. Failure to notify the Secretary at least 60 days before the anticipated effective date of the change may result in the Secretary recovering funds paid under the program.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

A. Waiver of Notice-and-Comment Procedure

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived under section 553(b)(3)(B) of the Administrative Procedure Act, however, if an agency finds good cause that notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Below, we discuss our reasons for the waiver of notice-and-comment procedure.

Section 1102(a)(1) of the Affordable Care Act requires the Secretary, not later than 90 days after enactment of the Act, to establish a temporary Early Retiree Reinsurance Program. The Affordable Care Act was enacted on March 23, 2010, which means that the Secretary must implement the Early Retiree Reinsurance Program by June 21, 2010. We believe this is insufficient time for notice-and-comment rulemaking. The 90 days Congress specified does not allow for development of the rule, a meaningful public comment period, and agency analysis of, and response to, those comments before this rule can be made final. Moreover, we need to actually establish a temporary Early Retiree Reinsurance Program—not simply issue this interim final rule—by June 1, 2010, in order to align the effective date of the program with some sponsors' plan year start dates and to simplify accounting for sponsors and the Secretary, as is discussed below. We must finalize this rule in order to take the multiple other steps necessary to establish the program. Within the time frame contemplated in the statute, we need to have regulations effective in time for applicants to be able to review them and begin to put together their information so that they can apply (once the application process is finalized). The application process cannot be finalized until the regulations are close to being finalized in this Interim Final Rule. Furthermore, the Secretary needs to have established the rules by which she is going to implement this program so that she can move forward with actually administering it, which includes contracting with a contractor to aid with administering the program. The regulations have to be close to finalized before the Secretary can draft a comprehensive scope of work for the contract that will be issued to aid the Secretary with administering this program.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis without prior comment. While we are not providing prior comment, we are providing a 30-day public comment period.

B. Waiver of Delay of Effective Date

In addition, section 553(d) of the APA ordinarily requires that a regulation be effective no earlier than 30 days after publication. Under section 553(d)(3) this requirement can be waived for good cause.

As explained above, Section 1102(a)(1) of the Affordable Care Act requires the Secretary to establish the Early Retiree Reinsurance Program by June 21, 2010. In order to better align the effective date of some sponsors' plan and/or fiscal years with the effective date of the program, to allow sponsors to be credited for claims starting at the beginning of a month in order to simplify accounting for sponsors and the Secretary, and to allow sponsors to be credited for claims incurred before June 21, 2010, we need to actually establish the program—not simply issue this Interim Final Rule—by June 1, 2010, as opposed to June 21, 2010. As a result, we find good cause to waive the 30-day delay in effective date that would otherwise apply under section 553(d) of the Administrative Procedure Act (APA) for this rule implementing the Early Retiree Reinsurance Program. This Interim Final Rule will become effective on June 1, 2010.

In addition, 5 U.S.C. 801 generally requires that agencies submit major rules to the Congress 60 days before the rules are scheduled to become effective. This delay does not apply, however, when there has been a finding of good cause for waiver of prior notice and comment as set forth above.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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. ICRs Regarding Requirements To Participate (§ 149.35)

Section 149.35(b)(1) requires plan sponsors to make available documentation, data, and other information related to this part and any other records specified by the Secretary, as stated in § 149.350. The burden associated with this requirement is detailed in our discussion of § 149.350.

Section 149.35(b)(2) states that a plan sponsor must have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan (as applicable) regarding disclosure of information, data, documents, and records to the Secretary, and the health insurance issuer or employment-based plan must

disclose to the Secretary, on behalf of the sponsor, the information necessary for the sponsor to comply with the program, this part, and program guidance. The burden associated with this requirement is the time and effort necessary for a plan sponsor to develop, sign, and maintain the aforementioned written agreement with its health insurance issuer or employment-based plan. We estimate that it will take 1 hour to develop, sign, and maintain one such written agreement. We also estimate that each plan sponsor on average will need to maintain and sign 3 such agreements. Using the RDS Program as a baseline, we estimate that 4,500 Early Retiree Reinsurance Program plan sponsors must comply with this requirement. The estimated annual burden associated with this requirement is 13,500 hours. The estimate cost of compliance with this requirement is $1,005,885, for the first year of the program. For the subsequent four years, we estimate that roughly one-quarter of the 4,500 sponsors (1,125) will contract with one different entity each year to disclose information, data, etc., to the Secretary. For each of those years, the estimated cost of compliance with this requirement is $83,824.

Section 149.35(b)(3) requires plan sponsors to have procedures to protect against fraud, waste and abuse under this program, and must comply timely with requests from the Secretary to produce the procedures and any documents or data to substantiate the implementation of the procedures and their effectiveness. Additionally, § 149.35(b)(5) requires plan sponsors to comply timely with requests from the Secretary to produce the procedures and any documents or data to substantiate the implementation of the procedures and their effectiveness. The burden associated with the requirements in § 149.35(b)(3) is the time and effort necessary to develop, implement, and maintain procedures to protect against fraud, waste and abuse under this program. There is also burden associated with producing the procedures and any supporting documentation up request by the Secretary. We estimate that it will take 20 hours for each plan sponsor or designee to develop, implement and maintain one set of such policies and procedures. We also estimate that with respect to each plan sponsor, an average of three separate sets of policies and procedures will have to be developed, implemented and maintained, to account for the fact that many sponsors will have multiple benefit options, each using a different entity that is submitting claims to the program on their behalf. However, we estimate that one-third of the 4,500 expected plan sponsors will be contracting with entities that submit claims to the program that already have fraud, waste and abuse programs and procedures in place. Therefore, we estimate that 3,000 plan sponsors will have to newly develop, implement, and maintain such program and procedures. The estimated annual burden for these requirements is 20 hours per set of fraud, waste and abuse procedures. The estimated cost associated with this requirement is $9,982,800 for the first year of the program. For the subsequent four years of the program, we estimate that roughly one quarter of the estimated 4,500 sponsors (roughly 1,125) will contract with one new entity each year, to submit claims to the program on the sponsor's behalf. For each of those years, the estimated annual burden associated with this burden is 1,125 sponsors multiplied by 20 hours, or 22,500 hours, with estimated costs equal to $1,247,850.

Section 149.35(b)(4) also requires plan sponsors to submit an application to the Secretary in the manner, and at the time, required by the Secretary, as specified in § 149.40. The burden associated with this requirement is detailed in our discussion of § 149.40.

B. ICRs Regarding Application (§ 149.40)

Section 149.40 discusses the application process for the early retiree reinsurance program. As stated in § 149.40(a) requires an applicant to submit an application to participate in this program to the Secretary, which is signed by an authorized representative of the applicant who certifies that the information contained in the application is true and accurate to the best of the authorized representative's knowledge and belief. Section 149.40(e) states that an applicant must submit an application for each plan for which it will submit a reimbursement request. Furthermore, as part of the application process, every application must be accompanied by the information listed in § 149.40(f).

The burden associated with the requirements in this section is the time and effort necessary for a plan sponsor or its designee to complete an application for each plan for which it will submit a reimbursement request. In addition, there is burden associated with compiling and submitting the required ancillary information listed in § 149.40(f). We estimate that the program will receive an average of 1 application each, from 4,500 plan sponsors or their designees. We further estimate that it will take 35 hours for a plan sponsor or designee to complete one application package. The total estimated annual burden associated with this requirement is 157,500 hours. The total estimated annual cost associated with this requirement is $8,820,675. This is a one-time burden, as sponsors are not required to submit a new application for each plan year.

C. ICRs Regarding Documentation of Actual Costs of Medical Claims Involved (§ 149.335)

Section § 149.335 requires that sponsors must submit claims, with each submission consisting of a list of early retirees for whom claims are being submitted, and documentation of the actual costs of the items and services for each claim being submitted. These material must be submitted in a form and manner specified by the Secretary. Additionally, in order for a sponsor to receive reimbursement for the portion of a claim that an early retiree paid, the sponsor must submit prima facie evidence that the early enrollee paid his or her portion of the claim. The burden associated with the requirements in this section is the time and effort necessary for sponsors to assemble and submit the aforementioned information. We estimate that it will take each sponsor an average of 45 hours to comply with these requirements, with the number of hours varying based upon the number of early retirees for whom claims are submitted, the number of claims, the technology used to generate the required information, etc. We estimate that each of the 4,500 participating sponsors will make two submissions annually. The total estimated annual burden associated with this requirement is 405,000 hours. The total estimated annual cost associated with these requirements is $15,758,550.

D. ICRs Regarding Maintenance of Records (§ 149.350)

Section 149.350(a) requires the sponsor of the certified plan (or a subcontractor, as applicable) must maintain and furnish to the Secretary, or its designee, upon request the records as specified in § 149.350(b). The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred, or longer if otherwise required by law. Similarly, as required by § 149.350(d), the sponsor must require its health insurance issuer or employment-based plan, as applicable, to maintain and produce upon request records to satisfy subparagraph (c) of this regulation. The

burden associated with the requirements in this section is the time and effort necessary to retain the specified records. We estimate that each of the estimated 4,500 sponsors will require 6 hours to retain the records. The total estimated annual burden associated with this requirement is 27,000 hours. The total estimated annual cost associated with this requirement is $1,050,570.

E. ICRs Regarding Appeals (§ 149.500 and § 149.510)

Section 149.500(d) states that if a sponsor appeals an adverse reimbursement determination, the sponsor must submit the appeal in writing to the Secretary within 15 days of receipt of the determination. Section 149.510 requires a request for appeal to specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. In addition, the request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider. The burden associated with the aforementioned requirements is the time and effort necessary for a sponsor to draft and submit an appeal, including supporting documentation. While this requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.4. In this case, the information associated with an appeal would be collected subsequent to an administrative action, that is, an adverse reimbursement determination or an application denial.

F. ICRs Regarding Sponsor's Duty To Report Data Inaccuracies (§ 149.600)

Section 149.600 requires a sponsor to disclose any data inaccuracies on which a reimbursement request has been made, including inaccurate claims data and negotiated price concessions, in a manner and at a time specified by the Secretary in guidance. The burden associated with this requirement is the time and effort necessary for a sponsor to comply with the reporting requirement. We estimate that 1,500 sponsors annually will be subject to this requirement, and that burden associated with this requirement is 32 hours per sponsor (two disclosures per year per sponsor, each disclosure having an estimated burden of 16 hours). The estimated annual burden associated with this requirement is 48,000 hours. The total estimated annual cost associated with this burden is $1,867,680.

G. ICRs Regarding Change of Ownership Requirements (§ 149.700)

Section 149.700(c) requires a sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership to notify the Secretary at least 60 days before the anticipated effective date of the change. The burden associated with the requirement is the time and effort necessary for a sponsor to comply with the reporting requirement. Based on our experience with the RDS Program, we estimate that it will take each sponsor an average of 1 hour to comply with these requirements, and that 50 sponsors per year will be subject to this requirement. The total estimated annual burden associated with this requirement is 50 hours. The total estimated annual cost associated with these requirements is $2,773.

All of the information collection requirements containing burden were submitted to the Office of Management and Budget (OMB) for emergency review and approval as part of a single information collection request (ICR). As part of the emergency review and approval process, OMB waived the notification requirements. The ICR was approved under OMB control number 0938–1087 with an expiration date of October 31, 2010. However, we are still seeking public comments on the information collection requirements discussed in this interim final rule with comment. All comments will be considered as we continue to develop the ICR as we must resubmit the ICR to obtain a standard 3-year approval.

TABLE 1—ANNUAL RECORDKEEPING AND REPORTING BURDEN

Regulation section	OMB Control No.	Respondents	Responses	Time per response (hours)	Total burden (hours)	Hourly labor cost ($)	Total labor cost ($)	Total capital/maintenance cost ($)	Total cost ($)
§ 149.35(b)(2)	0938–1087	4,500	13,500	1	13,500	74.51	1,005,885	0	1,005,885
		1,125	1,125	1	1,125	74.51	83,824	0	83,824
§ 149.35(b)(3)	0938–1087	3,000	9,000	20	180,000	55.46	9,982,800	0	9,982,800
		1,125	1,125	20	22,500	55.46	1,247,850	0	1,247,850
§ 149.40	0938–1087	4,500	4,500	35	157,500	**	8,820,675	0	8,820,675
§ 149.335	0938–1087	4,500	9,000	45	405,000	38.91	15,758,550	0	15,758,550
§ 149.350	0938–1087	4,500	4,500	6	27,000	38.91	1,050,570	0	1,050,570
§ 149.600	0938–1087	1,500	3,000	16	48,000	38.91	1,867,680	0	1,867,680
§ 149.700(c)	0938–1087	50	50	1	50	55.46	2,773	0	2,773
Total		11,300	45,800		854,675				39,820,607

**$74.51 per hour for 1 hour per response, $55.46 per hour for 34 hours per response.

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, Attn: CMS Desk Officer, CMS–9996–IFC, fax (202) 395–6974, or via email *OIRA_submission@omb.eop.gov.*

V. 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.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule will be economically significant because it sets out the requirements that sponsors will need to meet in order to participate in the Early Retiree Reinsurance Program and obtain a portion of the $5 billion the Congress appropriated for this program. While a small portion of the funds will be used to administer the program, the remainder of the $5 billion will be paid to eligible sponsors over the life of the program, resulting in economically significant net positive transfers to sponsors. We believe that the costs imposed on sponsors that want to receive the early retiree reimbursement will not be significant relative to the payments received. The costs will consist of staff or contractor time to complete the application to participate, to file claims for reimbursement, and to comply with program requirements such as any requests related to an audit, as well as any supplies necessary to perform these tasks summarized in Table 1 above. As a result this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. According to the Kaiser Family Foundation and Health Research & Educational Trust's 2009 Employer Health Benefits Survey, 5 percent of surveyed businesses with 3 to 199 workers offered retiree health benefits. See pg. 166 of the Survey. *http://ehbs.kff.org/pdf/2009/7936.pdf.* It is unclear how many offered health benefits to early retirees, but since there were about 3.3 million such firms (page 15 of the survey), even if only 5 percent provided such benefits, over 150,000 such firms would be eligible for the program. However, we estimate that the number of sponsors that will actually participate in the Early Retiree Reinsurance Program, will be similar to the number that participate in the Retiree Drug Subsidy Program. For purposes of the RFA, we estimate that 5 percent of sponsors are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). Ultimately, the number of small businesses affected will depend upon how many small businesses apply for the reimbursement, which we do not currently know. What we do know is that we have made, and will make, the application and claims submission processes as simple as possible, while still protecting the integrity of the program. Therefore, if small businesses want to participate, they may do so.

Turning to small business providers, 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 (SBA) definition of a small business (having revenues of less than $7.0 million to $34.5 million in any 1 year). While this rule does not directly impact providers (unless they apply to be sponsors), it does increase access to health insurance, which may then cause more individuals to be able to afford health care and therefore be able to utilize providers' services and products more often. Therefore, health care providers may see an increase in patients and may not be required to deliver health care free of charge or at reduced rates in as many instances as they may currently do.

Because much of the effect on health care providers depends upon where plan participants choose to receive these services, which must be from a provider that accepts the plan participant's coverage, the term "health care provider" is likely to include health care entities operated by small governmental entities such as counties or towns. Small governmental health care entities may include county hospitals, clinics or other such entities. Regardless of the entity, we expect a positive effect on these entities. For purposes of the RFA, a significant number of health care providers indirectly affected by the program are considered small businesses according to the SBA's size standards with total revenues of $7 million to $34.5 million or less in any 1 year and an undetermined percent are nonprofit organizations. Individuals and States are not included in the definition of a small entity. Uncertainty arises because we do not know how many small businesses or other small entities will apply to participate in the Early Retiree Reinsurance Program, nor do we know how the increased access to health insurance will affect small businesses that provide health care services and products to the participants affected by the program. We believe, however, that this interim final rule will have a significant positive economic effect on a substantial number of small businesses. The HHS interpretation of the Regulatory Flexibility Act has historically been that it does not trigger a regulatory flexibility analysis as a result of positive economic impacts (the statute requires that economic impacts be minimized, which makes no sense when applied to positive effects). The Department nonetheless usually prepares a voluntary regulatory flexibility analysis in such circumstances. In addition, because a regulatory flexibility analysis is only required for rules for which an NPRM must be prepared, there is an additional exemption that applies to this rule. Accordingly, we conclude that a regulatory flexibility analysis is not required. Nonetheless, we believe that this regulatory impact section, together with the remainder of the preamble, constitutes a voluntary analysis that meets the requirements that would otherwise be applicable.

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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this rule will have a significant impact on the operations of a substantial number of small rural hospitals because the increased access to health insurance, while positively affecting small rural hospitals' ability to collect payment for services rendered to plan participants affected by the program, will be unlikely to increase revenues in an economically significant amount. Therefore, the Secretary has determined that this interim final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. In addition, such an analysis is not required when an NPRM is not required, as in this case.

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 required spending in any 1 year of $100

million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. This rule does not mandate any spending by State, local, or tribal governments in the aggregate, or by the private sector. In fact, participation in the program is voluntary and for all sponsors participating, we expect in the aggregate that sponsors will receive $5 billion in reimbursement, less administrative costs.

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 rule will not have a substantial direct effect on State or local governments, preempt State laws, or otherwise have a Federalism implication.

B. Need for Regulatory Action

As previously discussed, the Affordable Care Act, includes this provision that establishes the temporary Early Retiree Reinsurance Program. Section 1102(a)(1) requires the Secretary to establish the program within 90 days of enactment of the law, which is June 21, 2010. This interim final rule is necessary to implement this program by the statutory deadline. The program is designed to assist people in the early retiree age group who often face difficulties obtaining insurance in the individual market because of advanced age or chronic conditions that make coverage unaffordable and inaccessible. The Early Retiree Reinsurance Program will provide financial help for employer-based plans to continue to provide coverage to plan participants, and provides financial relief to plan participants.

C. Anticipated Effects

1. Effects on Plan Sponsors

This rule will positively affect employers and employee organizations that self-fund health benefits or pay premiums to insure their early retirees' health benefits. The amount of the effects depends upon the sponsors' determination of the use of the reimbursement. Thus the positive effect will range from negligible if they use the reimbursement almost exclusively for plan participants' costs to just under $5 billion, minus the administrative costs of this program if they maximize the amount of reimbursement used to lower plan costs.

2. Effects on Plan Participants

We believe that this rule will have a positive effect on plan participants. We believe that the program will encourage sponsors to maintain coverage that they might not otherwise maintain, and will lower health benefit costs for plan participants and sponsors. With access to insurance, we believe, that plan participants will access health care as needed, instead of delaying a health care encounter until the condition progresses to a point when an encounter is unavoidable (and then more severe and expensive). Furthermore, we believe plan participants will not incur as much debt due to health care costs. The amount of the effects depends upon the sponsors' determination of the use of the reimbursement. Thus, the positive effect will range from moderate if sponsors use almost all of the reimbursement for sponsors' costs (in this case, the lower costs to the sponsor encourages continued provision of retiree coverage, which is of benefit to the retiree) to nearly $5 billion, minus administrative costs, if sponsors use the reimbursement almost exclusively to lower plan participants' costs.

3. Effects on Other Providers

We expect this rule to have an indirect positive effect on providers because more individuals will have access to health insurance, which will cause these individuals to seek health care when needed, as may not be the case currently, and health care providers will be able to receive payment for services provided. It is a two-fold benefit. Providers may have more patients and more of the patients will be able to pay for the services or products provided, whether directly (for example, co-insurance or co-payment) or via their insurance.

4. Effects on the Medicare and Medicaid Programs

This rule does not impose any consequential costs on Medicare or Medicaid. While sponsors may only submit claims for reimbursement for early retirees and early retirees' spouses, surviving spouses or dependents, the reimbursements paid to a sponsor must be used to lower costs for all plan participants, which may include enrollees who also have Medicare coverage. Other than increased utilization of health care services or products for plan participants that are covered by a certified plan, we do not expect any notable impact on Medicare. We expect the impact due to increased utilization to be minimal.

This rule may in fact lessen the number of individuals on Medicaid, or slow any growth in numbers of individuals eligible for Medicaid, because sponsors that are considering dropping health insurance for early retirees or plan participants may decide otherwise, once the sponsor becomes eligible for the program. Furthermore, it is possible that employers may decide to offer health insurance to early retirees because of the program.

D. Alternatives Considered

With respect to implementing this program, there is no alternative. The Congress requires that the program be in effect not later than 90 days after the enactment of the bill. The statute was enacted March 23, 2010. With respect to the application process, we considered numerous requirements as to what we would need in order to protect the integrity of the program, but ultimately settled on the requirements in the regulation. We had originally considered requiring an attestation from a qualified actuary, certifying that the sponsor's estimate of projected costs is reasonable. We decided against this requirement because the projection was merely for the purpose of letting us know if and when we should stop taking applications. Weighing the expense of requiring a sponsor to pay an actuary to make the certification against the benefit the certification would provide, we decided not to require this because we want this program to be as inclusive as possible.

We also considered how best to implement the provision relating to participants with chronic and high-cost conditions. We considered identifying specific conditions in sub-regulatory guidance but decided that such a policy would ultimately work against the goals of the program because we would not be able to do a comprehensive analysis to identify them in the time allotted to implement this program. Furthermore, because many sponsors' plans were initiated before the effective date of the statute and any guidance we may have developed, sponsors that covered what they think are chronic and high-cost conditions, but which we did not identify as such, would have been penalized. Because this is supposed to be an inclusive program, we defined the term "chronic and high-cost conditions" to be any condition for which the plan is likely to incur health benefits costs of at least $15,000 for any one plan participant in a plan year. If a sponsor has programs and procedures that have generated or have the potential to generate cost savings in place to address

any such conditions, it will meet the requirement.

Ultimately, the approach we took in these regulations is intended to balance the need to protect the integrity of the program with the inclusive nature of the program.

E. Accounting Statement and Table

Whenever a rule is considered an economically significant rule under Executive Order 12866, we are required to develop an Accounting Statement. We have prepared an accounting statement below (Table 2) showing the classification of the expenditures associated with the provisions of this interim final rule.

The terminology from this table may be interpreted as follows:

1. Annualized—means to determine cost/benefits on a yearly basis as opposed to quarterly. This would include both start-up and ongoing costs amortized over the number of years used in the RIA. Due to the uncertainty in estimating these costs/benefits we have estimated the amortization equally over the 4 years 2010 through 2013.

2. Monetized—means to develop quantitative estimates and convert them to dollar amounts, if possible.

3. Qualitative Benefits and Costs—means to categorize or rank the qualitative effects in terms of their importance (for example, certainty, likely magnitude, and reversibility).

4. Effects—means the effects on Medicare/Medicaid program, beneficiaries, and health care facilities, taken from the impact analysis. (We note that regulations with annual costs that are less than one billion dollars are likely to have a minimal effect on economic growth.)

5. All quantitative estimates must be presented as discounted flows using 3 percent and 7 percent factors.

TABLE 2—ACCOUNTING STATEMENT

Category	*Primary estimate*	*Year dollars*	*Discount rate*	*Period covered*	*Source citation (RIA, preamble, etc.)*
BENEFITS					
Annualized monetized benefits (in millions of dollars per year).	Not estimated.				
COSTS					
Annualized monetized costs (in millions of dollars per year).	39.8	2010	7%	2010–2013	Paperwork Reduction Act Burden in Preamble.
	39.8	2010	3%		
TRANSFERS					
Annualized monetized transfers: "on budget" (in millions of dollars per year).	$1,250	2010	7%	2010–2013	Statute.
	$1,250	2010	3%		
From whom to whom?	From the Federal Government to eligible sponsors and for administration of the program including to contractors.	From the Federal Government to eligible sponsors and for administration of the program including to contractors.	From the Federal Government to eligible sponsors and for administration of the program including to contractors.		
Category	Effects				*Source Citation (RIA, preamble, etc.).
Effects on State, local, and/or tribal governments.	Positive, but currently unable to be determined.				RIA.
Effects on small businesses.	Positive, but currently unable to be determined.				RIA.

E. Conclusion

We used statistics from the RDS Program as a model because it has similar characteristics to the characteristics of this new Early Retiree Reinsurance Program, and, based on this model, we expect that approximately 4,500 sponsors will apply to participate in the Early Retiree Reinsurance Program. Of those sponsors, we expect approximately 3,000 will be private entities and 1,500 will be State and local governments. Alternatively, the number of applicants could be substantially higher if small or other employers participate in this program in higher numbers than they did in the Retiree Drug Subsidy Program. Regardless, total spending cannot exceed the $5 billion appropriated for this program over the four-year period. While some of the funds allotted for the program are required to be used to implement the program, we anticipate an overall positive transfer of $5 billion to eligible sponsors (and indirectly a portion of those funds will be transferred for the benefit of plan participants), less administrative costs. The analysis above, together with the remainder of this preamble, provides a regulatory impact analysis and meets the

requirements for a Final Regulatory Flexibility Analysis.

In accordance with the provisions of Executive Order 12866 the Office of Management and Budget reviewed this regulation.

List of Subjects in 45 CFR Part 149

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, by adding a new part 149 to read as follows:

PART 149—REQUIREMENTS FOR THE EARLY RETIREE REINSURANCE PROGRAM

Subpart A—General Provisions

Sec.
149.1 Purpose and basis.
149.2 Definitions.

Subpart B—Requirements for Eligible Employment-based Plans

149.30 General requirements.
149.35 Requirements to participate.
149.40 Application.
149.41 Consequences of Non-Compliance, Fraud, or Similar Fault
149.45 Funding limitation.

Subpart C—Reinsurance Amounts

149.100 Amount of reimbursement.
149.105 Transition provision.
149.110 Negotiated price concessions.
149.115 Cost threshold and cost limit.

Subpart D—Use of Reimbursements

149.200 Use of reimbursements.

Subpart E—Reimbursement Methods

149.300 General reimbursement rules.
149.310 Timing.
149.315 Reimbursement conditioned upon available funds.
149.320 Universe of claims that must be submitted.
149.325 Requirements for eligibility of claims.
149.330 Content of claims.
149.335 Documentation of costs of actual claims involved.
149.340 Rule for insured plans.
149.345 Use of information provided.
149.350 Maintenance of records.

Subpart F—Appeals

149.500 Appeals.
149.510 Content of request for appeal.
149.520 Review of appeals.

Subpart G—Disclosure of Inaccurate Data

149.600 Sponsor's duty to report data inaccuracies.
149.610 Secretary's authority to reopen and revise reimbursement determination amounts.

Subpart H—Change of Ownership Requirements

149.700 Change of ownership requirements.

Authority: Section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

Subpart A—General Provisions

§ 149.1 Purpose and basis.

This part implements the Early Retiree Reinsurance Program, as required by section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

§ 149.2 Definitions.

For purposes of this part, the following definitions apply:

Authorized representative means an individual with legal authority to sign and bind a sponsor to the terms of a contract or agreement.

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within an employment-based plan.

Certified means that the sponsor and its employment-based plan or plans meet the requirements of this part and the sponsor's application to participate in the program has been approved by the Secretary.

Chronic and high-cost condition means a condition for which $15,000 or more in health benefit claims are likely to be incurred during a plan year by one plan participant.

Claim or *medical claim* means documentation, in a form and manner to be specified by the Secretary, indicating the health benefit provided, the provider or supplier, the incurred date, the individual for whom the health benefit was provided, the date and amount of payment net any known negotiated price concessions, and the employment-based plan and benefit option under which the health benefit was provided. The terms *claim* or *medical claim* include medical, surgical, hospital, prescription drug and other such claims as determined by the Secretary.

Early retiree means a plan participant who is age 55 and older who is enrolled for health benefits in a certified employment-based plan, who is not eligible for coverage under title XVIII of the Act, and who is not an active employee of an employer maintaining, or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan. In this part, the term *early retiree* also includes the enrolled spouse, surviving spouse, and dependents of such individuals. The determination of whether an individual is not an active employee is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed to be an active employee if, under the Medicare Secondary Payer rules in 42 CFR 411.104 and related guidance published by the Centers for Medicare & Medicaid Services, the person is considered to be receiving coverage by reason of current employment status. This presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor may also treat a person receiving coverage under its employment-based plan as a dependent in accordance with the rules of its plan, regardless of whether that individual is considered a dependent for Federal or state tax purposes. For purposes of this definition of early retiree, an employer maintaining, or currently contributing to, the employment-based plan or any employer that has made substantial contributions to fund such plan, means a plan sponsor (as defined in this section).

Employment-based plan means a group health plan as defined in this section of the regulation.

Good cause means:

(1) New and material evidence exists that was not readily available at the time the reimbursement determination was made;

(2) A clerical error in the computation of the reimbursement determination was made by the Secretary; or

(3) The evidence that was considered in making the reimbursement determination clearly shows on its face that an error was made.

Group health plan means group health plan as defined in 42 CFR 423.882 that provides health benefits to early retirees, but excludes Federal governmental plans.

Health benefits means medical, surgical, hospital, prescription drug, and other benefits that may be specified by the Secretary, whether self-funded or delivered through the purchase of health insurance or otherwise. Such benefits include benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body. Health benefits do not include benefits specified at 45 CFR 146.145(c)(2) through (4).

Incurred means the point in time when the sponsor, health insurance issuer (as defined in 45 CFR 160.103), employment-based plan, plan participant, or a combination of these or

similar stakeholders, become responsible for payment of the claim.

Negotiated price concession means any direct or indirect remuneration (including discounts, direct or indirect subsidies, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits) offered to some or all purchasers, which may include a sponsor, a health insurance issuer, or an employment-based plan) that would serve to decrease the costs incurred under the employment-based plan.

Plan participant means anyone enrolled in an applicable plan including an early retiree, as defined in this section, a retiree, a retiree's spouse and dependent, an active employee and an active employee's spouse and dependent.

Plan year means the year that is designated as the plan year in the plan document of an employment-based plan, except that if the plan document does not designate a plan year, if the plan year is not a 12-month plan year, or if there is no plan document, the plan year is:

(1) The deductible or limit year used under the plan;

(2) The policy year, if the plan does not impose deductibles or limits on a 12-month basis;

(3) The sponsor's taxable year, If the plan does not impose deductibles or limits on a 12-month basis, and either the plan is not insured or the insurance policy is not renewed on a 12-month basis, or;

(4) The calendar year, in any other case.

Post point-of-sale negotiated price concession means any negotiated price concession that an employment-based plan or insurer receives with respect to a given health benefit, after making payment for that health benefit.

Program means the Early Retiree Reinsurance Program established in section 1102 of the Patient Protection and Affordable Care Act.

Secretary means the Secretary of the United States Department of Health & Human Services or the Secretary's designee.

Sponsor means a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement between the sponsor and the United States Department of Health & Human Services, or its designee, which is made to comply with the provisions of this part.

Subpart B—Requirements for Eligible Employment-Based Plans

§ 149.30 General requirements.

A sponsor is eligible to participate in the program if it meets the requirements of section 1102 of the Patient Protection and Affordable Care Act, this part, and guidance developed by the Secretary.

§ 149.35 Requirements to participate.

(a) A sponsor's employment-based plan must—

(1) Be certified by the Secretary.

(2) Include programs and procedures that have generated or have the potential to generate cost-savings with respect to plan participants with chronic and high-cost conditions.

(b) A sponsor must—

(1) Make available information, data, documents, and records as specified in § 149.350.

(2) Have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan (as applicable) regarding disclosure of information, data, documents, and records, to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, the information, data, documents and records necessary for the sponsor to comply with the program, this part, and program guidance.

(3) Ensure that policies and procedures to protect against fraud, waste and abuse under this program are in place, and must comply timely with requests from the Secretary to produce the policies and procedures and any documents or data to substantiate the implementation of the policies and procedures and their effectiveness.

(4) Submit an application to the Secretary in the manner, and at the time, required by the Secretary as specified in § 149.40.

§ 149.40 Application.

(a) The applicant must submit an application to participate in this program to the Secretary, which is signed by an authorized representative of the applicant who certifies that the information contained in the application is true and accurate to the best of the authorized representative's knowledge and belief.

(b) Applications will be processed in the order in which they are received.

(c) An application that fails to meet all the requirements of this part will be denied and the applicant must submit another application if it wishes to participate in the program. The new application will be processed based on when the new submission is received.

(d) An applicant need not submit a separate application for each plan year but must identify in its application the plan year start and end date cycle (starting month and day, and ending month and day) for which it is applying.

(e) An applicant must submit an application for each plan for which it will submit a reimbursement request.

(f) In connection with each application the applicant must submit the following:

(1) Applicant's Tax Identification Number.

(2) Applicant's name and address.

(3) Contact name, telephone number and email address.

(4) Plan sponsor agreement signed by an authorized representative, which includes—

(i) An assurance that the sponsor has a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan, as applicable, regarding disclosure of information to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, information, data, documents, and records necessary for the sponsor to comply with the requirements of the program.

(ii) An acknowledgment that the information in the application is being provided to obtain Federal funds, and that all subcontractors acknowledge that information provided in connection with a subcontract is used for purposes of obtaining Federal funds.

(iii) An attestation that policies and procedures are in place to detect and reduce fraud, waste, and abuse, and that the sponsor will produce the policies and procedures, and necessary information, records and data, upon request by the Secretary, to substantiate existence of the policies and procedures and their effectiveness.

(iv) Other terms and conditions required by the Secretary.

(5) A summary indicating how the applicant will use any reimbursement received under the program to meet the requirements of the program, including:

(i) How the reimbursement will be used to reduce premium contributions, co-payments, deductibles, coinsurance, or other out-of-pocket costs for plan

participants, to reduce health benefit or health benefit premium costs for the sponsor, or to reduce any combination of these costs;

(ii) What procedures or programs the sponsor has in place that have generated or have the potential to generate cost savings with respect to plan participants with chronic and high-cost conditions; and

(iii) How the sponsor will use the reimbursement to maintain its level of contribution to the applicable plan.

(6) Projected amount of reimbursement to be received under the program for the first two plan year cycles with specific amounts for each of the two cycles.

(7) A list of all benefit options under the employment-based plan that any early retiree for whom the sponsor receives program reimbursement may be claimed.

(8) Any other information the Secretary requires.

(g) An application must be approved, and the plan and the sponsor certified, by the Secretary before a sponsor may request reimbursement under the program.

(h) The Secretary may reopen a determination under which an application had been approved or denied:

(1) Within 1 year of the determination for any reason;

(2) Within 4 years of the determination if the evidence that was considered in making the determination shows on its face that an error was made; or

(3) At any time in instances of fraud or similar fault.

§ 149.41 Consequences of Non-Compliance, Fraud, or Similar Fault.

Upon failure to comply with the requirements of this part, or if fraud, waste, and abuse, or similar fault are found, the Secretary may recoup or withhold funds, terminate or deny a sponsor's application, or take a combination of these actions.

§ 149.45 Funding limitation.

(a) Based on the projected or actual availability of program funding, the Secretary may deny applications that otherwise meet the requirements of this part, and if an application is approved, may deny all or part of a sponsor's reimbursement request.

(b) The Secretary's decision to stop accepting applications or satisfying reimbursement requests based on the availability of funding is final and binding, and is not appealable.

Subpart C—Reinsurance Amounts

§ 149.100 Amount of reimbursement.

(a) For each early retiree enrolled in a certified plan in a plan year, the sponsor receives reimbursement in the amount of 80 percent of the costs for health benefits (net of negotiated price concessions for health benefits) for claims incurred during the plan year that are attributed to health benefits costs between the cost threshold and cost limit, and that are paid by the employment-based plan or by the insurer (if an insured plan), and by the early retiree.

(b) Costs are considered paid by an early retiree, if paid by that individual or another person on behalf of the early retiree, and the early retiree (or person paying on behalf of the early retiree) is not reimbursed through insurance or otherwise, or other third party payment arrangement.

(c) Reimbursement is calculated by first determining the costs for health benefits net of negotiated price concessions, within the applicable plan year for each early retiree, and then subtracting amounts below the cost threshold and above the cost limit within the applicable plan year for each such individual.

(d) For purposes of determining amounts below the cost threshold and above the cost limit for any given early retiree, all costs for health benefits paid by the employment-based plan (or by the insurer, if applicable), or by or on behalf of, an early retiree, for all benefit options the early retiree is enrolled in with respect to a given certified employment-based plan for a given plan year, will be combined. For each early retiree enrolled in an employment-based plan, there is only one cost threshold and one cost limit per plan year regardless of the number of benefit options the early retiree is enrolled in during that plan year.

§ 149.105 Transition provision.

For a certified plan that has a plan year that begins before June 1, 2010 and ends on any date thereafter, the reinsurance amount for the plan year must be determined as follows:

(a) With respect to claims incurred before June 1, 2010, the amount of such claims up to $15,000 count toward the cost threshold and the cost limit. The amount of claims incurred before June 1, 2010 that exceed $15,000 are not eligible for reimbursement and do not count toward the cost limit.

(b) The reinsurance amount to be paid is based only on claims incurred on and after June 1, 2010, that fall between the cost threshold and cost limit for the plan year.

§ 149.110 Negotiated price concessions.

(a) The amount of negotiated price concessions that will be taken into account in determining the reinsurance amount will reflect negotiated price concessions that have already been subtracted from the amount the employment-based plan or insurer paid for the cost of health benefits and the amount of post-point-of-sale negotiated price concessions received.

(b) At a time specified by the Secretary, sponsors are required to disclose the amount of post-point-of-sale price concessions that were received but not accounted for in their submitted claims.

§ 149.115 Cost threshold and cost limit.

The following cost threshold and cost limits apply individually, to each early retiree as defined in § 149.2:

(a) The cost threshold is equal to $15,000 for plan years that start on any date before October 1, 2011.

(b) The cost limit is equal to $90,000 for plan years that start on any date before October 1, 2011.

(c) The cost threshold and cost limit specified in paragraphs (a) and (b) of this section, for plan years that start on or after October 1, 2011, will be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of $1,000) for the year involved.

Subpart D—Use of Reimbursements

§ 149.200 Use of reimbursements.

(a) A sponsor must use the proceeds under this program:

(1) To reduce the sponsor's health benefit premiums or health benefit costs,

(2) To reduce health benefit premium contributions, copayments, deductibles, coinsurance, or other out-of-pocket costs, or any combination of these costs, for plan participants, or

(3) To reduce any combination of the costs in (a)(1) and (a)(2) of this section.

(b) Proceeds under this program must not be used as general revenue for the sponsor.

Subpart E—Reimbursement Methods

§ 149.300 General reimbursement rules.

Reimbursement under this program is conditioned on provision of accurate information by the sponsor or its designee. The information must be submitted, in a form and manner and at the times provided in this subpart and

other guidance specified by the Secretary. A sponsor must provide the information specified in section § 149.335.

§ 149.310 Timing.

(a) An employment-based plan and a sponsor must be certified by the Secretary before claims can be submitted and a reimbursement request may be made. Reimbursement will be made with respect to submitted claims for health benefits at a time and in a manner to be specified by the Secretary, after the sponsor or its designee submits the claims to the Secretary. Claims must satisfy the requirements of this subpart in order to be eligible for reimbursement.

(b) Claims for health benefits may be submitted for a given plan year only upon the approval of an application that references that plan year cycle. Claims for an early retiree for a plan year cannot be submitted until the total paid costs for health benefits for that early retiree incurred for that plan year exceed the applicable cost threshold.

(c) For employment-based plans for which a provider in the normal course of business does not produce a claim, such as a staff-model health maintenance organization, the information required in a claim must be produced and provided to the Secretary, as set out in this regulation and applicable guidance.

§ 149.315 Reimbursement conditioned upon available funds.

Notwithstanding a sponsor's compliance with this part, reimbursement is conditioned upon the availability of program funds.

§ 149.320 Universe of claims that must be submitted.

(a) Claims submitted for an early retiree, as defined in § 149.2, must include claims below the applicable cost threshold for the plan year.

(b) Claims must not be submitted until claims are submitted for amounts that exceed the applicable cost threshold for the plan year for the early retiree.

(c) Sponsors must not submit claims for health benefits for an early retiree to the extent the sponsor has already submitted claims for the early retiree that total more than the applicable cost limit for the applicable plan year.

§ 149.325 Requirements for eligibility of claims.

A claim may be submitted only if it represents costs for health benefits for an early retiree, as defined in § 149.2, has been incurred during the applicable plan year, and has been paid.

§ 149.330 Content of claims.

Each claim on its face must include the information specified in, and meet, the definition of claim or medical claim found at § 149.2.

§ 149.335 Documentation of costs of actual claims involved.

(a) A submission of claims consists of a list of early retirees for whom claims are being submitted, and documentation of the actual costs of the items and services for claims being submitted, in a form and manner specified by the Secretary.

(b) In order for a sponsor to receive reimbursement for the portion of a claim that an early retiree paid, the sponsor must submit prima facie evidence that the early enrollee paid his or her portion of the claim.

§ 149.340 Rule for insured plans.

With respect to insured plans, the claims and data specified in the subpart may be submitted directly to the Secretary by the insurer.

§ 149.345 Use of information provided.

The Secretary may use data and information collected under this section only for the purpose of, and to the extent necessary in, carrying out this part including, but not limited to, determining reimbursement and reimbursement-related oversight and program integrity activities, or as otherwise allowed by law. Nothing in this section limits the Office of the Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 149.350 Maintenance of records.

(a) The sponsor of the certified plan (or a subcontractor, as applicable) must maintain and furnish to the Secretary, upon request the records enumerated in paragraph (b) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred, or longer if otherwise required by law.

(b) The records that must be retained are as follows—

(1) All documentation, data, and other information related to this part.

(2) Any other records specified by the Secretary.

(c) The Secretary may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

(d) The sponsor must require its health insurance issuer or employment-based plan, as applicable, to maintain and produce upon request records to satisfy subparagraph (a) of this regulation.

(e) The sponsor is responsible for ensuring that the records are maintained and provided according to this subpart.

Subpart F—Appeals

§ 149.500 Appeals.

(a) An adverse reimbursement determination is final and binding unless appealed pursuant to paragraph (e) of this section.

(b) Except as provided in paragraph (c) of this section, a sponsor may request an appeal of an adverse reimbursement determination.

(c) A sponsor may not appeal an adverse reimbursement determination if the denial is based on the unavailability of funds.

(d) An adverse reimbursement determination is a determination constituting a complete or partial denial of a reimbursement request.

(e) If a sponsor appeals an adverse reimbursement determination, the sponsor must submit the appeal in writing to the Secretary within 15 calendar days of receipt of the determination pursuant to guidance issued by the Secretary.

§ 149.510 Content of request for appeal.

The request for appeal must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider.

§ 149.520 Review of appeals.

(a) In conducting review of the appeal, the Secretary reviews the appeal, the evidence and findings upon which the adverse reimbursement determination was made, and any other written evidence submitted by the sponsor or the Secretary's designee and will provide a ruling on the appeal request.

(b) In conducting the review, the Secretary reviews the determination at issue, the evidence and findings upon which it was based, any written documents submitted to the Secretary by the sponsor and the Secretary's designee, and determines whether to uphold, reverse or modify the Secretary's initial reimbursement determination.

(c) A decision by the Secretary under this provision is final and binding.

(d) Regardless of the Secretary's decision, additional reimbursement is contingent upon the availability of funds at the time of the Secretary's determination.

(e) The Secretary informs the sponsor and the applicable Secretary's designee

of the decision. The Secretary sends a written decision to the sponsor or the applicable Secretary's designee upon request.

Subpart G—Disclosure of Data Inaccuracies

§ 149.600 Sponsor's duty to report data inaccuracies.

A sponsor is required to disclose any data inaccuracies upon which a reimbursement determination is made, including inaccurate claims data and negotiated price concessions, in a manner and at a time specified by the Secretary in guidance.

§ 149.610 Secretary's authority to reopen and revise a reimbursement determination.

(a) The Secretary may reopen and revise a reimbursement determination upon the Secretary's own motion or upon the request of a sponsor:

(1) Within 1 year of the reimbursement determination for any reason.

(2) Within 4 years of a reimbursement determination for good cause.

(3) At any time, in instances of fraud or similar fault.

(b) For purposes of this section, the Secretary does not find good cause if the only reason for the revision is a change of legal interpretation or administrative ruling upon which the determination to reimburse was made.

(c) A decision by the Secretary not to revise a reimbursement determination is final and binding (unless fraud or similar fault is found) and cannot be appealed.

Subpart H—Change of Ownership Requirements

§ 149.700 Change of ownership requirements.

(a) *Change of ownership consists of:*

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable state law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership; exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify the Secretary at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for health benefits, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

(f) Failure to notify the Secretary at least 60 days before the anticipated effective date of the change may result in the Secretary recovering funds paid under this program.

Dated: April 29, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: April 29, 2010

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–10658 Filed 5–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 159

RIN 0991–AB63

Health Care Reform Insurance Web Portal Requirements

AGENCY: Office of the Secretary, HHS.

ACTION: Interim final rule with comment period.

SUMMARY: The Patient Protection and Affordable Care Act (the Affordable Care Act) was enacted on March 23, 2010. It requires the establishment of an internet Web site (hereinafter referred to as a Web portal) through which individuals and small businesses can obtain information about the insurance coverage options that may be available to them in their State. The Department of Health and Human Services (HHS) is issuing this interim final rule in order to implement this mandate. This interim final rule adopts the categories of information that will be collected and displayed as Web portal content, and the data we will require from issuers and request from States, associations, and high risk pools in order to create this content.

DATES: *Effective Date:* These regulations are effective on May 10, 2010.

Comment Date: To be assured consideration, comments must be received at the address provided below, no later than 5 p.m. on June 4, 2010.

ADDRESSES: In commenting, please refer to file code DHHS–9997–IFC. 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):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions on the home page.
- *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: DHHS–9997–IFC, P.O. Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *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: DHHS–9997–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *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,