Supporting Statement for Early Retiree Reinsurance Program PRA Information Collection Package and Accompanying Instructions, as Revised and submitted to OMB on 10/31/2011
OMB #0938-1087

A. Background

Under 42 U.S.C. §18002 and implementing regulations at 45 CFR Part 149, employment-based plans that offer health benefits to early retirees and their spouses, surviving spouses and dependents are eligible under a temporary program to receive a tax-free reimbursement for the costs of certain health benefits for such individuals (the Early Retiree Reinsurance Program, or ERRP) In order to qualify, plan sponsors must submit a complete application to the Department of Health & Human Services (HHS), and must continually update any incorrect or outdated information in its application. As of May 6, 2011, plan sponsors may not longer submit applications to the program, pursuant to the HHS Secretary's authority under 42 U.S.C. 18002(f). However, sponsors must continue to update any incorrect or outdated information in their applications. In order to receive reimbursement under the program, they must also submit summary and detailed documentation of actual costs for health care benefits, which consists of documentation of actual costs for the items and services involved (including, but not limited to, prima facie evidence that an early retiree paid his or her share of a claim, as well as the Prima Facie Evidence Cover Sheet included in this PRA submission, in instances where the plan sponsor submits such costs), and a list of individuals to whom the documentation applies. Once HHS reviews and analyzes the information on the application, notification will be sent to the plan sponsor about its eligibility to participate in the program. Once HHS reviews and analyzes each reimbursement request, reimbursement under the program will be made to the sponsor, as appropriate. The program's funding is limited to $5 billion, and the program sunsets on January 1, 2014.

The ERRP requires the following collections of information.

Section 149.35(b)(1)

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 Sec. 149.350. The burden associated with this requirement is detailed in our discussion of Sec. 149.350.

Section 149.35(b)(2)

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.

Section 149.35(b)(3)

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, Sec. 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 Sec. 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.

Section 149.35(b)(4)

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 Sec. 149.40. The burden associated with this requirement is detailed in our discussion of Sec. 149.40.

The ERRP Application (45 CFR 149.40)

Section 149.40 discusses the application process for the early retiree reinsurance program. Sec. 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 Sec. 149.40(f).

The primary burden associated with the requirements in this section is the time and effort necessary for a plan sponsor or its designee to complete an entire 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 Sec. 149.40(f). However, this primary burden no longer exists, as the HHS Secretary has authorized her discretion under 42 U.S.C. §18002(f) to no longer accept applications under the program, as of May 6, 2011. (76 FR 18766). Nonetheless, sponsors are required to continually update their applications so they contain only accurate and current information. The burden estimate for doing so, is discussed below.

Documentation of Actual Costs of Medical Claims Involved (45 CFR 149.335)

Section Sec. 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 materials 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. Although the Prima Facie Evidence Cover Sheet (and accompanying instructions) is a collection instrument, it is an integral part of the overall collection of Documentation of Actual Costs of Medical Claim Involved, and the burden of completing the Cover Sheet is part of the overall burden associated with the Documentation of Actual Costs of Medical Claim Involved.

Maintenance of Records (45 CFR 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 Sec. 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 Sec. 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.

Appeals (45 CFR 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. HHS expects to issue clarifying guidance indicating that, in specifying the findings or issues with which the sponsor disagrees and the reasons for the disagreements, the sponsor should send a copy of the determination being appealed; the items and/or services at issue; the amount of program reimbursement at issue; the individuals to whom the items and/or services at issue, were provide; and any request for an extended due date for submitting supporting documentary evidence. 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, as specified in the draft appeals guidance submitted as part of this PRA submission.

Sponsor's Duty to Report Data Inaccuracies (45 CFR 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, as specified in the guidance submitted as part of this PRA submission.

Sponsor's Ability to Request a Reopening (45 CFR 149.610)

Section 149.610 permits a sponsor to request a reopening of a reimbursement determination. CMS expects to issue guidance stating that, as part of a request for reopening, a sponsor must submit its plan Sponsor ID (assigned by CMS), Application ID (assigned by CMS), a copy of the applicable reimbursement determination, a description of the issue, any sporting documentary evidence, and an analysis of the estimated financial impact, including the specific amount of ERRP reimbursement at issue. (A draft copy of this guidance, entitled Explanation of the Processes for Reporting Early Retiree and Claims Data Inaccuracies, and for Reopening, is included in this PRA submission). The burden associated with the aforementioned requirements is the time and effort necessary for a sponsor to read this guidance and draft and submit a reopening request, including supporting documentation.

Change of Ownership Requirements (45 CFR 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.

B. Justification

1 . Need and Legal Basis

Under 42 U.S.C. §18002 and its implementing regulations at 45 CFR Part 149, employment-based plans that offer health benefits to early retirees and their spouses, surviving spouses and dependents are eligible under a temporary program to receive a tax-free reimbursement for the costs of certain health benefits for such individuals. In order to qualify, plan sponsors must submit a complete application to HHS, and must continually update any incorrect or outdated information in its application. As of May 6, 2011, plan sponsors may not longer submit applications to the program, pursuant to the HHS Secretary's authority under 42 U.S.C. 18002(f). However, sponsors must continue to update any incorrect or outdated information in their applications. In order to receive reimbursement under the program, they must also submit summary and detailed documentation of actual costs for health care benefits, which consists of documentation of actual costs for the items and services involved, and a list of individuals to whom the documentation applies. Once HHS reviews and analyzes the

information on the application, notification will be sent to the plan sponsor about its eligibility to participate in the program. Once HHS reviews and analyzes each reimbursement request, reimbursement under the program will be made to the sponsor, as appropriate.

2. Information Users

HHS has contracted with outside contractors to assist in the administration of the program. Once the plan sponsor submits the program's application, HHS will analyze the application to determine whether the sponsor qualifies for the program. If so, in order to receive reimbursement under the program, they must also submit documentation of actual costs for health care benefits, which consists of summary and detailed documentation of actual costs for the items and services involved, and a list of individuals to whom the documentation applies.

3. Use of Information Technology

The application process for the program is a paper process. However, once an application is approved, HHS will send an email to the Account Manager and Authorized Representative identified on the application, inviting them to register with the ERRP Secure Website. Additionally, Account Managers and Authorized Representatives can identify for HHS other individuals to perform certain ERRP functions (e.g., request reimbursement, report costs) on behalf of the plan sponsor. Upon doing so, HHS will send emails to these other individuals, so they can register with the ERRP Secure Website. This process of electronically inviting individuals to register with the ERRP website, also applies when a sponsor changes the identity of the individuals serving in these roles, after the application has been completed and submitted. Collectively, these individuals can use the website to submit lists of early retirees, cost data, changes to plan sponsor and plan information, etc.

4. Duplication of Efforts

The data collected on the application and for the purpose of requesting reimbursement are not currently being collected through any other mechanism. Therefore, this information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

HHS has made efforts to minimize the burden that this collection of information will have on all submitting entities including small businesses. We expect that, for the majority of plan sponsors, the benefits of receiving the program's reimbursement payments will far exceed the cost associated with all aspects of the data collections associated with the program (to the extent the limited program funds permit).

6. Less Frequent Collection

A sponsor need only make one reimbursement request for each application per plan year (unless the sponsor discovers inaccuracies in data submitted for a previous reimbursement request).

7. Special Circumstances

A sponsor would have to report information to HHS more often than quarterly, in the unlikely event that a sponsor changed ownership more frequently than quarterly, as every change of ownership must be reported. Also, in the event the information in a sponsor's application becomes outdated, or the sponsor discovers that it provided incorrect information in its application, more frequently than quarterly, a sponsor would have to report information to HHS more often than quarterly.

There are no special circumstances where sponsors would be required to prepare a written response to a collection of information in fewer than 30 days after receipt of it.

There are no special circumstances where sponsors would be required to submit more than an original and two copies of any document.

There are special circumstances that would cause an information collection to be conducted which would require sponsors to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years. Program implementing regulations require that sponsors maintain the following records for 6 years after the expiration of the plan year in which costs were incurred:

1. All documentation, data, and other information related to 45 CFR Part 49, and any other records specified by the Secretary.
2. Any other records specified in additional guidance published by the Secretary of HHS.

-

There are no special circumstances that would cause an information collection in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study.

There are no special circumstances that would cause an information collection requiring the use of a statistical data classification that has not been reviewed and approved by OMB.

There are no special circumstances that include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.

There are no special circumstances where sponsors would be required to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has

instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on December 23, 2010 (76 FR 80817). The 30-day Federal Register notice published on June 28, 2011 (76 FR 37813). Our solicitation of comments constitutes our efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported.

In addition, HHS may periodically conduct industry focus groups to continue to improve the operations of the program.

9. Payments/Gifts to Respondents

There are no payments or gifts to respondents.

10. Confidentiality

We are assuring potential applicants to the ERRP that laws, regulations, and guidance associated with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, and the Privacy Act of 1974 (as amended) will apply to any information collected by HHS for purposes of this program.

The regulations governing the program will require that officers, employees, and contractors of the HHS may use information collected for the program only for the purposes of, and to the extent necessary, to carry out the requirements of the program. We have assured on an ongoing basis that any proprietary information submitted by applicants will not be disclosed.

11. Sensitive Questions

No questions of a sensitive nature, such as sexual behavior and attitude and religious beliefs are asked.

12. Burden Estimates (Hours & Wages)

CMS begin accepting applications for the ERRP on June 29, 2010. Thus, for purposes of this PRA submission, we consider July 1, 2010, through June 30, 2011, Year 1 of the program. We are not including burden estimates for Year 1 in this PRA package, as that year has passed. We are providing estimates for the remaining years of the program:

Year 2 (July 1, 2011 – June 30, 2012).

Year 3 (July 1, 2012 – June 30, 2013)
Year 4 (July 1, 2013 – June 30, 2014).

What follows are the burden estimates associated with each category of collection. Where such burden estimates vary based on the ERRP program year (i.e., Year 2, Tear 3, Year 4), that is specified.

Section 149.35(b)(1)

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 Sec. 149.350. The burden associated with this requirement is detailed in our discussion of Sec. 149.350.

Section 149.35(b)(2)

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.

Burden Estimates for 149.35(b)(2)

We believe that it will take 1 hour to develop, sign, and maintain one such written agreement, broken down as follows:

- Develop and sign written agreements: 55 minutes
- Maintain agreements: 5minute

For each remaining year of the program, we estimate that roughly one-quarter of 6,110 sponsors (1,528) will contract with one different entity each year to disclose information, data, etc. to the Secretary. Thus we estimate that the cost of compliance for each of those years is $113,851.28.

*Burden estimates for section 149.35(b)(2) are based on an hourly labor rate of $74.51, which is the hourly labor rate for a Federal GS 15, Step 10 employee in the Washington D.C./Baltimore locale.

Section 149.35(b)(3)

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, Sec. 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 Sec. 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.

Burden Estimates for Section 149.35(b)(3)

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.

- Develop and implement policies and procedures: 18 hours
- Maintain policies and procedures: 2 hours

For each remaining year of the program, we estimate that one-quarter of 6,110 sponsors (i.e., 11,528) will contract with one new entity each year that does not have fraud, waste, and abuse procedures in place, to participate in administering the plan. For each of those years, the annual burden estimated for this is 1,528 sponsors multiplied by 20 hours, or 30,560 hours, with estimated costs equal to$1,694,857.60. *

*Burden estimates for section 149.35(b)(3) are based on an hourly labor rate of $55.46, which is the hourly labor rate for a Federal GS 13, Step 10 employee in the Washington D.C./Baltimore locale.

Section 149.35(b)(4)

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 Sec. 149.40. The burden associated with this requirement is detailed in our discussion of Sec. 149.40.

The ERRP Application (45 CFR 149.40)

Section 149.40 discusses the application process for the early retiree reinsurance program. Sec. 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 Sec. 149.40(f).

The primary burden associated with the requirements in this section is the time and effort necessary for a plan sponsor or its designee to complete an entire 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 Sec. 149.40(f). However, this primary burden no longer exists, as the HHS Secretary has authorized her discretion under 42 U.S.C. §18002(f) to no longer accept applications under the program, as of May 6, 2011. (76 FR 18766). Nonetheless, sponsors are required to continually update their applications so they contain only accurate and current information. The burden estimate for doing so, is discussed immediately below.

Burden Estimates associated with Section 149.40 for updating data in application

We estimate that, for each remaining year of the program, 916 plan sponsors, or 15% of the total number of 6,110 plan sponsors, will be required to make one such update, and that each such update will take one hour, broken down as follows:

- Reporting the change: 1 hour

Thus, we estimate the total annual burden associated with this requirement to be 916 hours. The total estimated annual cost associated with this requirement for each remaining year of the program is $50,801.36*.

*This Burden estimate for section 149.40 is based on an hourly labor rate of $55.46 per hour. This is the hourly labor rate for a Federal GS 13, Step 10 employee, in the Washington D.C./Baltimore locale.

Documentation of Actual Costs of Medical Claims Involved (45 CFR 149.335)

Section Sec. 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 materials 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. Although the Prima Facie Evidence Cover Sheet (and accompanying instructions) is a collection instrument, it is an integral part of the overall collection of Documentation of Actual Costs of Medical Claim Involved, and the burden of completing the Cover Sheet is part of into the overall burden associated with the Documentation of Actual Costs of Medical Claim Involved.

Burden Estimates for Section 149.335

We estimate that it will take each sponsor an average of 88 hours per submission 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. The hours are broken down as follows:

- Reading instructions and related guidance: 4 hours
- Extract and compile identifying information on early retirees, spouses, surviving spouses, and dependents for whom a reimbursement request is being made: 23 hours
- Extract and compile documentation of actual costs of health benefits for which claims are being submitted, for each early retiree, spouse, surviving spouse, and dependent for whom a reimbursement request is being made: 61 hours

We estimate that, for Year 2 of the program, 3,000 sponsors will make two submissions annually. Thus, the total estimated burden associated with this requirement for Year 2 is 528,000 hours. The total estimated annual cost associated with these requirements for Year 2 is $20,544,480. For Year 3, we estimate that 1,200 plan sponsors will each make two submissions annually, with an estimated annual cost of $8,217,792. For Year 4, we estimate that 60 plan sponsors will make one submission, with an estimated annual cost of $205,444.80*.

*Burden estimates for section 149.335 are based on an hourly labor rate of $38.91, which is the hourly labor rate for a Federal GS 11, Step 10 employee in the Washington D.C./Baltimore locale.

Maintenance of Records (45 CFR 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 Sec. 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 Sec. 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.

Burden Estimates for Section 149.350

We estimate that each of 6,110 sponsors will require 6 hours to retain the records, for each remaining year of the program, broken down as follows

- Maintaining records: 1 hour
- Furnishing records: 5 hours

Thus, we estimate the total estimated annual burden associated with this requirement to be 36,660 hours. We estimate the total annual cost of this requirement to be $1,426,440.60*.

*Burden estimates for section 149.350 are based on an hourly labor rate of $38.91, which is the hourly labor rate for a Federal GS 11, Step 10 employee in the Washington D.C./Baltimore locale.

Appeals (45 CFR 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. HHS expects to issue clarifying guidance indicating that, in specifying the findings or issues with which the sponsor disagrees and the reasons for the disagreements, the sponsor should send a copy of the determination being appealed; the items and/or services at issue; the amount of program reimbursement at issue; the individuals to whom the items and/or services at issue, were provide; and any request for an extended due date for submitting supporting documentary evidence. 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, as specified in the draft appeals guidance submitted as part of this PRA submission.

Burden Estimates for Section 149.500 and 149.510

We expect to begin accepting appeals in October 2011. We anticipate an average burden of 8 hours to prepare, draft and submit an appeal, broken down as follows:

- Reading instructions and related guidance: 30 minutes
- Researching materials necessary to draft appeal: 4 hours, 30 minutes
- Drafting and submitting appeal request: 3 hours

In Year 2 and Year 3, we estimate that 200 sponsors will each draft and submit one appeal each. We estimate the total cost of drafting and submitting appeals in each of Year 2 and Year 3 is $88,736. In Year 4, we estimate that 30 sponsors will each draft and submit one appeal, with

estimated total costs for Year 4 of $13,310.40*.

*Burden estimates for section 149.500 and 510 are based on an hourly labor rate of $55.46, which is the hourly labor rate for a Federal GS 13, Step 10 employee in the Washington D.C./Baltimore locale.

Sponsor's Duty to Report Data Inaccuracies (45 CFR 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, as specified in the guidance submitted as part of this PRA submission.

Burden Estimates for Section 149.600

The draft guidance submitted as part of this PRA package that states that sponsors will make such disclosures by submitting a new reimbursement request (i.e., by submitting documentation of actual costs of medical claims involved, per 45 CFR 149.335 above) reflecting an accurate Early Retiree List, accurate Summary Cost Data, an accurate Claims File, and accurate Evidence of Early Retiree Payment (if applicable). We estimate that almost every reimbursement request submitted from now until the end of the program, that includes the disclosure of data inaccuracies, will also include new claims not previously submitted by the sponsor (i.e., will also include claims for which the sponsor previously did not request reimbursement, which are not reports of data inaccuracies) Thus the burden associated with such reimbursement requests is reflected in the burden associated with submitting documentation of actual costs of medical claims involved, per 45 CFR 149.335). However, for each remaining year of the program, we estimate that 40 sponsors will submit one reimbursement request consisting exclusively of disclosure of data inaccuracies, for a total estimate cost each year of $136,963.20*

*Burden estimates for section 149.600 are based on an hourly labor rate of $38.91, which is the hourly labor rate for a Federal GS 11, Step 10 employee in the Washington D.C./Baltimore locale.

Sponsor’s Ability to Request a Reopening

Section 149.610 permits a sponsor to request a reopening of a reimbursement determination. CMS expects to issue guidance stating that, as part of a request for reopening, a sponsor must submit its plan Sponsor ID (assigned by CMS), Application ID (assigned by CMS), a copy of the applicable reimbursement determination, a description of the issue, any sporting documentary evidence, and an analysis of the estimated financial impact, including the specific amount of ERRP reimbursement at issue. (A draft copy of this guidance, entitled Explanation of the Processes for Reporting Early Retiree and Claims Data Inaccuracies, and for Reopening, is included in this PRA submission). The burden associated with the aforementioned requirements is the time and effort

necessary for a sponsor to read this guidance and draft and submit a reopening request, including supporting documentation.

Burden Estimates for Section 149.610

The submission of an ERRP reopening request is similar to the submission of an ERRP appeal under 45 CFR 149.500. However, we believe that the process set forth for reporting data inaccuracies, largely obviates the need for sponsors to request a reopening. To the extent there is such a need, we expect a small number of reopenings to be requested. We anticipate an average burden of 8 hours to draft and submit a reopening request, broken down as follows:

- Reading instructions and related guidance: 30 minutes
- Researching materials necessary to draft appeal: 4 hours, 30 minutes
- Drafting and submitting reopening request: 3 hours

For each remaining year of the program, we estimate that 20 sponsors will submit one reopening request, with an estimated burden of 8 hours to prepare the request. Therefore, we estimate total costs associated with this burden, of $6,225.60*.

*Burden estimates for section 149.610 are based on an hourly labor rate of $38.91, which is the hourly labor rate for a Federal GS 11, Step 10 employee in the Washington D.C./Baltimore locale.

Change of Ownership Requirements (45 CFR 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.

Burden Estimates for Section 149.700

We estimate that it will take each sponsor an average of 1 hour to comply with these requirements, broken down as follows:

- Report details any of change of ownership: 40 minutes
- Complete any paperwork associated with change of ownership: 20 minutes

We estimate that 40 sponsors per year will be subject to these requirements Thus, for each remaining year of the program, we estimate the total annual burden associated with these requirements to be 40 hours, and the total cost associated with these requirements to be $2,218.40.*

*Burden estimates for section 149.700 are based on an hourly labor rate of $55.46, which is the hourly labor rate for a Federal GS 13, Step 10 employee in the Washington D.C./Baltimore locale.

What follows is a table that provides averages, over the three remaining program years, of the burden per task, number of respondents, frequency of response, and total burden. (The data populating this table is calculated from the above data).

Task	Burden Per Task	Respondents	Frequency of Response	Total Burden
149.35(b)(2), Written Agreement with Issuer or Plan	1 hour	1,528	1	1,528 hours
149.35(b)(3), Procedures to Protect Against Fraud, etc.	20 hours	1,528	1	30,560 hours
149.40, Updating Data in the Application	1 hour	916	1	916 hours
149.335, Documentation of Actual Costs of Medical Claims Involved	88 hours	1,420	1.67	208,683 hours
149.350, Maintenance of Records	6 hours	6,110	1	36,660 hours
149.500, 149.510, Requesting Appeals	8 hours	143	1	1,144 hours
149.600 Reporting Previous Data Inaccuracies	88 hours	40	1	3,520 hours
149.610, Requesting Reopenings	8 hours	20	1	160 hours
149.700, Reporting Change of Ownership	1 hour	40	1	40 hours
Totals	221 hours	11,745	9.67	283,211 hours

13. Capital Costs

(a) Total Capital and Start-up Cost

We have determined that there are no new capital outlays required to participate in the program. We have assumed that all businesses will own at least one computer and have access to the internet.

(b) Total Operation and Maintenance and Purchase of Service Component

We estimate that there may be expenses associated with hiring of vendors to assist plan sponsors in gathering and aggregating health benefit cost data for early retirees and their spouses, surviving spouses, and dependents and complying with ongoing information sharing requirements. Those expenses are subsumed in the burden estimates discussion contained in Section 12 of this paper.

14. Cost to Federal Government

The cost to the Federal Government is estimated to be $30 million annually. This amount includes the costs of 10 HHS full time employees (FTEs) and the necessary contractors to support the operations of the program. In order to not introduce unnecessary risk to the Federal Government's procurement strategy, more granular Federal Government cost estimates are not being provided at this time.

15. Change to Burden, Change to Information Collection

In the PRA package approved in December 2010, we estimated an average burden per entity of 338 hours to comply with the information collection requirements specified in the regulation at 45 C.F.R. Part 149, for the first year of the program (with the burden decreasing in subsequent years, to 293 hours). The revisions submitted as part of this revised PRA package do not include burden estimates for the first year of the program (July 1, 2010 through June 30, 2011), as that program year has expired. Rather, this revised PRA package includes burden estimates for each subsequent year of the program. For the two remaining program years with the highest burden estimate (July 1, 2011 through June 30, 2012, and July 1, 2012 through June 30, 2013), we estimate an average burden of 309 hours. This 16-hour increase in burden hours (from 293 to 309) is attributable to the fact that we are adding estimated burden hours associated with submitting appeals (8 hours), and for submitting reopening requests (8 hours). For the remaining program year (July 1, 2013 through June 30, 2014), the burden estimate decreases by 72 hours, from 293 hours to 221 hours, due the fact that we estimate that those plan sponsors that submit a reimbursement request (i.e., documentation of actual costs of medical claims involved) during that program year, will do so an average of one time, rather than two times. This decreases the burden estimate by 88 hours, but when accounting for the previously mentioned increase in burden of submitting appeals (8 hours) and reopening requests (8 hours), this results in the net decrease of 72 burden hours.

Based on program experience, we have also changed overall (as opposed to just per entity) burden estimates averaged per program year, based on estimated number of respondents. The table below first lists such estimates under the PRA package approved in December 2010, compared to such estimates in this package. (The first figures listed in each column, represent the previously approved figures). As indicated by this chart, the overall hourly burden estimate averaged per program year (not including the first year of the program which has passed), has decreased from 1,555,950 hours, to 283,211 hours.

Task	Burden Per Task	Respondents	Frequency of Response	Total Burden
149.35(b)(2), Written Agreement with Issuer or Plan	1 hour/1 hour	1,875/1,528	1/1	1,875 hours/1,528 hours
149.35(b)(3), Procedures to	20 hours/20	1,875/1,528	1/1	37,500

Protect Against Fraud, etc.	hours			hours/30,560 hours
149.40, Updating Data in the Application	1 hour/1 hour	1,500/916	1/1	1,500 hours/916 hours
149.335, Documentation of Actual Costs of Medical Claims Involved	88 hours/88 hours	7,500/1,420	2/1.67	1,320,000 hours/208,683 hours
149.350, Maintenance of Records	6 hours/6 hours	7,500/6,110	1/1	45,000 hours/36,660 hours
149.500, 149.510, Requesting Appeals	0 hours/8 hours	0/143	0/1	0 hours/1,144 hours
149.600, Reporting Previous Data Inaccuracies	88 hours/88 hours	3,750/40	1/1	150,000 hours/3,520 hours
149.610, Requesting Reopenings	0 hours/8 hours	0/20	0/1	0 hours/160 hours
149.700, Reporting Change of Ownership	1 hour/1 hour	75/40	1/1	75 hours/40 hours
Totals	205 hours/ 221 hours	24,075/11,745	8/9.67	1,555,950 hours/283,211 hours

Note that the burden hours associated with reading the guidance materials related to disclosing data inaccuracies that are being included with this revised PRA submission, and with completing the Prima Facie Evidence Cover Sheet that is being included with this revised PRA submission, were already accounted for in the PRA package OMB approved on December 22, 2010. Specially, the burden associated with completing the Prima Facie Evidence cover sheet, was included in the burden estimate for submitting a reimbursement request. The burden associated with reading the guidance paper on reporting data inaccuracies was already included in the burden estimate for disclosing data inaccuracies.

As compared with the PRA package approved in December 2010, the changes to the collection are as follows: (Note that all page numbers refer to pages in the “clean” Information Collection Instrument submitted with this revised PRA package).

<u>General Changes Made Throughout Document</u>

- The Information Collection Instrument has been heavily revised for purposes of making it 508 compliant.

- All previous statutory cites to the Public Law number for the Affordable Care Act (P.L. 111-148), are now immediately followed by the United States Code cite (42 U.S.C. §18002).

Specific Changes Made to the Document

Reimbursement Request Information

Part I. B (pages 13-14)

This paragraph B. has been retitled "Submit Claim List(s)." It formerly was titled "Submit Detailed Data List(s)." (This change of terms was made globally throughout the document).

Part II. E (page 21)

This paragraph E has been retitled "Submit Claim List(s)". It formerly was titled "Submit Detailed Claims Data List(s)."

Part II. E. (pages 21-91)

The previously submitted version of the Information Collection Instrument had listed all the data elements necessary for ERRP plan sponsors to include in a Claim List. This version of the document instead includes the actual required claims layout format for each type of claim (i.e., institutional, professional, prescription drug). Each data element that is relevant to that specific type of claim, is included in the layout for that specific type of claim. The data elements included, are the same data elements that had been listed in the previous version of the Information Collection Instrument, with three exceptions. The "Claim Type" and" Type of Service" data elements have been eliminated, as they duplicate the information that can be gleaned the "Record Type" data element. One new data element has been added. That new data element is Cost Adjustment (i.e., price concessions), to be reported at the individual early retiree level. A sponsor must include this data element with respect to each individual for which the sponsor is submitting claims data, to the extent any Cost Adjustments apply to the costs submitted for that individual. We estimate the burden of providing this information to be nominal. This is because the previous version of the Information Collection Instrument required sponsors to provide this Cost Adjustment data on an aggregate basis for all such individuals, which required the sponsor to first determine the amount of Cost Adjustments for each individual, before summing the amounts. We believe that most of the burden associated with reporting the amounts on an individual basis, is the burden of first determining the amounts for each such individual. That burden existed, and was already accounted for, in the previous PRA submission, as part of the burden associated with submitting a reimbursement request.

Part II.F (page 92)

This paragraph has been retitled “Submit Prima Facie Evidence of Early Retiree Payment.” It formerly was titled “Submit Evidence of Early Retiree Payment.” This language change makes the title consistent with the applicable regulatory provision (45 CFR 149.335(b)).

Part II.F lists the data elements that must appear on each piece of prima facie evidence, to demonstrate that an early retiree actually paid his or her share of a claim. It lists the same four data elements as in the previously submitted Information Collection Instrument, but clarifies that if the provider of services is an individual, as opposed to an entity, the individual must be named. It also adds a fifth data element – a description of the health benefit item or service for which the sponsor seeks reimbursement. There is no additional burden to the plan sponsor for providing this data, because the receipt itself (i.e., the piece of prima facie evidence) will already include that information.

Part II. F also lists the data elements that must appear on the Cover Sheet that accompanies prima facie evidence. All the data elements listed in the previously submitted Information Collection Instrument are listed here, except for the first and last name of the individual who paid the costs. (This information is not necessary for the plan sponsor to submit, as it can be identified through other information provided by the sponsor).

Part II, F also lists data elements that must appear on the Cover Sheet, that were not included in the previously submitted Information Collection Instrument. These data elements are: Plan Sponsor Name, Plan Year End Date, Today’s Date, Contact Name, Contact Phone Number, and the following information related to the Summary Cost Data for that reimbursement request: Reimbursement Request Number, Current Cost Paid by Early Retiree, Old Cost Paid by Early Retiree, Net Cost Paid by Early Retiree, Reimbursement Request Date, and Reimbursement Request Total.

A copy of the Cover Sheet, with separate detailed instructions for its completion, is being submitted with this PRA package. The burden associated with reading those detailed instructions and completing the Cover Sheet, was accounted for in the previous PRA submission under the burden hours for submitting a reimbursement request. The change to the data elements that must be submitted as part of a submission of prima facie evidence, as described in the immediately preceding three paragraphs, reduce burden nominally. This is because, as described above, a sponsor no longer must provide the first name and last name of every individual who paid costs, for each record of Prima Facie Evidence on the Cover Sheet. Although there are additional data elements that a sponsor must provide on the Cover Sheet that were not required in the previously submitted Information Collection Instrument, these additional data elements must be provided only once on the Cover Sheet, as opposed to providing the first and last name of each person for whom prima facie evidence is being submitted, a burden which has been eliminated in this Information Collection Instrument. Also, we believe that only a small fraction of plan sponsors will be subject to these prima facie evidence requirements, as they only apply to plan sponsors that submit costs paid by early retirees (as opposed to cost paid by the plan). Thus far in the program, only a small percentage of sponsors have submitted such costs.

Reopening Information (page 94)

We have added this section, which sets forth the data elements a sponsor must submit when submitting a request for a reopening. These data elements are discussed in the guidance document entitled Explanation of the Processes for Reporting Early Retiree and Claims Data Inaccuracies, and for Reopening, which is submitted as part of this PRA package. A plan sponsor has a right to request a reopening pursuant to the ERRP regulations at 45 CFR 149.610. We have added the associated burden, into this PRA package submission

16. Publication/Tabulation Dates

A very limited portion of the collection of information on the program application is and will continue to be published. Specifically, a list of the names of the plan sponsors identified on the applications will be periodically published and posted on the HHS and/or ERRP Web Site. The time schedule for such publication has yet to be determined. At this time, HHS has not conclusively decided whether to publish any additional information provided by sponsors, or what such information might be.

17. Expiration Date

This data information contains a data collection instrument to be used for several years or longer. Therefore, HHS would like an exemption from displaying the expiration date as this form is used on a continuing basis.

.

18. Certification Statement

There are no exceptions to the certification statement identified in Item 19, “Certification for Paperwork Reduction Act Submissions, “ of OMB Form 83-I.