**Summary of Burden Estimates Associated with Revised PRA Package 0938-1087 Submitted for OMB approval on DATE**

Note: 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).

**Requirements to Participate in Early Retiree Reinsurance Program (45 CFR 149.35)**

**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, 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.

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, or30,560 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., 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 estimates 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.

***Burden Estimates for Section 149.335***

We estimate that it will take each sponsor an average of 88 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, 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 is528,000 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. 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. 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***

tThe 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. 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, and 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.