A. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, the "Affordable Care Act"), provides for three premium stabilization programs – a reinsurance program, a risk corridors program, and a risk adjustment program – to mitigate the negative impacts of adverse selection and market uncertainty. On March 23, 2012, The Centers for Medicare & Medicaid Services (CMS) published the Premium Stabilization Rule (77 FR 17220) to implement and set standards for these premium stabilization programs. CMS also published a proposed Notice of Benefit and Payment Parameters for 2014 ("draft Notice") to implement sections 1311, 1341, 1342, 1343, 1401, 1402, 1411, and 1412 of the Affordable Care Act, as well as to expand on standards set forth in the Premium Stabilization Rule. On March 11, 2013, CMS published the final Notice of Benefit and Payment Parameters for 2014 ("final Payment Notice.")

The transitional reinsurance program and the temporary risk corridors program are designed to provide issuers with greater payment stability as insurance market reforms begin. The reinsurance program serves to reduce the uncertainty of insurance risk in the individual market in each State by making payments for high-cost enrollees. The HHS-administered risk corridors program serves to protect against rate-setting uncertainty with respect to qualified health plans by limiting the extent of issuer losses (and gains). The permanent risk adjustment program is intended to protect health insurance issuers that attract a disproportionate number of higher risk enrollees (*e.g.*, those with chronic conditions). These programs will support the effective functioning of the American Health Benefit Exchanges ("Exchanges"), which will become operational by January 1, 2014. The Exchanges are individual and small group health insurance marketplaces designed to enhance competition in the health insurance market and to expand access to affordable health insurance for millions of Americans. The reporting and data collection provisions described below apply to States and health plans both inside and outside of an Exchange.

B. Justification

1. Need and Legal Basis

Section 1341 of the Affordable Care Act provides that each State must establish a transitional reinsurance program to help stabilize premiums for coverage in the individual market during the first three years of Exchange operation. Section 1342 provides for the establishment of a temporary risk corridors program that will apply to qualified health plans in the individual and small group markets for the first three years of Exchange operation. Section 1343 provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. These risk-spreading programs, which will be

implemented by HHS and/or States, are designed to mitigate adverse selection and provide stability for health insurance issuers in the individual and small group markets as market reforms and Exchanges are implemented.

Section 1321(a) also provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, reinsurance, risk adjustment, and other components of title I of the Affordable Care Act.

2. Information Users

The data collection and reporting requirements described below will enable States and/or HHS to implement these programs, which will mitigate the impact of adverse selection in the individual and small group markets both inside and outside the Exchange.

3. <u>Use of Information Technology</u>

Information collected for this rule will be submitted electronically. HHS staff will communicate with States and the District of Columbia using standardized reporting, e-mail or telephone.

4. <u>Duplication of Efforts</u>

This information collection does not duplicate any other Federal effort.

5. Small Businesses

This information collection will not have a significant impact on small businesses.

6. Less Frequent Collection

The anticipated flows of funds for these programs require the collection of information as indicated. A less frequent collection could result in cash flow difficulties for issuers and logistical difficulties for issuers and the entities operating premium stabilization programs.

7. Special Circumstances

In order for payments to be made in a timely manner for these premium stabilization programs, it is necessary to collect information according to timeframes established by the State or HHS on behalf of the State.

8. Federal Register/Outside Consultation

CMS provided 60-day notice for this information collection in the Federal Register published as part of the proposed Notice of Benefit and Payment Parameters for 2014 (77 FR 73117). We have considered and responded to comments received in response to that information collection notice as part of the final Notice of Benefit and Payment Parameters for 2014 (78 FR 15410), and have revised this supporting statement to reflect our response to those comments. We have additionally consulted with contractors, academia, States, and industry on the feasibility of this information collection, and have based many of the requirements in this information collection on those consultations.

9. Payments/Gifts to Respondents

No payments or gifts will be provided to respondents.

10. Confidentiality

We will maintain respondent privacy with respect to the information collected to the extent required by applicable law and HHS policies.

11. Sensitive Questions

There are no sensitive questions included in this information collection effort.

12. Burden Estimates (Hours & Wages)

Below is a summary of the information collection requirements set forth in the final rule. Throughout this summary, the frequency of data collection is assumed to be the frequency discussed in the preamble to the rule.

A number of assumptions are made regarding the wages of personnel needed to accomplish the proposed collection of information. Wage rates are based on the Employer Costs for Employee Compensation report by U.S Bureau of Labor Statistics and represent a national average. Some States or employers may face higher or lower wage burdens. Wage rates estimates include a 35% fringe benefit estimate for State employees and a 30% fringe benefit estimate for private sector employees. We present an annualized estimate of the burden associated with these information collection requirements below.

I. Health Insurance Issuer Standards Related to the Transitional Reinsurance Program (§153.400-§153.420)

Within Part 153, subpart E we discussed reporting requirements for health insurance issuers related to the transitional reinsurance program. Based on data from the healthcare.gov website, we estimate there are approximately 1,800 issuers in the individual and small group markets. Based on 2012 data from the Department of Labor, we estimate that 22,900 entities (including self-insured and partially insured entities) will make reinsurance contributions.

Calculation of Reinsurance Contributions (§153.405)

As described in §153.400(b) all contributing entities both inside and outside of the Exchange will be required to provide enrollment data (covered lives and member months) to the applicable reinsurance entity or the Federal reinsurance contributions entity to substantiate contribution amounts. As described in §153.405, we propose requiring contributing entities to provide annual counts of their enrollment and reinsurance contributions to HHS based on their last reported Patient-Centered Outcome Trust Fund (PCORTF) number as modified for reinsurance purposes. The burden associated with this requirement is the time and effort required by an issuer or self-insured group health plan to derive an annual enrollment count. Because issuers and self-insured group health plans will already be under an obligation to determine a count of covered lives using a PCORTF method, the burden associated with this requirement is the additional burden of conducting these counts using the slightly modified counting methods specified in the final Payment Notice. On average, we estimate it will take each issuer 1 hour to reconcile and submit final enrollment counts to HHS. Assuming an hourly wage rate of \$55 for an operations analyst, we estimate an aggregate burden of \$1,259,500 for 22,900 reinsurance contributing entities subject to this requirement.

Request for Reinsurance Payments (§153.410)

As described in §153.410(a), health insurance issuers of reinsurance-eligible plans seeking reinsurance payment must make a request for payment in accordance with the requirements in the HHS notice of benefit and payment parameters or the State notice of benefit and payment parameters, as applicable. To the greatest extent possible, we wish to minimize burden for issuers. The data collected, and the manner in which that data will be collected, will be identical for both the reinsurance and risk adjustment programs. HHS has determined that issuers will need to maintain data elements identified in Appendix A in order to make reinsurance payment requests. A subset of issuers (specifically, issuers operating reinsurance-eligible plans in the individual market) subject to the risk adjustment data collection requirements are eligible to make reinsurance payment requests. As such, we anticipate minimal burden associated with this provision; the burden associated with this provision is described in Part III of this section.

As described in §153.420(a), to be eligible for reinsurance payments, an issuer must submit or make accessible all required reinsurance data in accordance with the reinsurance data collection approach established by the State or HHS on behalf of the State. As described in 153.420(b) the submission deadline is April 30 of the year following the applicable benefit year.

II. Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program (§153.520-§153.530)

Within Part 153, subpart F we discussed reporting and recordkeeping requirements for QHP issuers related to the risk corridors program. As described in §153.520(e), QHP issuers will be required to maintain data and supporting information used to make the required allocations and attributions of revenues and expenses, and to determine that the methods and bases detailed in the report described below were accurately implemented. As described in §153.520(c), we will require all QHP issuers to submit to HHS a detailed description of the methods and specific bases used to attribute revenues and expenses in allowable costs and target amount to each QHP and across plans. Under §153.530, we will also require all QHP issuers to submit data on premiums earned, allowable costs, and allowable administrative costs. While these information collection requirements are subject to the Paperwork Reduction Act, the associated requirements and instruments are currently under development. Upon their completion, we will seek OMB approval and solicit public comments.

III. Health Insurance Issuer Standards for the Risk Adjustment Program (§153.610-§153.630; and §153.700-730)

Within Part 153, subpart G, we described reporting requirements for health insurance issuers related to the risk adjustment program.

As described in §153.610, health insurance issuers will be required to maintain risk adjustment data in order for HHS to operate risk adjustment on behalf of the State. HHS has determined that issuers will need to maintain data elements identified in Appendix A. HHS intends to employ a distributed data approach when running risk adjustment on behalf of a State and will also use this data for the purpose of determining the risk adjustment user fee for each issuer.

Under §153.610(f), we establish a user fee to support Federal operation of risk adjustment. This per capita monthly fee will be charged to issuers of risk adjustment covered plans based on enrollment estimates provided to HHS in the distributed data environment. HHS will calculate user fees owed, and issuers will remit the fee owed only once, in June of the year following the benefit year, in connection with processing of payments and charges for risk adjustment.

We estimate that 1,800 issuers will be required to pay risk adjustment user fees, and the additional cost associated with this requirement is the time and effort for an issuer to provide monthly enrollment data and remit fees. Because HHS will utilize existing data collection and

payments and charges processing, we do not anticipate that this provision will alter the collection cost.

Under a distributed data approach, the required data is accessed and stored separately from other issuer data pursuant to formats specified by HHS. We propose in §153.700(a) to require that an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State where HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, must provide HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS. We estimate that this data submission requirement will affect 1,800 issuers, and will cost each issuer approximately \$342,086 in total labor costs. This cost estimate reflects the wages of 3 full-time equivalent employees (5,760 hours per year) at an average hourly rate of \$59.39 per hour for a technical employee. We anticipate that 400 data processing servers will be established across the market in 2014 (at an average cost of \$15,000) and issuers will process approximately 9 billion claims and enrollment files in 2014. Therefore, we estimate an aggregate burden, including labor and capital costs (as described in section 13 below), of \$621,754,800 for all issuers as a result of these requirements.

As described in 153.720(a), an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS operates risk adjustment or reinsurance, as applicable, must establish a unique masked enrollee identification number for each enrollee, in accordance with HHS-defined requirements, and maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year. Under §153.720(b), an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, may not include an enrollee's personally identifiable information in the masked enrollee identification number or use the same masked enrollee identification number for different enrollees enrolled with the issuer. As discussed in OMB Memorandum M-07-16, the term "personally identifiable information" is a broadly used term across Federal agencies, and has been defined in the Office of Management and Budget Memorandum M-07-16 (May 22, 2007).¹

We estimate that 1,800 issuers will be affected by the requirement to maintain a masked enrollee identification number for each enrollee. The cost of setting up a masked identity for each enrollee would be the time and effort required to assign an identification number to each enrollee and remove other identifying factors from the enrollee's profile or claims information as submitted to HHS. We estimate it would cost each issuer approximately \$178 per year, based on three hours of work by a technical analyst at \$59.39 per hour. Therefore, we estimate an aggregate cost of

¹ Visit the Office of Management and Budget website (http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-16.pdf) to learn about the memorandum.

\$320,706 for all issuers to maintain a masked enrollee identification number.

As described in §153.630, we will require health insurance issuers to comply with data validation activities as specified by HHS or States. The burden associated with this requirement is the issuer's time and effort to provide HHS with source claims, records, and enrollment information to validate enrollee demographic information for initial and second validation audits, and the issuer's cost to employ an independent auditor to perform the initial validation audit on a statistically valid sample of enrollees. We estimate that each issuer sample will consist of approximately 300 enrollees, with approximately two-thirds of the sample consisting of enrollees with HCCs. We also anticipate that this audit burden will affect about 1,800 issuers. Based on Truven Health Analytics 2010 MarketScan® data, we have determined that for enrollees with HCCs, the average number of HCCs to be reviewed by an auditor per enrollee is approximately two. Additionally, based on HHS audit experience, we estimate that it may cost approximately \$180 (\$90 per hour for 2 hours) for an auditor to review the medical record documentation for one enrollee with roughly two HCCs. We expect that it may cost approximately \$30 per enrollee (\$90 per hour for 20 minutes) to validate demographic information for all enrollees in the audit sample, totaling approximately \$210 per enrollee with HCCs and \$30 per enrollee with no HCCs. We assume that an initial validation audit will be performed on 180,000 enrollees without HCCs, and 360,000 enrollees with HCCs. For 1,800 issuers, we anticipate that the total burden of conducting initial validation audits will be \$86.4 million.

Table 1 - Burden Estimates for Risk Adjustment Data Collection and Data Validation

Forms (if necessary)	Type of Respondent	Frequency and Duration	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Risk adjustment and reinsurance distributed data collection		Annually, Permanent	1,800	5,000,000	0.001	10,368,000
Masked enrollee information	Issuer	Annually, Permanent	1,800	1	3	5,400
Risk adjustment data validation	Issuer	Annually, Permanent	1,800	300	1.78	960,000
Total			1,800			11,333,400

<u>Table 2 - Burden Estimates for Risk Adjustment Data Collection and Data Validation by Labor</u>
<u>Category</u>

Type of Respondent	Hourly Labor Cost of Reporting (\$)	Total Burden Hours	Average Labor Cost per Response	Number of Respondents	Total Labor Costs (All Respondents)
Technical Analyst	\$59.39	10,373,400	\$178	1,800	\$616,075,506
Auditor	\$90.00	960,000	\$160	1,800	\$86,400,000
Total		9,981,348		1,800	\$702,165,960

13. Capital Costs

Regardless of the data format and specifications for the reinsurance and risk adjustment programs, issuers will need to extract and, for purposes of audit, store the necessary data elements separately from data used during the normal course of business. We anticipate that approximately 400 data processing servers will be established across the market in 2014 to process the required data elements at an average one-time cost of \$15,000 each. Therefore, we estimate a total capital burden of \$6,000,000 for all issuers subject to this requirement. This estimate does not include the labor costs associated with data and server maintenance, which are estimated separately.

14. Cost to Federal Government

The initial burden to the Federal Government for the establishment of the risk-related programs is \$274,936. The calculations for CCIIO employees' hourly salary was obtained from the OPM website: http://www.opm.gov/oca/10tables/html/dcb_h.asp.

<u>Table 3 – Administrative Burden Costs for the Federal Government Associated with the Reinsurance, Risk Adjustment, and Risk Corridors Programs</u>

Task	Estimated Cost
Development of HHS notice of benefit and payment parameters	
15 GS-13: 15 x \$42.66 x 160 hours	\$102,384
Technical Assistance to States	
15 GS-13: 15 x \$42.66 x 240 hours	\$153,576
Managerial Review and Oversight	
2 GS-15: 2 x \$59.30 x 160 hours	\$18,976
Cost of Contracts for HHS-operated Reinsurance and Risk Adjustment	\$20,000,000
Total Costs to Government	\$20,274,936

15. Explanation for Program Changes or Adjustments

As detailed above, certain burden estimates for information collection requirements associated with the reinsurance, risk adjustment, and risk corridors programs have changed from what was previously estimated in the Premium Stabilization Rule due to policy changes in the final HHS notice of benefit and payment parameters for 2014. We have also updated the burden we described in the draft Payment Notice information collection notice published as part of the proposed Notice of Benefit and Payment Parameters for 2014 (77 FR 73117) to reflect—

- policy changes that were finalized in the final HHS notice of benefit and payment parameters for 2014,
- the agency's most current estimates of the reinsurance, risk adjustment, and risk corridors operations, and
- public comments on the information collection that were received during the 60-day comment period.

As a result of these adjustments, we are reducing the total annual burden estimate described in draft Payment Notice information collection notice by 9,741,696 hours, which results in an estimated total annual burden of 1,013,293 hours associated with the requirements set forth in the final HHS notice of benefit and payment parameters for 2014. This reduction reflects the following modifications—

• an adjustment to our estimate of the burden associated with the distributed data requirements under §153.610 and §153.700 to reflect only the incremental burden that was not already accounted for in the information collection for the Premium Stabilization Rule,

- addition of the burden associated with submission of a masked enrollee ID number under the distributed data approach set forth in §153.610 and §153.700,
- the removal of the burden associated with State operation of the risk adjustment and reinsurance programs because we expect fewer than 10 states to operate risk adjustment or reinsurance in the 2014 benefit year, and
- an increase in the number of reinsurance contributing entities based on the Department of Labor's current estimate of the number of self-insured plans.

16. Publication/Tabulation Dates

The following information described in part 12 of this document will be published annually in the HHS notice of benefit and payment parameters:

- Approved State alternate risk adjustment methodologies (as described in §153.330).
- States publishing a State notice of benefit and payment parameters described in §153.100-110 will include the following annually in that notice, as applicable. The risk adjustment methodology that will be used if the State is operating the risk adjustment program.
- The data validation standards, as described in §153.350, that will be used when operating the risk adjustment program.

Finally, States will publish information about their risk adjustment program in an annual summary report to be submitted to HHS. HHS intends that these reports will be made public soon after they are submitted.2

17. Expiration Date

Not applicable.

18. Certification Statement

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

² For 2014, two states have elected to operate reinsurance and only one state, Massachusetts, will operate risk adjustment. The number does not reach the required threshold of nine or more entities affected and, therefore, we are not submitting a PRA package. We will seek OMB approval in subsequent years if nine or more states decide to operate risk adjustment programs.

Appendix A

Data Elements for Risk Adjustment and Reinsurance			
Data Category	Data Elements	Submitting Entity	
Geographic Data	Metal level	State	
	Actuarial value		
	Benefit year		
	 Individual versus small-group 		
Market Level Data	 State average actuarial risk (HHS-sourced) 	State	
	State Rating Curve		
	Includes header, issuer, and enrollee data elements:		
	File ID		
	Execution Zone		
	Run Date		
	Report Type		
	 Total Number of Enrollee Records 	T	
	 Total Number of Enrollment Periods 	Issuers	
	Record ID		
	• Issuer ID		
	 De-Identified (Masked) Enrollee ID 		
Enrollee level data	Enrollee DOB		
	Enrollee Gender		
	 Enrollment Period Activity 		
	 Subscriber Indicator 		
	Subscriber ID		
	Plan ID		
	Enrollment start date		
	 Enrollment end date 		
	Premium Amount		
	Geographic Rating area		
	 Interface Control Release Number 		

Data Category	Data Elements	Submitting Entity
Pharmacy Claims	Includes header, issuer, plan and claim data elements: File ID Execution Zone Run Date Report Type Total Claims Total Plan Paid Amount Issuer ID Record ID Plan ID De-Identified (Masked) Enrollee ID Claim ID Claim Processed Date/Time Fill Date Paid Date Prescription/Service Reference Number Product/Service ID Dispensing Provider Service ID Qualifier Dispensing Provider Service ID Fill Number Dispensing Status Void/Replace Indicator Total Allowed Cost Derived Amount Indicator Interface Control Release Number	Pharmacy Claims

Data Category	Data Elements	Submitting Entity
Medical Claims	Includes header, issuer, plan and claim header and claim line data elements: File ID Execution Zone Run Date Report Type Total Claims Total Claim Lines Total Plan Paid Amount Record ID Issuer ID Plan ID De-Identified (Masked) Enrollee ID Interface Control Release Number Claim Header Level Data Elements Form Type Claim ID Original Claim ID Claim Processed Date/Time Bill type Date Paid Void/Replace Indicator Discharge Status Code Statement Covers From Statement Covers Through Billing Provider ID Total Amount Allowed Total Amount Paid Derived Amount Indicator Diagnosis Code Qualifier	Submitting Entity

Data Category	Data Elements	Submitting Entity
	Claim Line Level Data Elements	
	Record ID	
	Claim Line Sequence Number	
	 Date of Service - From 	
	Date of Service - To	
	Revenue Code	
Medical Claims	Service Code Qualifier	
(continued)	Service Code	
	Service Code Modifier	
	Place of Service	
	 Rendering Provider ID Qualifier 	
	Rendering Provider ID	
	Amount Allowed	
	Amount Paid	
	Derived Amount Indicator	