Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals CMS-10401/OMB Control Number 0938-1155

A. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, (PPACA) enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, the "Patient Protection and Affordable Care Act" (PPACA)), provided 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. The three-year transitional reinsurance program and temporary risk corridors programs ended after the 2016 benefit year, with program closeout work expected to continue into 2018 or beyond, as required. The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. The risk adjustment program relies on a HHS-developed methodology to adjust payments to health plans that attract higher-risk populations, such as those with chronic conditions, and thereby reduce incentives for issuers to avoid higher-risk enrollees. HHS collects this data from issuers via a distributed data environment. In 2018, HHS will introduce Risk Adjustment Data Validation (RADV) payment adjustments as a component of the risk adjustment program payment transfers. HHS continues to recalibrate the risk adjustment models and refine the HHS-developed risk adjustment methodology to better account for high-cost enrollees. This supporting statement proposes to revise the existing collection to eliminate programs, revise existing estimates based on current operations, and update data collections to conform to statute and regulations. In all of our revised estimates, we have reduced the number of issuers affected to 700, from 2,400, based on experience from the initial years, and adjusted burden accordingly.

The regulatory history of these programs is as follows:

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. On March 11, 2013, CMS published the HHS Notice of Benefit and Payment Parameters for 2014 final rule ("2014 Payment Notice") (78 FR 15410), to implement requirements for various programs established by the PPACA, including to provide for the collection of user fees from issuers to fund operations of the Federally-facilitated Exchange and the risk adjustment program in States where HHS operates risk adjustment, and to expand on standards set forth in the Premium Stabilization Rule. On March 11, 2014 CMS published the Notice of Benefit and Payment Parameters for 2015 final rule ("2015 Payment Notice") (79 FR 13743) to expand upon, modify and clarify the provisions of the Premium Stabilization Rule, the 2014 Payment Notice, including to reduce issuers' sample size for RADV, and the first and second final Program Integrity Rules (78 FR 54070 and 78 FR 65046). Subsequently, we published the HHS Notice of Benefit and Payment Parameters for 2018 final rule ("2018 Payment Notice") (81 FR 94058), which provided that issuers of plans with less than $15 million in premium statewide would be subject to RADV audits every third year, and subject to a default error rate in the off years. Also in the 2018 Payment Notice, we updated the risk adjustment methodology to incorporate enrollment duration factors and prescription drug categories, adjust for

extremely high-cost enrollees through the incorporation of the high-cost risk pool, and established the use of enrollee-level EDGE data collected for actual risk adjustment calculations for calibration of HHS programs and to better understand these markets. In the HHS Notice of Benefit and Payment Parameters for 2019 proposed rule (82 FR 51052), we proposed to postpone the $15 million materiality threshold for RADV audits until 2018 benefit year RADV. We also proposed that State regulators could request a reduction in the statewide average premium factor of the risk adjustment transfer formula, beginning for the 2019 benefit year.

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 PPACA 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 PPACA market reforms, and that HHS will operate reinsurance in States that do not elect to establish a reinsurance program. 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 PPACA market reforms. Section 1343 provides for a permanent risk adjustment program for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchanges. Sections 1402 and 1412 of the Affordable Care Act establish a program for reducing cost sharing for individuals with lower household income and Indians. Sections 1401 and 1411 of the Affordable Care Act provide for advance payments of the premium tax credit for low- and moderate-income individuals enrolled in a QHP through an Exchange.

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 PPACA. These risk-spreading and insurance affordability programs as implemented by HHS and/or States, are designed to mitigate adverse selection, to provide stability for health insurance issuers in the individual and small group markets as market reforms and Exchanges are implemented, and to make health insurance more affordable and accessible to millions of Americans who currently do not have affordable options available to them.

2. Information Users

The data collection and reporting requirements described below will be used by HHS to run the permanent risk adjustment program, including validation of data submitted by issuers, on behalf of States that requested HHS to run it for them. Risk adjustment is one of 3 market stability programs established by the PPACA and is intended to mitigate the impact of adverse selection in the individual and small group health insurance markets inside and outside of the Health Insurance Exchanges. HHS will also use this data to adjust the payment transfer formula for risk associated with high-cost enrollees.

State regulators can use the reporting requirements outlined in this collection to request a reduction to the statewide average premium factor of the risk adjustment transfer formula, beginning for the 2019 benefit year, and thereby avoid having to establish their own programs.

Issuers and providers can use the alternative reporting requirements for mental and behavioral health records described herein to comply with State privacy laws.

3. Use of Information Technology

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. Duplication of Efforts

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 to implement these programs according to the timelines established in PPACA and implementing regulations, 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

A 60-day Notice will publish in the Federal Register on _____.

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 rules and guidance cited above. Throughout this summary, the frequency of data collection is assumed to be the frequency discussed in these rules and guidance.

A number of assumptions are made regarding the wages of personnel needed to accomplish this annual 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. We have updated wage rates estimates to include a 100 percent fringe benefit estimate for all 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. As discussed above, this program ended in 2016 after most health plan issuers and identified contributing entities provided HHS with data and made required reinsurance contributions or received payment. However, CMS will continue to collect contributions from entities subject to reinsurance that were not identified until the last year of the program or that were known to CMS but still owe contributions. CMS will also make additional reinsurance payments, as applicable. As a result, we propose to retain reinsurance data elements in this collection. Based on data from the HealthCare.gov website and prior year data submissions, we estimate there are approximately 700 issuers in the individual and small group markets. We previously estimated based on 2012 Department of Labor data that, overall, 22,000 entities (including self-insured and partially insured entities) would make reinsurance contributions. Based on current Department of Labor data, we estimate that of the original number, approximately 1,500 contributing entities have not yet remitted a payment to HHS for reinsurance contributions and will be required to make a reinsurance contribution as part of program closeout activities.

Calculation of Reinsurance Contributions (§153.405)

As described in §153.400(b) all contributing entities both inside and outside of the Exchanges were required to provide enrollment data (covered lives and member months) to HHS to calculate contribution amounts in each year of the three-year program. As described in §153.405, we require contributing entities to provide annual counts of their enrollment and reinsurance contributions to HHS based on modified counting methods used for Patient-Centered Outcome Trust Fund (PCORTF) reporting. 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 2014 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 $63.18 for a business operations specialist, we estimate an aggregate burden of $94,770 for an estimated 1,500 remaining reinsurance contributing entities subject to this requirement.

All health insurance issuers, group health plans and third party administrators are required to register in Pay.gov in order to access the form for the reinsurance contributions process. The "Initial Plan Data Collection to Support QHP Certification and other Financial Management and Exchange Operations" (OMB Control No. 0938-1187) details data submission required when an entity is remitting payment for an invoice or receiving a payment from HHS. The data elements that will be requested through the reinsurance contribution form on Pay.gov are detailed in Appendix C.

Audits of Reinsurance Contributing Entities and Reinsurance Eligible Issuers (§153.405(i))

Under §153.405(i), HHS or its designee has the authority to audit reinsurance contributing entities to assess compliance with the requirements of subparts E, G and H of Part 153, as applicable. For contributing entities, we estimate that complying with this audit would take a business operations specialist at an hourly wage rate of $63.18, approximately 37 hours at a cost of approximately $2,337.66 for each contributing entity. Because we have not finalized the audit protocols, it is difficult to accurately estimate an audit rate. However, we estimate that approximately 1 percent of the original 22,000 contributing entities will be audited, representing 220 contributing entities. Therefore, we estimate an aggregate burden of 8,140 hours, or $514,285 as a result of this proposed requirement.

We discuss the audit burden for reinsurance-eligible plans along with the audit burden for risk adjustment covered plans in section III of this supporting statement.

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

As discussed above, the risk corridors program ended in the 2016 benefit year. HHS may permit resubmission of risk corridors data based on changes in data related to other PPACA programs, such as risk adjustment, reinsurance contributions, reinsurance payments or cost-sharing reduction payments; however, that data would be collected on the forms used for MLR data collection, approved under OMB control number 0938-1164.

Risk corridors submissions are subject to the data validation process established in §§153.530 and 153.540. Because the MLR program and the risk corridors program require similar data, we estimate that submitting the data elements required for the risk corridors program will impose limited additional burden on issuers. We estimate that it will take each QHP issuer approximately 1.5 hours, representing 1 hour for a business operations specialist (at an hourly wage rate of $63.18) and 30 minutes for an operations manager (at an hourly wage rate of $117.40), to input and review data that is specific to the risk corridors program in the MLR and risk corridors reporting form. We estimate that fewer than 50 QHP issuers will resubmit risk corridors data in future years. Therefore, we estimate an aggregate burden of 75 hours at a total cost of approximately $9,141 for QHP issuers as a result of this requirement.

Additionally, HHS intends to conduct audits of risk corridor data to assess compliance with the requirements of subpart F of Part 153, as provided under §153.540(a), at the same time it conducts audits of MLR, and this burden is also accounted for under OMB control number 0938-1164.

III. Health Insurance Issuer Standards for the Risk Adjustment Program (§153.320, 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.

State Flexibility for Risk Adjustment (§153.320)

In the proposed HHS Notice of Benefit and Payment Parameters for 2019, we proposed that State regulators could request a reduction to the statewide average premium factor of the risk adjustment transfer formula, beginning for the 2019 benefit year. HHS would require any State that intends to request this flexibility to submit its proposal for an adjustment to the statewide average premium in the small group market within 30 calendar days after publication of the HHS Notice of Benefit and Payment Parameters proposed rule for the applicable benefit year for timely review and issuer notification and HHS approval prior to issuers' rate setting timelines. The burden associated with this requirement is the time and effort for State regulators to submit a proposal to HHS. We estimate that it will take a business operations specialist 32 hours (at a rate of $63.18 per hour) to prepare the request and 16 hours for an operations manager (at a rate of $117.40 per hour) to review the request and transmit it electronically to HHS. We estimate that each State seeking a reduction in the average premium calculation will incur a burden of 48 hours at a cost of approximately $3,900 per State to comply with this reporting requirement (32 hours for the business operations specialist and 16 hours for the operations manager). Although we are unable to precisely estimate the number of States that will make this request, we expect that no more than 25 States will make these requests annually, resulting in a total annual burden of approximately 1,200 hours with an associated total cost of $97,504. We note that this proposal to allow certain State-by-State adjustments to the HHS risk adjustment transfer formula to account for State-specific differences in risk would reduce or eliminate the far more burdensome necessity for States to undertake operation of their own risk adjustment program.

High-Cost Risk Pool Adjustment (§153.320)

HHS finalized a high-cost risk pool adjustment in the 2018 Payment Notice to account for the incorporation of risk associated with high-cost enrollees in the risk adjustment model. Beginning for the 2018 benefit year, HHS will reimburse issuers for a percentage of claims amounts above a certain threshold for high-cost enrollees, calculated using EDGE server data and funded by a charge on all issuers of risk adjustment covered plans equal to a percent of premium, by market nationally.

All issuers of risk adjustment covered plans are subject to this high-cost risk pool adjustment and risk adjustment user fees. Since HHS will assess charges to all issuers of risk adjustment covered plans to fund the high-cost risk pool adjustment, issuers will be required to submit premium and enrollment data to HHS beginning for the 2018 benefit year, so that HHS can calculate the national high-cost risk pool charge and the risk adjustment user fee. Issuers that are the sole issuer in a risk pool will also be required to submit enrollment and premium data, even if they choose not to submit data to the EDGE server due to the lack of a risk adjustment transfer based on plan liability risk scores with another issuer in their risk pool. In a single issuer risk pool with an issuer that does not submit data via an EDGE server, the issuer would report premium and enrollment data via an electronic submission form annually. We propose to add nine data elements to the form: State, market type, issuer ID and legal name, billable member months, total premium, attestation, and contact information for the attester and the submitter (See new Appendix D, below). Issuers already submit some of this data and already have all of it at hand, so the burden to submit it would be minimal; we anticipate it will take 10 minutes for a management analyst (at an hourly wage rate of $91.10) to submit this data, and that fewer than 10 issuers would be required to submit it. Therefore the total annual burden for this requirement would be approximately 1 hour and 40 minutes (100 minutes total) with an associated total cost of $151.83.

Distributed Data and Risk Adjustment Data Submission Requirements (§153.610, §153.700(a), and §153.720)

As described in §153.610, health insurance issuers are required to maintain risk adjustment data in order for HHS to operate risk adjustment on behalf of a State. HHS has determined that issuers will need to maintain data elements identified in Appendix A. HHS employs a distributed data approach when running risk adjustment on behalf of a State and uses the same data for the purpose of determining the risk adjustment user fee for each issuer. We propose one new data element in Appendix A, below, regarding pharmacy claims: the number of days' supply for prescription drugs, to improve our analysis of risk adjustment data.

Under §153.610(f), we established a user fee to support Federal operation of risk adjustment. This per capita monthly fee is charged to issuers of risk adjustment covered plans based on enrollment estimates provided to HHS in the distributed data environment. HHS calculates risk adjustment user fees, and issuers will remit the assessed user fee once annually, in June of the year following the benefit year, in connection with processing payments and charges for risk adjustment. We estimate that approximately 700 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. In §153.700(a), we require that an issuer of a risk adjustment covered plan in a State where HHS is operating the risk adjustment program 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 approximately 700 issuers, and will cost each issuer approximately $524,736 in total labor costs, including for one new data element we propose below in Appendix A regarding pharmacy claims: the number of days' supply for prescription drugs. This cost estimate reflects the wages of 3 full-time equivalent employees (5,760 hours per year) at an average hourly rate of $91.10 per hour for a management analyst. Issuers have already established data servers to process claims, so we are reducing the capital cost in section 13 below to a total of $30,000 to account for the possibility that only two new issuers a year would be required to set up a server. We anticipate that issuers will process approximately 9 billion claims and enrollment files annually for risk adjustment. Therefore, we estimate an aggregate burden, including labor and capital costs (as described in section 13 below), of $367,345,200 for all issuers as a result of these requirements. To ensure timely and accurate risk adjustment transfers, HHS asks issuers to make complete, current enrollment and claims files accessible through its dedicated distributed data environments no less frequently than quarterly.

HHS has issued guidance giving issuers the option of uploading supplemental diagnoses to the dedicated distributed data environment in addition to the other enrollee, claims and medical data elements that are required for the risk adjustment program (see Appendix A). If an issuer chooses to submit supplemental diagnosis information, HHS has determined that issuers will need to maintain data elements identified in Appendix B. In this collection, we rename 10 data elements in Appendix B to accurately reflect existing data specifications for this optional submission. The burden associated with this requirement is the additional effort for an issuer to gather and submit supplemental diagnoses to HHS. We estimate that all 700 issuers of risk adjustment covered plans will submit this information

for 30 percent of their enrollees. In the 2014 Payment Notice, we estimated the time and effort associated with submitting risk adjustment and reinsurance data through the distributed data environment. Because issuers will only submit supplemental diagnoses for 30 percent of their enrollees, we believe that the time and effort associated with this process will be approximately 30 percent of the time and effort associated with uploading information to the distributed data environment. We anticipate that issuers will process approximately 2.7 billion supplemental diagnoses claims or about 3.8 million per issuer. We estimate that it will take 3 full-time equivalent employees (at an average hourly wage rate of $91.10 for a management analyst) approximately 1,728 hours per year to submit supplemental diagnoses to HHS. For 700 issuers, we estimate an aggregate burden of 1,209,600 hours and $110,194,560 associated with this option.

As described in §153.720(a), an issuer of a risk adjustment covered plan in a State in which HHS operates risk adjustment 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 in a State in which HHS is operating the risk adjustment program 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 700 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 $273.30 per year, based on three hours of work by a management analyst at $91.10 per hour. Therefore, we estimate an aggregate total annual burden of 2,100 hours at an estimated cost of $191,310 for all issuers to maintain a masked enrollee identification number.

Under §153.710(d), an issuer must either confirm to HHS that the information in the final dedicated distributed data environment report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with §153.700(a) for the benefit year specified in the report, or describe to HHS any inaccuracy it identifies in the final dedicated distributed data environment report within 15 calendar days of the date of the report.

We estimate that 700 issuers of risk adjustment covered plans will be subject to this requirement, and that issuers will compare enrollee condition codes with risk scores and analyze claims costs to confirm information in the final dedicated distributed data environment reports. On average, in any given benefit year, we estimate that it will take a business operations specialist (at an hourly wage rate of $63.18) approximately 6 hours to respond to the final dedicated distributed data

[1] Available at: http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2007/m07-16.pdf.

environment report. Therefore, we estimate an aggregate burden of 4,200 hours and $265,356 for 700 issuers as a result of this requirement.

Data Validation Requirements when HHS Operates Risk Adjustment (§153.630)

As described in §153.630, health insurance issuers must comply with risk adjustment 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. In the 2015 Payment Notice, we revised the audit sample size downward so that each issuer's audit sample consists of approximately 200 enrollees, with approximately two-thirds of the sample consisting of enrollees with HCCs. As proposed in the 2019 Payment Notice, issuers with 500 or fewer billable member months Statewide would be excluded from performing an initial validation audit for 2017 benefit year RADV. In addition, beginning with 2018 benefit year RADV, under our proposal, an estimated 50 issuers with annual premiums of less than $15 million will be subject to an initial validation audit only every third year, as established in the 2017 Payment Notice; during the off years, CMS will adjust their risk scores by a default error rate annually equal to the lower of either the national average negative error rate, or the average negative error rate within a State, as set forth in the 2018 Payment Notice.

Based on a review of EDGE data, we have determined that for enrollees with HCCs, the average number of HCCs to be reviewed by a certified senior medical coder per enrollee is approximately two. Additionally, based on HHS audit experience, we estimate that it may cost approximately $242.28 ($53.84 per hour for 4.5 hours on average) for a certified senior medical coder to review and, in some cases, for a second senior medical coder to re-review the medical record documentation for one enrollee with roughly two HCCs. For 134 enrollees with HCCs in an issuer sample, the total cost would be $32,466. We expect that it may cost approximately $17.95 per enrollee ($53.84 per hour for 20 minutes) to validate demographic information for 50 enrollees in each audit sample totaling $897.50 per issuer. In 2017 benefit year RADV, we assume that an initial validation audit will be performed on 46,666 enrollees without HCCs, and 93,334 enrollees with HCCs. We estimate this would require approximately 619.6 hours of coding by an outside entity per issuer, at a cost of $33,364 per issuer. In addition, for each issuer, we expect it would require a compliance officer working 40 hours at $67.40 per hour, and 2 operations managers working a total of 80 hours at $117.40 per hour to make available claims documents for external medical coders (120 hours at a cost of $12,088). The combined burden for coding and administration would be approximately 739.6 hours at a cost of $45,452 per issuer. For an estimated 700 issuers required to submit samples in 2017 benefit year RADV, we anticipate that the aggregate burden of conducting initial validation audits will be approximately 517,720 hours and $31,816,400. We note that this is the upper bound burden, and fewer issuers will be subject to this requirement in future years.

Under §153.630(b)(1), an issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. Under this provision, the issuer must provide HHS with the identity of the initial validation auditor, and attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), in a timeframe and manner specified by HHS. The

additional burden associated with this reporting requirement is the time and effort necessary to report the auditor's identity to HHS. We estimate it will take a business operations specialist (at an hourly wage rate of $63.18) and an operations manager (at an hourly wage rate of $117.40) each approximately 15 minutes to prepare and send an electronic report to HHS. Therefore, for the estimated 700 issuers submitting reports in 2017 benefit year RADV, the aggregate burden associated with this reporting requirement is 350 hours, at an approximate cost of $31,605.

Under §153.630(b)(8), the initial validation auditor is required to measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. This provision also requires that beginning with 2017 benefit year RADV, the initial validation auditor must achieve a minimum consistency measure of 95 percent for demographic, enrollment, and health status review outcomes. We believe establishing inter-rater reliability among reviewers is standard practice in the industry and will not result in extra cost for the initial validation auditor. Therefore, the burden associated with this reporting requirement is the time and effort for the initial validation auditor to report the inter-rater reliability rate to the issuer and to HHS. We estimate it will take a business operations specialist (at an hourly wage rate $63.18) and an operations manager (at an hourly wage rate of $117.40) each approximately 15 minutes to report the inter-rater reliability rate to the issuer and to HHS. Therefore, for the estimated 700 issuers submitting reports in the 2017 benefit year RADV, the aggregate burden associated with this requirement is 350 hours at an approximate cost of $31,605. (In Table 1, below, we estimate a combined burden for these two issuer reporting requirements: identification of the auditor, and the inter-rater reliability rate.)

Mental and behavioral health records §153.630

For risk adjustment data validation, HHS requires issuers to document mental and behavioral health records included in audit sampling. Without the necessary mental and behavioral health information for each sample, the diagnosis code for an applicable enrollee cannot be validated and, therefore, it would be rejected during risk adjustment data validation.

Because providers may be prevented under some State privacy laws from furnishing a full mental health or behavioral health record, we propose in the 2019 Payment Notice at §153.630(b)(6) to allow issuers an additional avenue to achieve compliance with data validation requirements by permitting abbreviated mental or behavioral health assessments for risk adjustment data validation in the event that a provider is subject to State privacy laws that prevent the provider from providing HHS with a complete mental or behavioral health record. To submit a mental or behavioral health assessment, a provider would be required to attest that relevant State privacy laws prevent him or her from providing the entire mental or behavioral health record.

HHS expects that this provision may affect 10 percent of issuers or approximately 70 issuers in States with stricter privacy laws on medical records. Based on our experience with the first pilot year RADV audits, we estimate that approximately 40 enrollees in any initial validation audit sample of 200 enrollees could be affected. Providers routinely prepare assessments to validate diagnoses, therefore, we believe the additional burden is the time it would take to seek patient consent to provide the assessment, in States that require such permission, and for a provider to prepare an abbreviated assessment for each medical record and to attest that relevant State privacy laws prohibit him or her from providing the entire mental or behavioral health record.

We estimate it would take a medical records technician (at an hourly wage of $39.86) 15 minutes to obtain consent from each patient, or approximately 10 burden hours at an estimated cost of $398.60 per issuer. In addition, we estimate a qualified licensed provider (at an hourly wage of $192.52) would need 45 minutes to prepare an abbreviated assessment and sign an attestation, for a total of $144.39 per enrollee, or $5,775.60 per issuer. Therefore, for 40 patients, the total burden per issuer for the provision to obtain consent from each patient and prepare an abbreviated assessment and signed attestation would be 40 hours and approximately $6,174.20. The aggregated burden for the estimated 70 affected issuers would be 2,800 hours and approximately $432,194.

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
State Flexibility for Risk Adjustment	State	Annually	25	1	48	1200
High-Cost Risk Pool Adjustment	Issuer	Annually	10	1	0.17	1.67
Risk adjustment distributed data collection	Issuer	Annually	700	1	5,760	4,032,000
Supplemental Diagnoses	Issuer	Annually	700	1	1,728	1,209,600
Masked enrollee information	Issuer	Annually	700	1	3	2,100
Confirmation of Final Reports	Issuer	Annually	700	1	6	4,200

Risk adjustment data validation	Issuer	Annually	700	200	3.698	517,720
IVA Auditor and Inter-rater Reliability Reports	Issuer	Annually	700	2	0.50	700
Mental Health Assessment & Attestation	Issuer	Annually	70	40	.75	2,100
Mental Health patient record permission	Issuer	Annually	70	40	.25	700
Total						**5,770,321.7**

Table 2 - Burden Estimates for Risk Adjustment Data Collection and Data Validation by Labor Category

Type of Respondent	Hourly Labor Cost of Reporting ($) (wage includes 100% fringe benefits rate)	Total Burden Hours	Average Labor Cost per Response	Number of Respondents	Total Labor Costs (All Respondents)
Business Operations Specialist (BLS 13-1199	$63.18	5350	$466.22	725	$338,011
Management Analyst (BLS 12-1111	$91.10	5,318,581.67	$682,445.58	710	$484,536,366.7
Operations Manager BLS 11-1021	$117.40	67,550	$11,329.1	700	$7,930,370

Compliance Officer (BLS 13-1041)	$67.40	28,000	$2,696	700	$1,887,200
Certified Senior Medical Coder	$53.84	433,720	33,359	700	$23,351,484
Medical Records Technician (BLS 29-2071)	$39.86	700	398.6	70	$27,902
Qualified Licensed Provider (BLS 29-1066)	$192.52	2,100	5,775.60	70	$404,292
Total		**5,825,201.67**			**$518,475,625.77**

Administrative Burden Related to Audits of the Risk Adjustment Covered Plans and Reinsurance Eligible Plans (§153.410(d);§153.620(c))

Under §153.620(c) and §153.410(d), HHS or its designee has the authority to audit issuers of risk adjustment covered plans or reinsurance-eligible plans to assess compliance with the requirements of subparts E, G and H of Part 153, as applicable. For issuers of risk adjustment covered plans and issuers of reinsurance-eligible plans, these provisions would result in a third party disclosure requirement for issuers to prepare and compile the financial and programmatic information necessary to comply with the audit. The three-year temporary reinsurance program ended in benefit year 2016 as required by statute; however, CMS audits of these plans will be conducted in the future as needed. (Under §153.620(b) and §153.410(c), issuers of reinsurance eligible and risk adjustment covered plans are required to keep program records for 10 years.) For each onsite review we estimate that it will take an average of 40 hours for administrative work to assemble the requested information, 19.5 hours to review the information for completeness, and 30 minutes to submit the information to HHS in preparation for an onsite review. We estimate that an onsite review would require an additional 2 hours to schedule the onsite activities with the compliance reviewer (at an hourly wage rate of $63.18, 4 hours for introductory meeting, 8 hours to tour reviewers onsite, 10 hours of interview time, 2 hours to walk through processes with the reviewer, and 4 hours for concluding meetings, resulting in a total of approximately 60 hours of preparation time and an additional 30 hours for onsite time for each issuer. We estimate it will take 90 hours at a cost of approximately $5,686.20 for each issuer to make information available to HHS for an onsite review. We estimate that approximately 40 issuers, representing roughly 5 percent of issuers of risk adjustment covered plans or reinsurance-eligible plans would be audited annually. Therefore, we estimate an aggregate burden of 3,600 hours and $227,448 for issuers as a result of this requirement.

IV. Administrative Appeals for Premium Stabilization Programs, Federal Exchange User Fees, Premium Tax Credits, and Cost-sharing Reductions (§156.1220)

Under §156.1220 and associated guidance, issuers may use an administrative appeals process to address unresolved discrepancies for advance payment of the premium tax credit, reconciled cost-sharing reduction amounts,[2] FFE user fees, and the premium stabilization programs, as well as any assessment under §153.740(b) of a default risk adjustment charge. Under §156.1220(a), which includes programs that expired in 2016, an issuer may file a request for reconsideration to contest a processing error by HHS (i.e., an incorrect loading or use of data), an incorrect application of the relevant methodology, or a mathematical error for the amount of: (1) advance payment of the premium tax credit, advance payment of cost-sharing reductions[3] or Federally-facilitated Exchange user fee charges for a particular month; (2) risk adjustment payments or charges for a benefit year, including an assessment of risk adjustment user fees; (3) reinsurance payments for a benefit year; (4) a risk adjustment default charge for a benefit year; (5)

[2] The reconciled CSR payment amount is the final CSR payment amount for appeals (see https://www.regtap.info/uploads/library/FT_CSRAppealsGuidance_5CR_121916.pdf). In October 2017, HHS discontinued payment of cost-sharing reductions to issuers.

[3] The reconciled CSR payment amount is the final CSR payment amount for appeals (see https://www.regtap.info/uploads/library/FT_CSRAppealsGuidance_5CR_121916.pdf).

a reconciliation payment or charge for cost-sharing reductions for a benefit year; or (6) risk corridors payments or charges for a benefit year. While the hours involved in a request for reconsideration may vary, for the purpose of this burden estimate we estimate that it will take a business operations specialist 4 hours (at an hourly wage rate of $63.18) to make the comparison and submit a discrepancy report, if applicable, and a request for reconsideration to HHS. We estimate that 12 issuers, representing approximately 1.5 percent of all issuers that may be eligible for reinsurance payments, risk adjustment payments or charges (including any assessment of risk adjustment user fees or a default risk adjustment charge), advance payment and reconciliation of cost-sharing reductions, advance payment of the premium tax credit, and FFE user fees, will submit a request for reconsideration for a total aggregate burden of approximately 48 hours and an estimated cost of $3,032.64.

Additionally, under §156.1220(b), an issuer dissatisfied with the reconsideration decision regarding: (1) risk adjustment payments and charges, including an assessment of risk adjustment user fees, (2) reinsurance payments, (3) default risk adjustment charges, (4) reconciled cost-sharing reduction amounts, (5) risk corridors payments or charges, provided under paragraph (a) of §156.1220, is entitled to an informal hearing before a CMS hearing officer, if a request is made in writing within 30 calendar days of the date the issuer receives the reconsideration decision. Further review is available from the CMS Administrator. However, because we believe these processes will occur extremely infrequently, we are not estimating the burden related to this requirement.

13. Capital Costs

Regardless of the data format and specifications for the risk adjustment program, 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. Issuers have already established the data processing servers used for risk adjustment data validation. We now estimate that in any given year, two new issuers will need to establish a server and that the one-time cost will be on average $15,000. Therefore we estimate a total capital burden for all issuers subject to this requirement of $30,000. This estimate does not include the labor costs associated with data and server maintenance, which are estimated separately.

14. Cost to Federal Government

The annual burden to the Federal government to operate the risk adjustment program, including to update the risk adjustment methodology, run the program, and conduct outreach to issuers is $694,755. (We note that contractor costs for risk adjustment and RADV are included in the risk adjustment user fee and reported annually in the Payment Notice.) The calculations for CCIIO employees' hourly salary was obtained from the OPM website: http://www.opm.gov/oca/10tables/html/dcb_h.asp.

Table 3 – Administrative Burden Costs for the Federal Government Associated with the Reinsurance and Risk Adjustment

Task	Estimated Cost
Development of HHS notice of benefit and payment parameters	
GS-13: x $90.84 x 160 hours	$14,534.40
Technical Assistance to States	
15 GS-13: 15 x $90.84 x 240 hours	$327,024.00
Risk Adjustment Operations (includes data analysis, quantity & quality analysis and payment processing)	
2 GS-13: 2 x $90.84 x 400 hours (payment processing)	$72,672
2 GS-13: 2 x $90.84 x 240 hours (data analysis)	$43,603.2
2 GS-13: 2 x $90.84 x 320 hours (quantity and quality analysis)	$58,137.6
2 GS-12: 2 x $76.39 x 320 hours (quantity and quality analysis)	$48,889.6
Managerial Review and Oversight	
2 GS -15: 2 x $118.60 x 160 hours	$37,952
2 GS-15: 2 x $126.28 x 160 hours	$40,409.60
2 GS-14 2 x 107.36 x 240 hours	$51,532.8
Total Costs to Government	$694,755.20

15. Explanation for Program Changes or Adjustments

This proposed revision includes a significant decrease in burden due to the termination of the reinsurance and risk corridors programs as required by the PPACA. In addition, we reduced the number of issuers participating in various programs by more than two thirds, to 700, from 2,400, to reflect actual experience. We also reduced enrollee audit sample size to 200, from 300, for risk adjustment data validation. As discussed earlier, wage rates are increased to reflect a 100 percent fringe benefit.

16. Publication/Tabulation Dates

The data collection will be published for this revision.

17. Expiration Date

The expiration date and OMB control number will be displayed on each instrument (first page, top right corner).