FEDERAL REGISTER

Vol. 76 Friday,
No. 136 July 15, 2011

Part III

Department of Health and Human Services

45 CFR Part 153
Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 153

[CMS–9975–P]

RIN 0938–AR07

Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment

AGENCY: Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. These programs will mitigate the impact of potential adverse selection and stabilize premiums in the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges (''Exchanges'') are implemented, starting in 2014. The transitional State-based reinsurance program serves to reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. The temporary Federally-administered risk corridor program serves to protect against uncertainty in the Exchange by limiting the extent of issuer losses (and gains). On an ongoing basis, the State-based risk adjustment program is intended to provide adequate payments to health insurance issuers that attract high-risk populations (such as individuals with chronic conditions).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (E.S.T.) on September 28, 2011.

ADDRESSES: In commenting, please refer to file code CMS–9975–P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''More Search Options'' tab.

2. *By regular mail.* You may mail written comments to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9975–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By express or overnight mail.* You may send written comments to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–9975–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification; commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD: Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Sharon Arnold at (301) 492–4415 for general information.

Wakina Scott at (301) 492–4393 for matters related to reinsurance and risk corridors.

Kelly O'Brien at (301) 492–4399 for matters related to risk adjustment.

Grace Arnold at (301) 492–4272 for matters related to the collection of information requirements.

Brigid Russell at (301) 492–4421 for matters related to the summary of preliminary regulatory impact analysis.

Abbreviations:

Affordable Care Act—The collective term for the Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152)

CMS Centers for Medicare & Medicaid Services

HHS U.S. Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)

MLR Medical Loss Ratio

PHS Act Public Health Service Act (42 U.S.C. 201 *et seq.*)

QHP Qualified Health Plan

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. Comments will be most useful if they are organized by the section of the proposed rule to which they apply. You can assist us by referencing the file code [CMS–9975–P] and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on the following public Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at Room 445–G, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call 1–800–743–3951.

Table of Contents

I. Background

A. Legislative Overview

Starting in 2014, individuals and small businesses will be able to purchase private health insurance through State-based competitive marketplaces called Affordable Insurance Exchanges, or ''Exchanges.'' Exchanges will offer Americans competition, choice, and clout. Insurance companies will compete for business on a level playing field, driving down costs. Consumers will have a choice of health plans to fit their needs. And Exchanges will give individuals and small businesses the same purchasing clout as big businesses. The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are working in close coordination to release guidance related to Exchanges in several phases. The first in this series was a Request for Comment relating to Exchanges, published in the **Federal Register** on August 3, 2010. Second, Initial Guidance to States on Exchanges was issued on November 18, 2010. Third, a proposed rule for the application, review, and reporting process for waivers for State innovation was published in the **Federal Register** on March 14, 2011. Fourth, two proposed regulations, including this one, are published in this issue of the **Federal Register** to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act.

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 (2014–2016). Section 1342 provides that the Secretary must establish a transitional risk corridor program that will apply to the qualified health plans in the individual and small group markets for the first three years of Exchange operation (2014–2016). Section 1343 provides that each State may establish 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 mechanisms, which will be implemented by the Secretary and the States, are designed to mitigate the potential impact of adverse selection and provide stability for health insurance issuers in the individual and small group markets.

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. Section 1321(a)(2) requires, in issuing such regulations, the Secretary to engage in stakeholder consultation in a way that ensures balanced representation among interested parties. We describe the consultation activities the Secretary has undertaken later in this introduction. Section 1321(c)(1) authorizes the Secretary to establish Exchanges and implement reinsurance, risk adjustment and other components of title I of the Affordable Care Act in States that have not done so.

B. Introduction

Underpinning the goals of high-quality, affordable health insurance coverage is the need to minimize the possible negative effects of adverse selection. Adverse selection occurs when each new health insurance purchaser understands his or her own potential health risk better than health insurance insurers do, and health insurance issuers are therefore less able to accurately price their products.

To avoid adverse selection, issuers may set premiums higher than necessary in order to offset the potential expense of high-cost enrollees. This uncertainty could also result in an issuer being more cautious about offering certain plan designs in the Exchange. This risk will be greatest in the first years of the Exchange, and become less as the new market matures and issuers learn more about new enrollees.

As experience in States has shown, offsetting the adverse selection from insurance reforms may be best accomplished by broadening the risk pool: making coverage affordable through lower premiums and targeted financial assistance and making coverage a responsibility so that people pay premiums in sickness and in health. In addition, to minimize the negative effects of adverse selection and foster a stable marketplace from year one, the Affordable Care Act establishes transitional reinsurance and temporary risk corridor programs, and a permanent risk adjustment program to provide payments to health insurance issuers that cover higher-risk populations and to more evenly spread the financial risk borne by issuers.

The transitional reinsurance program and temporary risk corridor program, which begin in 2014, are designed to provide issuers with greater payment stability as insurance market reforms are implemented. The reinsurance program, which is a State-based program, will reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. This program will attenuate individual market rate increases that might otherwise occur because of the immediate enrollment of individuals with unknown health status, potentially including, at the State's discretion, those currently in State high risk pools. The risk corridor program, which is a Federally-administered program, will protect against uncertainty in setting rates in the Exchange by limiting the extent of issuer losses (and gains). Under the risk corridor program, an issuer of a qualified health plan (QHP) plan whose gains are greater than three percent of the issuer's projections must remit charges to HHS, while HHS must make payments to an issuer of a QHP plan that experiences losses greater than three percent of the issuer's projections. On an ongoing basis, the risk adjustment program is intended to provide adequate payments to health insurance issuers that attract high-risk populations (such as those with chronic conditions). Under this program, generally, funds are transferred from issuers with lower risk enrollees to issuers with higher risk enrollees. Section 1343 indicates that the Secretary may utilize criteria and methods similar to the criteria and methods utilized under part C or D of title XVIII of the Social Security Act. Proposed standards for these critical programs are addressed in this proposed rule. The chart below summarizes theses programs:

Program	Reinsurance	Risk corridors	Risk adjustment
What	Provides funding to plans that enroll highest cost individuals.	Limit issuer loss (and gains)	Transfers funds from lowest risk plans to highest risk plans.
Program Oversight	State or State Option if no State-Run Exchange.	HHS	State Option in a State-Run Exchange.
Who Participates	All issuers and TPAs contribute funding; non-grandfathered individual market plans (inside and outside the Exchange) are eligible for payments.	Qualified Health Plans (QHPs)	Non-grandfathered individual and small group market plans, inside and outside the Exchange.
When	Throughout the year 2014–2016	After reinsurance and risk adjustment 2014–2016.	After end of benefit year 2014 and subsequent years.
Why	Offsets high cost outliers	Protect against inaccurate rate-setting.	Protects against adverse selection.
Time Frame	3 years (2014–2016)	3 years (2014–2016)	Permanent.

On August 3, 2010, HHS published a Request for Comment (RFC) inviting the public to provide input regarding the rules that will govern the Exchanges and related functions such as reinsurance and risk adjustment. In particular, HHS asked States, tribal representatives, consumer advocates, employers, issuers, and other interested stakeholders to comment on the types of standards Exchanges and related functions should be required to meet. The comment period closed on October 4, 2010. In this proposed rule, we do not directly respond to comments from the RFC; however, we generally describe the comments received at the beginning of each subpart and refer to them, where applicable, when discussing specific regulatory proposals. We intend to respond to comments from the RFC, along with comments received on this proposed rule, as part of the final rule. We also plan to disseminate parameters that will rely on factors that may change each year, such as the national reinsurance contribution rate and the Federally-certified risk adjustment model, in an annually updated Federal notice of benefit and payment parameters. In addition to the RFC, we have consulted with stakeholders through weekly meetings with the National Association of Insurance Commissioners, regular contact with States that received Exchange planning grants, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

II. Provisions of the Proposed Regulation

A. Subpart A—General Provisions

1. Basis and Scope (§ 153.10)

Section 153.10(a) of subpart A specifies that the general statutory authority for the standards proposed in part 153 are based on the following sections of title I of the Affordable Care Act: sections 1321 and 1341–1343. Section 153.10(b) specifies that this part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors, and a permanent risk adjustment program.

2. Definitions (§ 153.20)

Under § 153.20, we set forth definitions for terms that are used throughout part 153. Many of the definitions presented in § 153.20 are taken directly from the Affordable Care Act, from existing regulations, or from § 155.20 of the notice of proposed rulemaking entitled ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,'' published in this issue of the **Federal Register**. New definitions were created for the purposes of carrying out regulations proposed in part 153. When a term is defined in part 153 other than in subpart A, the definition of the term is applicable only to the relevant subpart or section. The application of the terms defined in this section is limited to this proposed rule.

Specifically, several terms are defined by the Affordable Care Act, including ''individual market'' (section 1304(a)(2)), ''qualified health plan'' (section 1301(a)(1)), and ''health plan'' (section 1301(b)(1)). The definition for an ''Exchange'' is drawn from the statutory text in section 1311(d)(1) and 1311(d)(2)(A). The term ''State'' is also taken directly from section 1304(d) of the Affordable Care Act to mean the 50 States and the District of Columbia.

Some definitions were taken from other interim final regulations issued pursuant to the Affordable Care Act, including the term ''grandfathered plan'' from § 147.140. The definitions for the terms ''group health plan,'' ''health insurance issuer,'' and ''health insurance coverage'' are cross-referenced to the definitions established in § 144.103. The definitions for the terms ''enrollee,'' ''benefit year,'' and ''small group market'' are cross-referenced to the definitions in the notice of proposed rulemaking entitled ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,'' published in this issue of the **Federal Register**. Other definitions used throughout this proposed rule are established for specific purposes. For example, the terms ''applicable reinsurance entity,'' ''contributing entity,'' and ''reinsurance-eligible plan'' relate to reinsurance programs, while the term ''risk adjustment covered plan'' relates to the risk adjustment program.

B. Subpart B—State Notice of Insurance Benefits and Payment Parameters

In this subpart, we propose a process by which the States that are operating an Exchange or establishing a reinsurance program issue an annual notice to disseminate information to issuers and other stakeholders about specific requirements to support payment-related functions. This notice may also be a mechanism to address updates to other Exchange-related provisions proposed elsewhere that impact payment and benefit design. This provides a practical way to update certain payment and benefit factors that may change annually, such as reinsurance contribution rates that are based on annually changing thresholds.

1. Establishment of State insurance benefits and payment parameters (§ 153.100)

In § 153.100(a), we propose that a State operating an Exchange, as well as a State establishing a reinsurance program, issue an annual notice to describe the specific parameters that the State will employ if that State intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the forthcoming annual Federal notice of benefit and payment parameters. We believe the

information contained in the State notice should be provided one year in advance of the benefit year so that issuers may account for any updates in their design and review of plan benefits and in establishing and reviewing rates. As such, in paragraph (b), we propose specific deadlines for the State notice, if it intends on modifying Federally-proposed parameters, which will be tied to a forthcoming annual Federal notice of benefit and payment parameters, upon which the public will have an opportunity to comment. Below are charts detailing the schedules for the forthcoming annual Federal notice of benefit and payment parameters for 2014 and subsequent years, with the first two dates occurring in the calendar year two years before the effective date.

ANNUAL FEDERAL NOTICE OF BENEFIT AND PAYMENT PARAMETERS

HHS publishes advance notice.	Mid-October.
Comment period ends	Mid-November.
HHS publishes final notice	Mid-January.

We propose that States that plan to modify Federal parameters issue their notice by early March in the calendar year before the effective date. We understand that States may have their own timelines for public notice; this proposed requirement sets an outer bound for the final notice to be issued by a State that intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the forthcoming annual Federal notice of benefit and payment parameters. We seek comment on whether the proposed timing allows issuers sufficient time to reflect these State requirements in setting rates. In particular, we seek comment as to whether the schedule should be adjusted in the initial year to provide issuers additional time for setting rates for 2014.

We also propose in paragraph (c) that if a State operating an Exchange or establishing a reinsurance program does not provide public notice of its intent to have State-specific parameters for any provision within the period specified in paragraph (b) of this section, the parameters set forth in the forthcoming annual Federal notice of benefits and payment parameters will serve as the State parameters.

2. Standards for the State Notice (§ 153.110)

In paragraph (a)(1), we propose that content related to the reinsurance program include the data requirements and data collection frequency for health insurance issuers to receive reinsurance payment. In paragraph (a)(2), we propose that the State specify the attachment point, reinsurance cap, and coinsurance rate if the State plans to use different values than those set forth in the forthcoming annual Federal notice of benefit and payment parameters. In paragraph (a)(3), we propose that if a State plans to use more than one reinsurance entity, the State must include in the notice information related to the geographic boundaries of each applicable reinsurance entity and estimates related to the number of enrollees, payments, and premiums available for contributions in each region. We note that the forthcoming annual Federal notice of benefit and payment parameters will provide States with estimates for these values at the State level.

In paragraph (b), we propose content related to the risk adjustment program if the State intends to modify the risk adjustment parameters set forth in the forthcoming annual Federal notice of benefits and payment parameters, including a detailed description of and rationale for any modification. Specifically, the State description of modifications should include: the methodology for determining average actuarial risk, including the establishment of risk pools and the Federally-certified risk adjustment model; and the risk adjustment data validation methodology.

C. Subpart C—State Standards for the Transitional Reinsurance Program for the Individual Market

Section 1341 of the Affordable Care Act provides that a transitional reinsurance program is established in each State to help stabilize premiums for coverage in the individual market during the years 2014 through 2016. Under this provision, all health insurance issuers, and third-party administrators on behalf of self-insured group health plans, must make contributions to a not-for-profit reinsurance entity to support reinsurance payments to individual market issuers that cover high-cost individuals, except for high-cost individuals in grandfathered individual market health plans. As a basis for reinsurance payments, the law directs the Secretary to develop a list of 50 to 100 medical conditions to identify high-cost individuals or to identify alternative methods for payment in consultation with the American Academy of Actuaries (AAA). In this subpart, we codify section 1341 of the Affordable Care Act as it relates to establishing a reinsurance program. Related standards on health insurance issuers with respect to reinsurance are proposed in subpart E.

We identified three critical policy goals of the transitional reinsurance program. First, the transitional reinsurance program should offer protection to health insurance issuers against medical cost overruns for high-cost enrollees in the individual market, particularly those that are newly insured or those with previously excluded conditions, thereby allowing issuers to set lower premiums.

Second, a transitional reinsurance program should permit early and prompt payment of reinsurance funds during the benefit year to help offset the potential high costs of health insurance issuers early in the benefit year. This objective is particularly important since the two other risk sharing protections against adverse selection—risk adjustment and risk corridors—are likely to be calculated after the end of the benefit year.

Third, the transitional reinsurance program should require minimal administrative burden since it is a temporary program. Given the short-term nature of the program, the costs of setting up and administering this program must be commensurate with its benefits over the three-year window.

We received a number of comments on the transitional reinsurance program in response to the RFC. Multiple respondents emphasized that, although underlying conditions are referenced in the Affordable Care Act with respect to the reinsurance provisions, reinsurance programs typically do not consider the health status of the individual. Health insurance issuers seek traditional reinsurance to protect against unusually high medical cost of enrollees during a coverage year. Generally, reinsurance is not tied to underlying conditions that lead to high enrollee medical costs but to high claims costs beyond a specific dollar threshold within a coverage period, regardless of health condition.

Several commenters asserted that coverage of specific conditions under a reinsurance program could lead to discriminatory practices toward certain individuals, with one commenter noting that identifying medical conditions as a basis for reinsurance payments requires a level of verification beyond that of traditional reinsurance. Another commenter contended that traditional reinsurance that makes payments based solely on incurred costs does not encourage efficient and effective care.

We considered all of these comments in the development of this subpart, along with commenter suggestions on entities that could serve as the

applicable reinsurance entity for a State. As explained more fully below, we believe that States should have discretion to make a number of decisions within the proposed standards, including the appropriateness of any specific entity as an administrator of the reinsurance program.

1. Definitions (§ 153.200)

In § 153.200, we propose several definitions that are critical to the establishment of a properly functioning transitional reinsurance program. We define an ''attachment point'' as the threshold dollar amount of costs incurred by a health insurance issuer for payment of essential health benefits provided for an enrolled individual, after which threshold, the costs for covered essential health benefits are eligible for reinsurance payments. The definition of ''essential health benefits'' will be proposed in future rulemaking. We define ''coinsurance rate'' as the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for costs incurred to cover essential health benefits after the attachment point and before the reinsurance cap. We define the ''reinsurance cap'' as the threshold dollar amount for costs incurred by a health insurance issuer for payment of essential health benefits provided for an enrolled individual, after which threshold, the costs for covered essential health benefits are no longer eligible for reinsurance payments. In order to ensure reinsurance payments are made on a comparable set of benefits, we propose that payments be calculated for costs to cover the essential health benefits package. We solicit comments on alternatives to the use of the essential health benefits package.

We define ''contribution rate'' as the rate, based on a percent of premium, used to determine the dollar amounts each health insurance issuer and third party administrator, on behalf of a self-insured group health plan, must contribute to a State reinsurance program. We define the ''percent of premium'' as the percent of total revenue, based on earned premiums as described in § 158.130(a), in all fully-insured markets (inside and outside of the Exchange) or the percent of total medical expenses in a self-insured market. Part 158 describes standards for health insurance issuers implementing the medical loss ratio requirements under section 2718 of the PHS Act. Finally, we define ''third party administrator'' as the claims processing entity for a self-insured group health plan. As such, if a self-insured group health plan processes its own claims, the self-insured plan will be considered a third-party administrator for the purpose of the reinsurance program.

2. State Establishment of a Reinsurance Program (§ 153.210)

In § 153.210, we describe standards for States regarding the establishment of a reinsurance program. We propose in paragraph (a) that each State that elects to operate an Exchange must also establish a reinsurance program as required by the law. In paragraph (a)(1), we codify section 1341(a) of the Affordable Care Act, which requires that such States must either enter into a contract with an existing applicable reinsurance entity or establish an applicable reinsurance entity to carry out the provisions for the reinsurance program discussed in this subpart. We believe the statute allows State flexibility in selecting an applicable reinsurance entity and do not propose more specific guidelines.

The Affordable Care Act also allows States to set up more than one reinsurance entity, although this option may increase administrative costs. We propose in paragraph (a)(2) that, for any State that chooses to have more than one reinsurance entity, the State must publish in a State notice, described in § 153.110, information regarding the geographic divisions between the applicable entities. We further interpret the statute to imply that the geographic divisions of the applicable reinsurance entities must be distinct and, together, cover the entire individual market in the State and not just certain areas or populations. In paragraph (a)(3), we propose to allow the State to permit a reinsurance entity to subcontract administrative functions, provided that the State reviews and approves these subcontracted arrangements as described in paragraph (a)(4). We interpret the statute to allow flexibility in the performance of administrative functions, with the understanding that the responsible party must be the applicable reinsurance entity.

We propose in paragraph (a)(5) that the establishment of, or contract with, the applicable reinsurance entity must extend for a sufficient period to ensure that the entity can fulfill all reinsurance requirements for all benefit years through 2016 and any activities required to be undertaken in subsequent periods. Any State in which contributions remain to be disbursed for benefit years beyond 2016 must ensure that an applicable reinsurance entity is available for required payment activities for additional benefit years. When establishing or contracting with an applicable reinsurance entity, States must establish sufficient time to pay reinsurance claims after 2016. This time cannot extend past December 31, 2018 as described in section 1341(b)(4) of the Affordable Care Act.

We clarify in paragraph (b) that there may be situations in which an applicable reinsurance entity operates a reinsurance program for more than one State. In other words, several States may contract with one reinsurance entity, but that entity must maintain separate risk pools for each State's reinsurance programs. In such cases, we consider each contract to be an individual reinsurance arrangement between a specific State and the applicable reinsurance entity.

We propose in paragraph (c) to allow a State that does not elect to establish an Exchange to operate its own reinsurance program. Under this circumstance, the State will be required to carry out the provisions of this subpart. In paragraph (d), we propose that, if a State does not elect to establish an Exchange and does not determine to operate its own reinsurance program, HHS will establish the reinsurance program to perform all the reinsurance functions for that State. These functions would include the collection of all contributions described in § 153.220, including funds required to operate and administer the applicable reinsurance functions. In paragraph (e), we propose that each State that establishes an Exchange or operates a reinsurance program must ensure that each applicable reinsurance entity complies with all provisions of this subpart and with subpart E.

3. Collection of Reinsurance Contribution Funds (§ 153.220)

In § 153.220, we describe standards for how States must ensure that the reinsurance entity collects reinsurance contribution funds. Section 1341 provides for the collection of contribution funds to cover all reinsurance payments and also permits the collection of funds to cover administrative costs incurred by the applicable reinsurance entity. These contribution funds must be collected by the reinsurance entity from all health insurance issuers and third party administrators on behalf of self-insured plans. The aggregate contribution funds for purposes of making reinsurance payments are specified as $10 billion in 2014, $6 billion in 2015, and $4 billion in 2016 as described in section 1341(b)(3)(B)(iii). None of these funds can be used for any purpose other than paying reinsurance or administering the reinsurance programs. The aggregate

contribution funds would be returned to those issuers that qualify for the transitional reinsurance program. In paragraph (a)(1), we codify the aggregate contribution amounts.

The statute also requires that the reinsurance entity collect specified additional contribution funds for deposit into the general fund of the U.S. Treasury. The additional contribution funds to the general fund are set at $2 billion in calendar years 2014 and 2015, and $1 billion in 2016 as described in section 1341(b)(3)(B)(iv). The Congressional Budget Office considered the additional contributions to score as an offset for the costs of administering the Early Retiree Reinsurance Program within the 10 year budget window, however, these funds will not be used to directly pay for ERRP costs. In paragraph (a)(2), we codify these additional contribution amounts.

Although the transitional reinsurance program is State-based, section 1341(b)(3) sets contribution levels for the program on a national basis. We considered two approaches by which to collect contribution funds: (1) Use of a national uniform contribution rate, and (2) use of a State-level allocation, both set by HHS to ensure that the sum of all contribution funds equals the national amounts set forth in statute. In paragraph (b) we propose the first approach to collect contribution funds for amounts listed in paragraph (a)(1) and (a)(2). Use of a national contribution rate is a simpler approach. Further, since there is significant uncertainty about Exchange enrollment, the overall health of the enrolled population, and the cost of care for new enrollees, we believe that a national contribution rate would be the less ambiguous approach of the two. All contribution funds collected by a State establishing a reinsurance program, using the national contribution rate, will stay in that State and be used to make reinsurance payments on valid claims submitted by reinsurance-eligible plans in that State. A State-level allocation would be more complex to administer. We solicit comments regarding whether to use a State-level allocation or a national rate.

There are two methods we considered for determining contributions using a national rate: (1) A percent of premium amount applied to all contributing entities, and (2) a flat per capita amount applied to all covered enrollees of contributing entities. In paragraph (b)(1), we propose the percent of premium method as the fairest method by which to collect these contributions, as it allows States that tend to have higher premium and health care costs, and thus reinsurance claims, to collect additional funds towards reinsurance. A flat, per capita amount could represent an excessively high percent of premium for products that are designed and intended to have low premiums targeted toward a population such as young adults and children. HHS will establish the percentage through a forthcoming annual Federal notice of benefit and payment parameters, based on its estimate of total premiums in the fully insured market and medical expenses in the self-insured market. We invite comments regarding the preferred method for calculating health insurance issuer contribution funds using a national rate.

In paragraph (b)(2), we also propose that all contribution funds collected for reinsurance payments must be used for reinsurance, and all contribution funds collected for the U.S. Treasury must be paid to the U.S. Treasury. In paragraph (b)(3)(i), we propose that a State may collect more than its amount collected in the national rate, if the State believes that these amounts are not sufficient to cover the payments it will make under the payment formula. Nothing in the Affordable Care Act precludes a State from supplementing this program. In paragraph (b)(3)(ii), we also propose that a State may collect more than its amount collected at the national rate to cover the administrative costs of the applicable reinsurance entity.

We have also considered the frequency by which applicable reinsurance entities should collect contribution funds from contributing entities. For example, applicable reinsurance entities could collect contribution funds intended for reinsurance payments and payments to the U.S. Treasury on a monthly basis beginning in January 2014 so that reinsurance payments could begin in February 2014. We invite comments on the most appropriate method and frequency to collect reinsurance contribution funds.

4. Calculation of Reinsurance Payments (§ 153.230)

As required, in § 153.230 we set the payment policy for the reinsurance program based upon consultation with the AAA. The reinsurance payment policy addresses two basic issues: (1) How to determine the individuals who are covered by reinsurance, and (2) how to determine appropriate payment amounts. Given the short-term nature of the program, our primary objective is to select an implementation approach that is administratively and operationally simple, but satisfies the goals of the program. Therefore, we would use reliable and readily accessible data sources that would allow health insurance issuers to receive prompt payment. We propose in paragraph (a) of this section that coverage be based on items and services within the essential health benefits for an individual enrollee that exceeds an attachment point. We invite comments regarding this proposed provision or if we should allow reinsurance payment for more generous coverage beyond that provided by essential health benefits.

In paragraph (b), we propose to announce the reinsurance payment formula and State-specific values for the attachment point, reinsurance cap, and coinsurance rate in the forthcoming annual Federal notice of benefits and payment parameters. We believe that publishing this information in a Federal notice is the best approach for announcing the attachment point and reinsurance cap as these values may change in years 2015 and 2016. The Affordable Care Act does not suggest that the three-year reinsurance program should replace commercial reinsurance or internal risk mitigation strategies. There will be a continued need for ongoing commercial reinsurance. Therefore, we propose establishing a reinsurance cap set at the attachment point of traditional reinsurance. We seek comment on this approach.

In paragraph (b)(1), we propose that the reinsurance payment amount be a percentage of those costs above an attachment point and below a reinsurance cap. However, we believe States may have unique situations and recommend allowing a State that runs the reinsurance program to establish its own payment formula by varying the attachment point, coinsurance rate, and reinsurance cap. The reasoning for the policy proposed in paragraph (b)(1) follows below, along with a discussion of some operational issues related to the timing of reinsurance payments.

In our consultation, AAA laid out a number of different ways to implement the reinsurance payment provisions. A letter outlining this issue can be found on their Web site at *https://www.actuary.org/pdf/health/Reinsurance%20Options%209%2022%202010.pdf.* With respect to the determination of who will be covered, AAA identified four possible approaches:

(1) Identification of individuals with specific conditions based on claims data.

(2) Identification of individuals with specific conditions based on survey data.

(3) Identification of high-risk individuals using risk adjustment data

and a condition-based risk adjustment model.

(4) Identification of reinsurance-eligible individuals based on medical cost to the health insurance issuer for covered benefits.

The last option, which we propose to adopt, focuses on all high-cost enrollees without respect to the conditions that caused the increased cost. This approach would be most familiar to health insurance issuers and administratively less burdensome than the first and second options. Data will be immediately available and dependent only on health insurance issuers filing proof of payment for claims. While the third option might mitigate some of the burden and cost concerns, it would not eliminate the timing issues that are critical to effective reinsurance implementation. In 2014, we will be able to collect reliable condition information only for those conditions that are diagnosed during that benefit year. In other words, condition-based reinsurance will not be a predictive model until at least 2015 due to lack of sufficient and timely data. As a result, we found all of the condition-based approaches to eligibility identification to be considerably more burdensome in comparison to the medical cost approach without significant improvement in outcomes from a determination standpoint. We solicit comments for a suitable method for ensuring that issuer costs are appropriate and accurate.

With respect to the decision on how to calculate payments, AAA discussed the following two principal approaches:

(1) Payments for costs incurred above an attachment point.

(2) Fixed payment schedule for specific conditions.

The first option, payment for costs incurred above an attachment point, aligns compensation with cost by reimbursing health insurance issuers that have enrollees in the individual market who actually experience higher health costs. We propose this approach, which represents a more traditional view of reinsurance. It is also consistent with the Early Retiree Reinsurance Program. Health insurance issuers are eligible for reinsurance payments only when costs are in excess of a certain level. The proposed approach is simpler from an operational perspective; the only data required to implement it will be cost and claims data for individuals. This approach also works in tandem with the medical-cost method of determining eligibility.

The fixed payment schedule option, which we are not proposing to adopt, has the effect of paying the same amount for all individuals who present with a specific condition regardless of actual enrollee cost. This method assumes that high-cost individuals incurring highest costs across plans are of equal care mix and does not make distinctions. This method also penalizes issuers that attract more individuals with higher disease burden within disease categories, and thus may be less effective in mitigating the actual financial impact of adverse selection.

In sum, we propose using medical cost experience only to identify eligible enrollees for which health insurance issuers would receive reinsurance. Accordingly, we also propose to use the attachment point approach for determining payment. As described by AAA, an attachment method for calculating reinsurance payments considers costs only for high-risk individuals and may reduce incentives for health insurance issuers to control costs. However, use of a reinsurance cap, as well as the requirement for health insurance issuer coinsurance rate above the attachment point and below the cap, may incentivize health insurance issuers to control costs. We invite comment regarding the best method of determining payments for the reinsurance program, which can relate to either our criteria for selecting eligible enrollees for payment or the method for calculating the payment amounts.

We propose in § 153.230(b)(2) that all payments to the general fund of the U.S. Treasury be made in a manner specified in the forthcoming annual Federal notice of benefits and payment parameters. We have also considered the frequency for which payments should be made to the U.S. Treasury. For example, the applicable reinsurance entities could remit payment on a monthly or quarterly basis commencing February 28, 2014, continuing through January 31, 2017 or until States have remitted the full amount of all payments. We invite comment as to the most appropriate frequency and method for applicable reinsurance entities to remit payment to the U.S. Treasury.

We propose in § 153.230(c) to allow some degree of State variation from the reinsurance parameters proposed by HHS. The Affordable Care Act contemplates the potential of modifications to the payment parameters through a statutory reference to ''model regulation'' as opposed to strict Federal regulation. Therefore, we propose in paragraph (c)(1) that the State may alter the attachment point, reinsurance cap, including elimination of the cap, and coinsurance rate. We propose in paragraph (c)(2) that States must publish any modification to the reinsurance payment formula and parameters in a State notice as described in § 153.110 of this part. We propose in paragraph (c)(3) that the State must ensure that all proposed alterations to the reinsurance formulas proposed by HHS, including payments and contributions, result in the applicable reinsurance entity having sufficient contributions to meet of all of its obligations for payments. Such alterations to reinsurance parameters do not require HHS approval.

We believe that a State may have many reasons to make adjustments to the HHS reinsurance payment formula. First, the State may determine to increase the reinsurance benefit above the level established by HHS. Second, the State may have additional unexpended funds from a prior contribution period and may seek to adjust the reinsurance formulas to disburse the unexpended funds. Third, the State may elect to pay the same amounts recommended by HHS, but may wish to make those payments either earlier or later in the medical cost experience. Finally, the State may decide to vary the annual amounts without varying the total across all three years.

5. Disbursement of Reinsurance Payments (§ 153.240)

In § 153.240, we propose parameters for the timing of reinsurance payments. In paragraph (a) of this section, we propose that States must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection frequency specified by the State in the notice described in § 153.110 or in the forthcoming annual Federal notice of benefit and payment parameters.

Since we are proposing that reinsurance eligibility and payments be based on the health insurance issuer medical costs, we believe that a standard method of collecting the required information should be a reasonable goal and easily achievable. Further, a standard method will enable multi-State health insurance issuers to submit data promptly without causing disruption for any single-State health insurance issuer.

In paragraph (b), we propose that the State must ensure that each applicable reinsurance entity makes payments that do not exceed contributions and makes payments to health insurance issuers of reinsurance-eligible plans according to § 153.230. We also propose in paragraph

(b)(2) to allow States to reduce payments on a pro rata basis to match the amount of contributions received by the State in a given reinsurance year. Any pro rata reductions made by the State must be made in a fair and equitable manner for all health insurance issuers in the individual market.

In paragraph (b)(3), we propose that the State must ensure that an applicable reinsurance entity makes payments as specified in § 153.410(b) to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment. We invite comments as to the most appropriate timeframe that an applicable reinsurance entity should make payments for reinsurance claims submitted, particularly, since reinsurance claims may exceed contributions for a given month, but not total projected contributions for the entire year.

We have also considered deadlines by which a health insurance issuer could submit a claim for a given reinsurance benefit year. For example, Medicare Part D has a requirement for data submission within 6 months after the end of the coverage year, and we believe this is an appropriate standard. We seek comment as to whether the deadline for health insurance issuers for submitting reinsurance claims should be the same or different.

A standard deadline would allow for an orderly completion of the payment processes that depend upon reinsurance, specifically the risk corridors program and the medical loss ratio (MLR) reporting to support the rebate calculations in section 2718 of the PHS Act. Health insurance issuers must know the value of their reinsurance payments and must report that value to HHS under the risk corridor and MLR reporting provisions. Failure to establish a standard deadline could result in excessive delays in the completion of the rebate calculations under section 2718 of the PHS Act. Such delays would in turn delay receipt of rebate payments by the affected enrollees. We invite comment on the use of a standard deadline and the most appropriate deadline considering the interaction of the reinsurance program with risk corridor and the MLR process.

Finally, in paragraph (c), we propose that for each benefit year, the State maintains all records related to the reinsurance program for 10 years, consistent with requirements for record retention under the False Claims Act. We solicit comments on this record retention requirement.

5. Coordination With High-Risk Pools (§ 153.250)

In § 153.250, we codify the requirement under section 1341(d) of the Affordable Care Act that States shall eliminate or modify high risk pools to the extent necessary to carry out the reinsurance program. As stated in the introduction to this subpart, the reinsurance program required under the Affordable Care Act is designed to help mitigate adverse selection risks in the first three years of Exchange operation. In paragraph (a), we codify the above-referenced section. In paragraph (b), we propose to allow a State that continues its high risk pool to coordinate its high risk pool with its reinsurance program to the extent it conforms to the provisions of this subpart. We seek comment regarding whether a high risk pool that continues operation after January 1, 2014 should be considered an individual market plan eligible for reinsurance under this provision.

D. Subpart D—State Standards Related to the Risk Adjustment Program

In subpart D, we propose standards for States with respect to the risk adjustment program required under section 1343 of the Affordable Care Act. Parallel provisions on health plans are proposed in subpart G of this subpart. 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. Under this provision, the Secretary, in consultation with the States, must establish criteria and methods to be used by States in determining the actuarial risk of plans within a State. States electing to operate an Exchange, or HHS on behalf of States not electing to operate an Exchange, will assess charges to plans that experience lower than average actuarial risk and use them to make payments to plans that have higher than average actuarial risk. Thus, the risk adjustment program is intended to reduce or eliminate premium differences between plans based solely on expectations of favorable or unfavorable risk selection or choices by higher risk enrollees in the individual and small group market. The risk adjustment program also serves to level the playing field inside and outside of the Exchange, reducing the potential for excessive premium growth or instability within the Exchange.

We received a variety of comments on the risk adjustment process in response to the RFC. Many commenters expressed strong opinions about the extent of Federal oversight in risk adjustment and the level of flexibility afforded States for developing a risk adjustment model and how much to rely on current prospective models being used, for example, in Medicare Advantage or concurrent risk adjustment models being used.

We also received comments related to data standards and the role of the Federal government. Commenters noted difficulties in obtaining certain types of data accurately and expressed concerns about audit requirements. Commenters discussed upcoding problems, as well as issues of credibility of the underlying systems to support risk adjustment. Commenters also raised issues related to the transition both to the Exchanges and the risk adjustment program, with the primary issue being the timing of claims data availability in the early years of the program. Some States indicated that they are developing ''all payer claims databases,'' although not all of these databases are expected to be complete by 2014. However, even existing ''all payer'' databases will not contain any data from the currently uninsured individuals, who are expected to comprise a segment of new individual market enrollees.

Overall, we believe that States have discretion to make a number of decisions within the standards we propose herein.

1. Definitions (§ 153.300)

We propose several definitions that are specifically applicable to this subpart in § 153.300. First, we distinguish between risk adjustment models and risk adjustment methodologies. We define ''risk adjustment model'' as an actuarial tool used to predict health plan costs based on the relative actuarial risk of enrollees in risk adjustment covered plans, which we had previously defined as non-grandfathered plans in the individual and small group market. We define ''risk adjustment methodology'' as the specific set of procedures used to determine average actuarial risk.

A ''Federally-certified risk adjustment methodology'' is a risk adjustment methodology that has been developed and promulgated by HHS or has been certified by HHS. As explained further in § 153.330, States may use a modified methodology if it has been certified by HHS and deemed a Federally-certified risk adjustment methodology. An ''alternate risk adjustment methodology'' is a risk adjustment methodology proposed by one or more States for use in place of the Federally-certified risk adjustment methodology, not yet certified by HHS. Additionally, we define ''risk pool'' as the population

across which risk is distributed in risk adjustment.

2. Risk Adjustment Administration (§ 153.310)

Section 1343(a) of the Affordable Care Act establishes that States must assess risk adjustment charges and provide risk adjustment payments based on plan actuarial risk as compared to a State average. We interpret this provision to mean that risk pools must be aggregated at the State level, even if a State decides to utilize regional Exchanges. Furthermore, section 1343(c) indicates that risk adjustment applies to individual and small group market health insurance issuers of non-grandfathered plans within a State, both inside and outside of the Exchange. Accordingly, similar to our approach in reinsurance, if multiple States contract with a single entity to administer risk adjustment, risk may not be combined across State lines, but must be pooled at the individual State-level.

In this section, in paragraph (a)(1), we specify that any State electing to establish an Exchange is eligible to establish a risk adjustment program. Pursuant to section 1321(a)(1)(D) of the Affordable Care Act, we propose in paragraph (a)(2) that for States that do not operate an Exchange, HHS will establish a risk adjustment program. We also clarify in (a)(3) that HHS will administer all of the risk adjustment functions for any State that elects to establish an Exchange but does not elect to administer risk adjustment. In paragraph (b), we clarify that the State may elect to have an entity other than the Exchange perform the risk adjustment functions of this subpart provided that the selected entity meets the requirements for eligibility to serve as the Exchange proposed in § 155.110 of the notice of proposed rulemaking entitled, ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans.''

In paragraph (c), we propose timeframes for completion of the risk adjustment process. We propose that all payment calculations must commence with the 2014 benefit year. The Affordable Care Act does not explicitly set forth a timeframe by which risk adjustment programs must start. However, we believe risk adjustment must be coordinated with reinsurance and risk corridors to help stabilize the individual and small group markets and ensure the viability of the Exchanges, which begin in 2014. Timely completion of the risk adjustment process is important because risk adjustments affect calculations of both risk corridors and the rebates specified under section 2718 of the PHS Act. By law, HHS will be performing the risk corridors calculations for all qualified health plans (QHP) in all States. Therefore, we seek comment on the appropriate deadline by which risk adjustment must be completed. For example, HHS may require that States complete risk adjustment activities by June 30 of the year following the benefit year. This timing assumes at least a three-month lag from items and services furnished in a benefit year and the end of the data collection period. This approach is similar to the Medicare Advantage (Part C) risk adjustment data submission, in which the annual deadline for risk adjustment data submission is 2-months after the end of the 12-month benefit period, but may, at CMS's discretion, include a 6-month lag time.

Since risk adjustment is designed as a budget neutral activity, States would likely need to receive remittances from issuers of low actuarial risk plans before making payments to issuers of high actuarial risk plans. We seek comment on an appropriate timeframe for State commencement of payments.

To ensure the each State's risk adjustment program is functioning properly, we believe that States should provide HHS with a summary report of risk adjustment activities for each benefit year in the year following the calendar year covered in the report. The summary report should include the average actuarial risk score for each plan, corresponding charges or payments, and any additional information HHS deems necessary to support risk adjustment methodology determinations. We seek comment on the requirements for such reports, including data elements and timing.

3. Federally-Certified Risk Adjustment Methodology (§ 153.320)

Section 1343(b) of the Affordable Care Act requires HHS to establish criteria and methods for risk adjustment in coordination with the States. We interpret this provision to mean that HHS will establish a baseline methodology to be used by a State, or HHS on behalf of the State, in determining average actuarial risk. To fulfill the terms of that basic requirement, we propose in paragraph (a)(1) a Federally-certified risk adjustment methodology that will be developed and authorized by HHS. Section 1343 indicates that the Secretary may utilize criteria and methods similar to the criteria and methods utilized under part C or D of title XVIII of the Social Security Act. We seek to minimize issuer burden and will leverage existing processes of part C and D wherever appropriate while recognizing the differences in market demographics in determining methodologies.

We considered proposing a requirement that all States utilize a Federally-certified risk adjustment methodology that was developed and promulgated by HHS. However, we recognize that States may have alternative methods that can achieve similar results. We also know that some States have already implemented risk adjustment models for programs such as Medicaid. We believe that the terms ''methods and criteria'' in the Affordable Care Act can be interpreted to allow certain levels of State variation provided that States meet basic Federal standards. Therefore, we propose in paragraph (a)(2) that a State-submitted alternative risk adjustment methodology may become a Federally-certified risk adjustment methodology through HHS certification. States that would like to use other methodologies should view the Federally-certified risk adjustment methodology as a comparative standard for their alternate risk adjustment methodologies. A State's alternate risk adjustment methodology should offer similar or better performance in that State than the Federally-certified risk adjustment methodology as determined based on the criteria set forth in § 153.330(a)(2). After HHS approves a State alternative risk adjustment methodology, that methodology is considered a Federally-certified risk adjustment methodology.

We propose in paragraph (b) of this section that a State that is operating a risk adjustment program must use one of the Federally-certified risk adjustment methodologies that HHS will publish in a forthcoming annual Federal notice of benefit and payment parameters or that has been published by the State in that State's annual notice, as described in § 153.110(b). These notices will include a full description of the risk adjustment model, including but not limited to: demographic factors, diagnostic factors, and utilization factors if any; the qualifying criteria for establishing that an individual is eligible for a specific factor; the weights assigned to each factor; the data required to support the model; and information regarding the deadlines for data submission and the schedule for risk adjustment factor determination. We seek comments on other information that should be included in this notice.

In paragraph (b)(2), we propose that the risk adjustment methodology will also describe any adjustments made to

the risk adjustment model weights when calculating average actuarial risk, including premium rating variation. Under section 2701 of the PHS Act as amended by the Affordable Care Act, issuers may vary rates within defined maximum ranges based on age and tobacco use. Plans may also vary rates by geographic rating area and family size. An approach is needed to account for this allowed variation in rating so that risk adjustment does not adjust for the actuarial risk that issuers have been allowed to incorporate into their premium rates.

We invite comments on possible approaches to achieving the stated policy goals. In particular, we request comments on the implications of approaches for market efficiency, potential incentives created in how issuers set rates, and how approaches address allowed rating variation for age, family size, and tobacco use. We request comments on other approaches to determining average actuarial risk and whether links exist between potential actuarial risk methodology and potential payments and charges methodology as described in § 153.345. We also request comments on the extent of State flexibility that should be allowed in adopting an approach to determine average actuarial risk.

In paragraph (c), we propose that HHS will specify in a forthcoming annual Federal notice of benefit and payment parameters the Federally-certified risk adjustment methodology that will apply when the Federal government operates the risk adjustment program in States that do not elect to operate an Exchange, or that elect to operate an Exchange but not a risk adjustment program.

To assist States in assessing a potential alternate risk adjustment methodology, HHS will publish the basic standards any alternate risk adjustment methodology must meet in the forthcoming annual Federal notice of benefit and payment parameters that contains the details of one or more Federally-certified risk adjustment methodologies. These standards will likely include the minimum number or types of factors that must be included and the statistical metrics the models will be expected to achieve. Prior to that formal publication of standards, and as part of the development of the Federally-certified methodologies and associated standards for alternate risk adjustment methodologies, HHS will consult with States regarding its development and the minimum standards for alternate risk adjustment methodologies. States may use information from the consultation process to either develop their own methodologies or decide to utilize the Federally-certified risk adjustment methodology.

The statute is not specific with respect to the method by which States are expected to determine the precise value of payments and charges. We believe the payments and charges methodology should mitigate the financial impact of adverse selection on risk adjustment covered plans, while limiting overall issuer uncertainty. We have identified two methods that may achieve those goals—multiplying plan average actuarial risk by the State average normalized premiums and multiplying plan average actuarial risk by the specific premiums collected for each plan. To determine the precise value of payments and charges using State average normalized premiums, plan average premiums are first normalized to the actuarial value of their benefits by dividing each plan's premiums by the plan's actuarial value. This step is necessary because plan premiums reflect differences in the benefits and administration, including actuarial value.

Next, States would use these normalized average premiums as the basis for the State normalized average premiums, weighted by enrollee months, for all plans in a specific risk pool. The State normalized average premium represents the premium that will be used in the charges and payments calculation. Next, the amount by which a plan's average actuarial risk deviates from the state average actuarial risk is calculated. This deviation in actuarial risk is multiplied by the State normalized average premium, the plan's enrollee months, and the plan's actuarial value.

The alternative methodology uses plan-specific premiums as the basis for calculating the gross plan charges and gross plan payments, assuming that health plan premiums reflect State average actuarial risk and the expectation that risk adjustment accounts for favorable or adverse selection. Under this methodology, the deviation in actuarial risk is multiplied by the aggregated plan premiums to determine the gross plan charges and total plan payments that should be collected from or disbursed to health plans through risk adjustment. We request comment on the validity of these assumptions, including the two methods described, and any alternative methods that could be used to calculate payments and charges that would reduce uncertainty for plans. Finally, we request comment on any intentional and unintentional consequences from the use of either methodology.

Due to premium variance, we expect inequalities between payments and charges, which could result in aggregate surpluses or deficits if a simple collection of gross plan charges and disbursement of gross plan payments is implemented. We have identified at least three methods for adjusting gross calculations when gross plan payments are greater than gross plan charges: decrease plan payments on a prorated basis to equal plan charges; increase plan charges on a prorated basis to equal plan payments; or split the shortfall between high-risk and low-risk plans and pro-rating in both directions. We also identified two methods for when gross plan charges are greater than the sum of gross plan payments: reducing gross plan charges on a prorated basis such that the net plan charges are sufficient to cover total plan payments; and putting excess plan charges in a reserve account that would provide a margin of error to ensure that all necessary payments can be covered by charges.

We request comment on these methodologies and whether there are alternative methodologies that might be used, including their strengths, limitations, intentional or unintentional consequences and any links that exist between the payments and charges methodology and the actuarial risk methodology.

4. State Alternate Risk Adjustment Methodologies (§ 153.330)

We interpret the statutory provision regarding the Secretary's establishment of criteria and methods for risk adjustment under section 1343(b) to require substantive Federal oversight of the risk adjustment process. Accordingly, while we propose to allow States to utilize alternate risk adjustment methodologies, we also propose in paragraph (a) of § 153.330 that States taking advantage of this flexibility must submit their proposed alternate risk adjustment methodologies for HHS review and certification.

As outlined in paragraph (a)(1), the State request must include certain information about the State's proposed risk adjustment methodology. As noted in paragraph (a)(1)(i), any request must identify the risk pools to which the methodology will apply. Paragraph (a)(1)(ii) also indicates that the proposed risk adjustment methodology must include a full description of the risk adjustment model, consisting of: factors employed in the model; weights associated with each factor; the data collection method; the schedule for data collection and risk adjustment factor calculation; and the calibration

methodology. HHS will also review the relevant statistical performance metrics of the model, such as R-squared or predictive ratios, which indicates the predictive power of the model. If the State wants to use a Federally-certified risk adjustment model but with State-specific weights, retaining all other characteristics of that model, the State would only need to provide the State-specific weights and a description of the calibration methodology, as well as an attestation that all other model attributes will be implemented consistently with the Federally-certified methodology.

As with the Federally-certified risk adjustment methodology, the schedule for collection and submission of data and calculation of factors are critical success elements for any State-proposed alternate risk adjustment methodology. If a State proposes to deviate from the Federally-certified methodology with respect to these elements, HHS expects to evaluate a State proposed alternate risk adjustment methodology to ensure that the proposed approach will meet HHS goals for the risk adjustment program.

We propose in paragraph (a)(1)(iii) that States must describe any adjustments they propose to make to the risk adjustment model weights when determining average actuarial risk. We expect that States will also incorporate a rating factor into the proposed risk adjustment methodology.

In paragraph (a)(2), we propose that all requests be evaluated against criteria that HHS establishes for risk adjustment methodologies. Alternate risk adjustment methodologies should be evaluated based on the extent to which the methodology: accurately explains cost variation within a given population; chooses risk factors that are clinically meaningful to providers; encourages favorable behavior and discourages unfavorable behavior; uses data that is complete, high in quality and available in a timely fashion; provides stable risk scores over time and across plans; and minimizes administrative burden. This criteria is based on the principles that guided the creation of the hierarchical condition categories (HCC) model used in Medicare's risk adjustment program, as well as criteria described by AcademyHealth in its 2004 risk assessment paper (see *http://www.hcfo.org/pdf/riskadjustment.pdf*) and criteria described by the American Academy of Actuaries in its 2010 risk adjustment paper (see *http://www.actuary.org/pdf/health/Risk_Adjustment_Issue_Brief_Final_5-26-10.pdf).*

To ensure the stability and predictability of payments, we contemplated proposing that requests must be submitted to HHS no later than early November in the calendar year two years before the effective date. HHS recognizes that health insurance issuers must have detailed information about risk adjustment prior to setting rates for any benefit year because the risk adjustment methodology will affect both the total value of premiums received after accounting for payments and charges, as well as health plan administrative costs. Therefore, under this scenario, HHS would evaluate the proposed alternate risk adjustment methodologies submitted within the required timeframes and notify States within 60 days, at the time of the publication of the forthcoming annual Federal notice of benefits and payment parameters whether such methodologies have been certified. In this scenario, if HHS approves an alternate risk adjustment methodology, such a methodology would be considered a Federally-certified risk adjustment methodology and could be implemented in the State that proposed the methodology as well as any other State that elects to implement an Exchange.

We recognize that the above contemplated timeframe requires States to submit requests for alternate methodology certification only 30 days after the advance annual Federal notice of benefit and payment parameters and prior to publication of the final annual Federal notice of benefit and payment parameters. However, we believe any advantage in allowing States additional time would be offset by a lesser ability to leverage State alternative models and inadequate time for issuers to reflect methodology decisions in setting rates. We seek comments regarding our contemplated timeline and potential alternatives for States to request submissions for alternate risk adjustment methodology.

In paragraph (b), we propose that States that operate a risk adjustment program must renew HHS certification of alternate risk adjustment methodologies whenever changes occur, including at the time of recalibration, which the State must identify when initially requesting certification for the alternate risk adjustment model. The proposed requirements for describing an update to a certified risk adjustment model are the same as those for the initial model. The State must describe any change to the model between the last certified version and the recalibrated version. For example, if the only change was to the schedule for data submission, then the State would need to provide that update when seeking certification. Additionally, we propose that States send a notification if they intend to use the certified alternate risk adjustment model with no changes to any of the basic parameters. We expect to use this certification process to ensure that States make updates to their alternate risk adjustment methodologies at reasonable intervals.

5. Data Collection Under Risk Adjustment (§ 153.340)

As described above, a robust risk adjustment process requires data to support the determination of an individual's risk score and the corresponding plan and State averages. In paragraph (a) we propose that a State, or HHS on behalf of the State, is responsible for collecting the data for use in determining individual risk scores.

HHS considered three possibilities for data collection: (1) A centralized approach in which issuers submit raw claims data sets to HHS; (2) an intermediate State-level approach in which issuers submit raw claims data sets to the State government, or the entity responsible for administering the risk adjustment process at the State level; and (3) a distributed approach in which each issuer must reformat its own data to map correctly to the risk assessment database and then pass on self-determined individual risk scores and plan averages to the entity responsible for assessing risk adjustment charges and payments.

A fully distributed approach would leverage existing infrastructures established to support Exchanges. A distributed approach also keeps individual-level data with the issuers, eliminating privacy risks related to transmission. However, there is reason to be concerned that some issuers would make errors in calculating individual risk scores and plan averages. Furthermore, we believe that the complicated nature of a distributed risk adjustment model may prove challenging for some issuers, especially smaller issuers and would thus require significant involvement by the State, or HHS on behalf of the State. In addition, this approach would require issuers to be able to respond to multiple queries to support other functions, such as data to recalibrate the Federally-certified risk adjustment model, reconciling cost-sharing reductions payments, verifying risk corridor submissions, or auditing cost-sharing reductions or reinsurance payments. We seek comment on use of this data for auditing purposes. We believe the proposed intermediate approach would result in the most

complete, actuarially sound risk adjustment methodology and provides support for other functions that also require encounter level data, while maintaining State flexibility. We recognize this approach may raise concerns related to consumer privacy and standard submission formats. Accordingly, we propose national standards to address each of these issues. We seek comment on the proposed approach, as well as comments on the potential advantages and disadvantages of the alternative approaches.

We propose in paragraph (b) that States, or HHS on behalf of the State, use standard HIPAA transaction standards for data collection. We note that HIPAA provides measures to achieve cost savings through administrative simplification. As described in Health Insurance Reform: Standards for Electronic Transactions, ''The purpose of this part is to improve the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information.'' (65 FR 50312) ''We estimated that the impact of the proposed rules would result in net savings to health plans and health care providers of $1.5 billion during the first 5 years; use of the standards would continue to save the industry money.'' (65 FR 50345)

Although the transaction standards promulgated under the HIPAA administrative simplification provisions do not specifically apply to data collections under section 1343 of the Affordable Care Act, we propose in paragraph (b)(1) and (b)(2) to require States to utilize two specific HIPAA transaction standards for risk adjustment data collection: the ASC X12N 837 Health Care Claim transaction standard for any claims-related data including encounters; and the ASC X12N 834 Enrollment and Maintenance transaction standard for any enrollment or demographic data. In this paragraph, we also allow the use of the NCPDP claims transaction standard for prescription drug, claims and encounter data. We solicit comment on whether we should rely on the existing HIPAA and NCPDP standards or engage stakeholders to develop a new set of national standards for use in risk adjustment, for example, leveraging the claims standards developed with stakeholder input by the Agency for Healthcare Research and Quality. In paragraph (b)(3), to address consumer privacy concerns, we propose that States must utilize specific privacy standards in its data collection risk adjustment procedures. We solicit comments on whether submission of issuers' rate setting rules should be required.

We believe that standardizing data collection will allow State flexibility in modeling while not unreasonably increasing issuer burden for multi-State issuers. Under the proposed approach, States may limit the minimum information required to specific data elements, provided that the information submitted represents standard code sets and values on the HIPAA transactions. We also propose that States must accept any valid transaction submitted by an issuer provided that the transaction contains the minimum data required by the State. In other words, the State may not reject a HIPAA compliant transaction strictly on the basis that it contains more data than the State requires.

In paragraph (c), we propose that States with existing all payer claims databases may request an exception from the minimum standards for data collection. We are contemplating syncing the timing of the request submission with requirements for alternate risk adjustment models. Similarly, we are contemplating that HHS will notify States as to exception status concurrently with the publication of the forthcoming annual Federal notice of benefit and payment parameters. We seek comment on these contemplated timelines. We propose that requests for exception from minimum data collection standards must include technical specifications, as well as proposed modifications to support risk adjustment and other claims-related activities.

Seeking data submission efficiencies, in paragraph (d), we propose that the State must make certain claims and encounter data collected under risk adjustment available to support other activities including: recalibrating Federally-certified risk adjustment models; verifying of risk corridor submissions; and verifying and auditing reinsurance claims. We also anticipate encounter and claims data collected for risk adjustment may be required to support other Exchange-related functions such as cost-sharing requirements and quality reporting. We solicit comment on these alternative uses of risk adjustment data.

6. Risk Adjustment Data Validation Standards (§ 153.350)

In § 153.350, we propose that States have a reliable data validation process, which is essential to the establishment of a credible risk adjustment program. The credibility of risk adjustment is important to establishing the issuer confidence required for risk adjustment to have a positive impact on premium reduction. We propose that States, and HHS, when HHS performs the risk adjustment function on behalf of States, will perform some form of validation regarding the data submitted. We also believe that issuers will want such data validations to be performed since the effect of risk adjustment will be a transfer of premiums between issuers. One of the critical aspects of risk adjustment under the Affordable Care Act is that it represents a relative actuarial risk calculation. Therefore, for any data validation to have the capacity to extrapolate to adjust specific charges and payments, the validation must cover a sufficient number of plans to allow an equitable adjustment to all health plan risk adjustment factors.

In paragraph (a) of § 153.350, we propose that the State, or HHS on behalf of the State, validate a statistically valid sample of all issuers that submit data for risk adjustment every year. We also propose an appropriate use of the information derived from the data validation. For a validation to work under this form of risk adjustment, States must be able to adjust the average actuarial risk of each plan to account for the inaccuracies noted during the data validation process. As such, we propose in paragraph (b) that the State, or HHS on behalf of the State, may adjust the average actuarial risk for each plan based on the error rate found in the validation. In paragraph (c), we further propose that the State, or HHS on behalf of the State, adjust payments and charges based on the changes to average actuarial risk. We seek comment on appropriate timeframes for completion of the data validation process. For example, we may propose a three-year deadline for completing data validation, so as to ensure some finality in the risk adjustment process. Finally, in paragraph (d), we propose that States, or HHS on behalf of the State, must provide an appeals process for issuers. We believe that there may be alternative methods that allow sufficient coverage to estimate the validation impact on all plans. We solicit comments on this data validation provision and any alternatives that may be able to satisfy the need to provide assurance that the charges and payments truly represent relative plan risk.

E. Subpart E—Health Insurance Issuer Standards Related to the Transitional Reinsurance Program

In this subpart, we propose requirements for health insurance issuers that complement the requirements for the transitional reinsurance program fully described in the preamble for subpart C. Since the reinsurance program is operated at the State level, many elements related to the purpose, methods, and operation of this program will vary across States and are discussed in greater detail in the preamble for subpart C. In this subpart, we discuss the elements of the program that relate specifically to the requirements for health insurance issuers and third party administrators on behalf of self-insured group health plans.

1. Reinsurance Contribution Funds (§ 153.400)

In § 153.400, we codify section 1341 of the Affordable Care Act, which requires that the reinsurance program be funded by contribution funds from contributing entities. In paragraph (a), we propose that all contributing entities make contributions, in a frequency and manner to be determined by the State or HHS, to the applicable reinsurance entity in the State. For example, contributing entities may be required to submit contributions on a monthly or quarterly basis starting in January 2014. We invite comments on the appropriate frequency and manner in which payments should be made by contributing entities.

In paragraph (b), we propose that if any State establishes multiple applicable reinsurance entities, the contributing entities must contribute an appropriate payment to each applicable reinsurance entity according to the formula established by the State. We propose in paragraph (c) that contributing entities will be required to provide the data necessary for the applicable reinsurance entity to calculate the amounts due from each contributing entity. The type of data required will depend on the contributing entity. For contributing entities in the individual and fully insured market, we propose that data on enrollment and premiums be required. For contributing entities in the self-insured market, data on covered lives and total medical expenses would be required. This data, for example, could be collected on a monthly or quarterly basis beginning January 2014. We invite comments on the appropriate timing to collect data submissions from contributing entities. We also seek comment on whether there are existing sources of this data that can be drawn upon.

2. Requests for Reinsurance Payment (§ 153.410)

The reinsurance program as proposed in subpart C will make payments to reinsurance-eligible plan issuers. In paragraph (a), we propose that reinsurance-eligible plan issuers must submit a request for reinsurance payment to the applicable reinsurance entity. We propose in paragraph (b) that this request is made according to the method that will be specified in the forthcoming annual Federal notice of benefit and payment parameters. We invite comments regarding methods for requesting payments, and the frequency and deadline for such requests. We also invite comments on how to manage late claims from reinsurance eligible plan issuers.

F. Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program

In this subpart, we propose requirements on health insurance issuers related to the temporary risk corridor program. Section 1342 of the Affordable Care Act establishes a program of risk corridors for the first three years of Exchange operation. In addition to risk adjustment and reinsurance, the risk corridor program limits adverse selection and stabilizes markets as changes are implemented starting in 2014. Risk corridors create a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. QHP issuers of QHPs with costs that are less than 97 percent of the QHP's costs projections will remit charges for a percentage of those savings to HHS, while QHP issuers of QHP's with costs greater than 103 percent of cost projections will receive payments from HHS to offset a percentage of those losses. The Affordable Care Act directs HHS to administer the risk corridors program.

1. Definitions (§ 153.500)

In § 153.500, we propose a number of definitions for the purpose of administering risk corridors. First, we define ''allowable costs'' as an amount equal to the total medical costs, which include clinical costs, excluding allowable administrative costs, paid by the QHP issuer in providing benefits covered by the QHP. We define ''allowable administrative costs'' as total non-medical costs defined in § 158.160(b), including costs for the administration and operation of the health insurance issuer. We invite comment on whether we should consider costs for activities that improve health care quality as described in § 158.150 and § 158.151 for allowable costs to be consistent with the medical loss ratio (MLR) policy in the Affordable Care Act. We also invite comment on whether we should limit administrative costs to 20 percent consistent with MLR. If the allowable administrative costs differ from calculations for the MLR rebate, issuers may be incentivized to use risk corridors payments to pay for their MLR rebates.

We define ''charge'' as the flow of funds from QHP issuers to HHS. We define ''direct and indirect remuneration'' in the same way it was defined in the risk corridor provision implemented as a result of Medicare Prescription Drug, Improvement, and Modernization Act of 2003. It means prescription drug price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by a QHP issuer or an intermediary contracting organization with which a QHP issuer has contracted. Such concessions include but are not limited to: discounts, charge backs, rebates, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, and grants. We further specify that the term applies regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the QHP issuer and regardless of the terms of the contract between the issuer and the intermediary contracting organization.

We define ''payment'' as the flow of funds from HHS to QHP issuers. We define ''qualified health plan'' consistent with the term proposed in the general definitions section of the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, published in this issue of the **Federal Register**. We define ''risk corridor'' as any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount. Finally, we define ''target amount'' to be the amount equal to the total premiums incurred by the QHP, including any premium tax credits or financial assistance from any governmental program, reduced by the allowable administrative costs of the health insurance issuer.

2. Risk Corridor Establishment and Payment Methodology (§ 153.510)

The risk corridor provision in 1342 of the Affordable Care Act directs HHS to

establish and administer a program of risk corridors. In § 153.510, HHS proposes to establish risk corridors by specifying risk percentages above and below the target amount. In paragraph (a), we propose to require a QHP issuer to adhere to the requirements set by HHS for the establishment and administration of a risk corridor program for calendar years 2014 through 2016. We will issue guidance in the forthcoming annual Federal notice of benefits and payment parameters for QHPs regarding reporting and the administration of payments and charges similar to part 158. Risk corridors guidance will be plan specific and not issuer specific as indicated in part 158. We interpret the risk corridor provision to apply to all QHPs offered in the Exchange.

In § 153.510, we also establish the payment methodology for the risk corridor program, using the thresholds and risks-sharing levels specified in statute. The risk corridor thresholds are applied when a QHP's allowable costs reach plus or minus three percent of the target amount. Accordingly, HHS will pay a QHP issuer whose QHP incurred allowable costs for a benefit year that are greater than 103 percent of its target amount. Conversely, a QHP issuer must pay HHS if its QHP's allowable costs for a benefit year are less than 97 percent of its target amount. A QHP issuer whose QHP's allowable costs for a benefit year are greater than 97 percent but less than 103 percent of the target amount will neither make nor receive payments for risk corridors. For example, a QHP issuer with a QHP that has a target amount of $10 million will not receive or pay a risk corridor payment if its allowable charges range between $9.7 million and $10.3 million.

Paragraph (b) of this section describes the method for determining payment amounts to QHP issuers as well as the timing of those payments. For a QHP with allowable costs in excess of 103 percent but not more than 108 percent of the target amount, HHS will pay the QHP issuer 50 percent of the amount in excess of 103 percent of the target amount. For example, a QHP has a target amount of $10 million, and the QHP has allowable costs of $10.5 million, or 105 percent of the target amount. Since 103 percent of the target amount would equal $10.3 million, the amount of allowable costs that exceed 103 percent of the target amount is $200,000. Therefore, HHS would pay 50 percent of that amount, or $100,000 to the QHP issuer.

For QHPs that have allowable costs that exceed 108 percent of the target amount, the Affordable Care Act directs HHS to pay the QHP issuer an amount equal to 2.5 percent of the target amount plus 80 percent of the amount in excess of 108 percent of the target amount. For example, a QHP has a target amount of $10 million. The QHP has allowable costs of $11.5 million, or 115 percent of the target amount. Since 108 percent of the target amount would be $10.8 million, the amount of allowable costs that exceed 108 percent of the target amount is $700,000. Therefore, HHS pays 2.5 percent of the target amount, or $250,000, plus 80 percent of $700,000, or $560,000, for a total of $810,000.

Paragraph (c) describes the circumstances under which QHP issuers will remit charges to HHS, as well as the means by which HHS will determine those charge amounts. We propose that QHP issuers will begin to remit charges to HHS for the first dollar of allowable charges less than 97 percent of the target amount. For a QHP that has allowable costs that are less than 97 percent of the target amount but greater than 92 percent of the target amount, HHS will charge the QHP issuer an amount equal to 50 percent of the difference between 97 percent of the target amount and the actual value of allowable costs. For example, a QHP has a target amount of $10 million. The amount of allowable costs for this QHP is $9.3 million, or 93 percent of the target amount. The difference between 97 percent of the target amount, or $9.7 million, and the actual allowable charges is $400,000. The QHP issuer must pay HHS 50 percent of that amount, or $200,000.

For QHPs with allowable costs below 92 percent of the target amount, the QHP issuer will remit charges to HHS an amount equal to 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the actual value of allowable costs. For that same QHP with a $10 million target amount, assume the allowable charges are now $8.8 million, or 88 percent of the target amount. Ninety-two percent of the target amount would be $9.2 million, and the difference between 92 percent of the target amount and the actual value of allowed costs is $400,000. The QHP issuer will remit charges to HHS an amount equal to 2.5 percent of the target amount, or $250,000, plus 80 percent of $400,000, or $320,000, for a total of $570,000.

While we are not proposing deadlines at this time, HHS has considered timeframes for QHP issuers to remit charges to HHS. For example, a QHP issuer required to make a risk corridor payment may be required to remit charges within 30 days of receiving notice from HHS. Similarly, HHS would make payments to QHP issuers that are owed risk corridor amounts from HHS within a 30-day period after HHS determines that a payment should be made to the QHP issuer. We believe that QHP issuers who are owed these amounts will want prompt payment, and also believe that the payment deadlines should be the same for HHS and QHP issuers. We invite comments as to the appropriate frequency QHP issuers should remit charges to HHS.

3. Risk Corridor Standards for QHP Issuers (§ 153.520)

To support the risk corridor program calculations, we propose in § 153.520 that all QHP issuers submit data needed to determine actual performance relative to their target amounts. The data would be collected in standard formats specified by HHS. We propose in paragraph § 153.520(a) that QHP issuers must submit data related to actual premium amounts collected by QHP issuers, including premium amounts paid by parties other than the enrollee in a QHP and specifically advance premium tax credits paid by the government. We also regard risk adjustment and reinsurance as an after-the-fact adjustment to premiums for purposes of determining risk corridor amounts. Medicare Advantage, Medicare Prescription Drug Benefit Program and Medicaid managed care risk adjustment programs similarly result in adjustments to total payments to plans. However, in these programs, the adjustment occurs concurrently with payments because they are made by the government (excluding monthly premium payments made by beneficiaries). For reinsurance, we anticipate health insurance issuers will reduce their premiums by an amount that would approximate the average reinsurance that they expect to receive, filling in the gap between the premium charged and the health insurance issuer's revenue needs.

Therefore, in paragraph (a)(1), we propose that the reported premium amounts must be increased by the amounts paid to the QHP issuer for risk adjustment and reinsurance. Similarly, we propose in paragraph (a)(2) that the reported premium amounts be reduced for any risk adjustment charges the QHP issuer pays on behalf of the plan, reinsurance contributions that the QHP issuer makes on behalf of the plan, and Exchange user fees that the QHP issuer pays on behalf of the plan. We invite comment on the treatment of reinsurance and risk adjustment as after-the-fact adjustments to premium for purposes of determining risk corridor amounts.

In paragraph (a)(3), we propose rules for accounting for reinsurance claims submitted on a date to be determined by HHS for a given reinsurance benefit year. Specifically, we propose that QHP issuers attribute reinsurance payments to risk corridors based on the date on which the valid reinsurance claim was submitted. For example, if the QHP issuer submits a claim on or before the deadline for a benefit year, that QHP issuer would attribute the claim payment to risk corridor calculation for the benefit year in which the costs were accrued. Conversely, if the QHP issuer submits a claim after the deadline for a benefit year, that health QHP would attribute the claim payment to risk corridor calculation for the following benefit year. We invite comments on how the risk corridor calculations would interact with the MLR process.

We propose in paragraph (b) that QHP issuers must submit allowable cost data to calculate the risk corridors in a format specified by HHS. We propose that allowable costs must be reduced for any direct or indirect remuneration received in paragraph (b)(1). In paragraph (b)(2), we also propose that the allowable costs must be reduced by the amount of any cost-sharing reductions received from HHS. We invite comment on an appropriate deadline for QHP issuers to complete submission of all risk corridor data especially since this would interact with the MLR process. We also invite comment as to how HHS could determine allowable costs for QHP issuers in calculating risk corridors, if a QHP issuer fails to comply with the reporting provisions in paragraph (b).

HHS seeks to limit the reporting requirements on issuers in submitting this information and would like to prevent duplicative data collection requirements on issuers for the temporary risk corridors program. As such, we seek comment on how we can utilize data from 2718 to meet the data submission requirements for risk corridors.

G. Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

Section 1343 of the Affordable Care Act 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. We noted in the introduction to subpart D of this part that the risk adjustment program described in section 1343 employs a model to determine comparative actuarial risk of plans within a State. That overview can serve as a reference for this subpart as well. We note that subpart D of this part describes some of the comments to the RFC related to risk adjustment and our approach to the process, methodology, and model for implementing the risk adjustment program under section 1343 of the Affordable Care Act. This subpart proposes the health issuer standards that are necessary to carry out risk adjustment as described in subpart D.

1. Definitions (§ 153.600)

In § 153.600, we define ''risk adjustment data'' to mean any data that is used in a risk adjustment model.

2. Risk Adjustment Issuer Requirements (§ 153.610)

We propose in paragraph (a) of § 153.610 that all issuers of risk adjustment covered plans submit risk adjustment data according to the timetable and format prescribed by the State, or HHS on behalf of the State. Since there will be some variety in approaches to risk adjustment, both across States as well as over time, we expect that these data will include demographic data; encounter data for items and services provided in conjunction with a risk adjustment covered plan; and prescription drug utilization data. We seek comment on whether other categories of data such as methods for setting rates should be required in support of risk adjustment.

We considered proposing the following timelines for risk adjustment data submission: claims and encounter data must be submitted every 30 days and no later than the end of 180 days following the date of service; enrollment and demographic information must be submitted by the end of the month following enrollment; issuer rate-setting rules must be submitted by the end of the month in which they become effective; prescription drug utilization data must be submitted every 30 days, and no later than the end of 90 days following date of service. We recognize that these timeframes may limit the ability of States to collect a full calendar year of data on risk adjustment. However, given the traditional lag of claims submissions, we did not think a shortened timeframe was feasible. Additionally, monthly data submission would address anticipated issuer difficulty in transmitting large volumes of data at the end of the data collection period. We solicit comments on these and alternative data submission timeframes.

We interpret the Affordable Care Act to require participation in the risk adjustment program for all risk adjustment covered plans. We believe that any voluntary participation provisions would result in non-participation by the lowest actuarial risk plans, which in turn would defeat the purpose of the provision. Additionally, in paragraph (b), we propose to permit contractual arrangements between issuers and providers, suppliers, physicians, and other practitioners to ensure that issuers receive the necessary risk adjustment data.

We discuss the calculation of payments and charges extensively describing the methods by which we propose States could perform that function. After the State, or HHS on behalf of the State, has calculated all payments and charges for all risk adjustment covered plans, the State, or HHS on behalf of the State, will determine a net value of payments and charges for each risk adjustment covered plan issuer. In paragraph (c), we propose that risk adjustment covered plan issuers who owe a net balance of risk adjustment charges will be assessed those net charges upon completion of the risk adjustment process. We interpret the Affordable Care Act to mean that the payment of charges is mandatory for issuers who have a net charges payable balance based on the difference between the charges calculated for their low actuarial risk plans and the payments calculated for their high actuarial risk plans. Additionally, we considered proposing that issuers be given a 30 day timeframe in which to pay all these net charges to the State that assessed those charges, or to HHS on behalf of the State. We solicit comment on this and alternative timelines. Since risk adjustment pools individual and small group market risk on a State level, payments and charges will be netted out at the State level, and issuers in multiple States must settle with each State individually.

3. Compliance With Risk Adjustment Standards (§ 153.620)

The credibility of risk adjustment is important to making health insurance premiums in Exchanges stable. Issuers should have confidence that, if they experience adverse selection, their actuarial risk as calculated under this risk adjustment program will reflect the degree to which they have experienced adverse selection and that, if competing plans have low actuarial risk, that those plans cannot inflate their risk score. Therefore, a data validation program is necessary. Consistent with proposed § 153.350, we propose in § 153.620 that risk adjustment covered plan issuers provide the required documentation in response to any HHS or State validation to substantiate the risk adjustment data that they have submitted. We believe

that all risk adjustment covered plans should support such an audit to ensure the integrity of charges they may be required to pay, as well as to ensure that any payments they receive are sufficient to cover additional medical costs incurred due to adverse selection. In paragraph (b), we propose that risk adjustment covered plan issuers must retain the required documentation to substantiate the risk adjustment data that they have submitted for a period of ten years.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Below is a summary of the proposed information collection requirements outlined in this regulation. Throughout this section we employ assumptions regarding the frequency of data collection as this level of detail is not proposed in regulation text, but is discussed in preamble. 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. For purposes of presenting an estimate of paperwork burden for States, we reflect full participation of all States and the District of Columbia in operating an Exchange and assume all States operate the reinsurance and risk adjustment programs. However, we recognize that not all States will elect to operate their own Exchanges, so these estimates should be considered an upper bound of burden estimates. These estimates may be adjusted proportionally in the final rule based upon additional information as States progress in their Exchange development processes.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding the State Notice of Insurance Benefits and Payment Parameters (§ 153.100)

As discussed in § 153.100, States would issue an annual notice of benefits and payment parameters specific to that State. We estimate a minimum burden for the development of the State notice as States have the option to adopt the parameters in the forthcoming annual Federal notice of benefits and payments parameters, and would only have to indicate their intention of using these parameters in their annual notice.

We assume that all 50 States and the District of Columbia would be subject to these reporting requirements. Again, this estimate should be considered an upper bound, and we may revise these estimates in the final rule based upon additional information as States progress in their Exchange development processes. We estimate that it will take each State approximately 160 hours to meet the requirements of this subpart with a total estimated burden of 8,160 hours. We estimate that it will take a financial analyst 120 hours (at an average wage rate of $62 an hour) and a senior manager 40 hours (at $77 an hour) to meet these requirements. The cost estimate for each State is $10,520 for a total estimated cost burden of $536,520.

B. ICRs Regarding State Standards for the Transitional Reinsurance Program in the Individual Market (§ 153.240)

Within Part 153, subpart C we describe reporting requirements and maintenance of records for States for reinsurance. States would ensure that the applicable reinsurance entity collects the data required from issuers to make reinsurance payments. The type of data required is currently not described in this proposed rule to allow for State flexibility in determining the data type and collection method. However, the type of data that might be used to make reinsurance payments may include claims data or encounter data. We estimate that it will take about 12 hours on an annual basis for the applicable reinsurance entity to collect this information in an electronic format from issuers on an annual basis. This estimate is similar to estimates provided in Medicare Part D rule for data submission. For example, Medicare Part D estimated that it would take plan sponsors approximately 10 hours annually for plan sponsors to submit data on aggregated negotiated drug pricing from pharmaceutical companies described in § 423.104. We provide a slightly higher estimate for the collection of data from issuers for reinsurance payments due to the complexity of the program.

States that operate an Exchange would also maintain any records associated with the reinsurance program. For this requirement, we estimate that it will take approximately 52 hours annually for States to maintain records. This is a broad estimate that includes not only the maintenance of data for the reinsurance program, but all books, records, documents, and other evidence of accounting procedures and practices related to the reinsurance program. This estimate is similar to Medicare Part D, where is was estimated that it will take 52 hours on an annual basis for plan sponsors to maintain books, records, and documents on accounting procedures and practices as described in § 423.505.

We assume that 50 States and the District of Columbia will be subject to the reporting requirements in this subpart. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take each State approximately 64 hours to meet the provisions of this subpart for a total burden estimate of 3,264 hours. We presume that it will take a financial analyst 54 hours (at $55 an hour) and a senior manager 10 hours (at $77 an hour) to meet the reporting requirements. The burden cost estimate for each State is $3,740 for a total burden cost estimate of $190,740.

C. ICRs Regarding State Standards for the Risk Adjustment Program (§ 153.310–§ 153.340)

Part 153, subpart D describes reporting requirements for States related to the risk adjustment program. We provide minimum burden estimates in this section for the collection and submission of risk-related data, particularly encounter data, as States would be required to collect this information for Medicaid beginning in 2012.

States would be required to implement privacy standards for all data

to be collected for the risk adjustment program. We estimate it will take States approximately 40 hours to create and implement privacy standards for this data collection. This estimate presumes it will take a policy analyst 10 hours (at $55 per hour), an operations analyst 25 hours (at $55 per hour) and a senior manager 5 hours (at $77 per hour). We expect it will cost each state $2,310 to create and implement privacy standards. The total burden of this requirement is $117,810.

States may file for an exception from minimum data collection standards, as described in § 153.430(c). We estimate that filing for an exception would take 17 hours and that 5 states will elect to file for exception. This includes 15 hours for an operations analyst (at $55 per hour) and 2 hours for a senior manager (at $77 per hour). The total burden of a minimum data reporting exception is $979 and a total of $4,895.

States would also collect risk-related data from health insurance issuers. This risk-related data includes claims, encounter, demographic, and enrollment data as described in § 153.340. While we do not specify the data collection timeframe for risk adjustment data, we provide an assumption on the timing of submission of this data. We estimate that it will take an issuer approximately 12 hours to collect this data electronically on an annual basis. We estimate that it will take an operations analyst 12 hours (at $55 per hour) to collect this data annually.

States would submit to HHS de-identified claims and encounter data for use in recalibrating Federally-certified risk adjustment models. We estimate that it will take 3 hours for States to submit this information to HHS. This estimate is slightly lower that Medicare Part D estimates for data submission as discussed previously and is a minimum burden estimate for this requirement since States will have already collected this data in the format requested for the risk adjustment program. States would submit summarized claims cost for use in verifying risk corridor submissions. Again we provide a minimum burden estimate of 2 hours since States would have already collected this information for risk adjustment.

States would submit summarized and individual-level claims and encounter data from reinsurance-eligible plans for audit purposes. We estimate a minimum burden of 2 hours for States to submit this information to HHS. Finally, States would also provide claims and encounter data for Exchange-related activities such as cost-sharing requirements and quality reporting. We estimate a minimum burden of 3 hours for States to submit this information for this purpose.

We assume that all 50 States and the District of Columbia will be subject to these reporting requirements. This estimate is an upper bound of burden as a result of the reporting requirements in this subpart; we will revise these estimates in the final rule as States progress in their Exchange development. We estimate that it will take each State approximately 30 hours to meet these requirements with a total estimated burden of 1,530 hours. We presume that it will take an operations analyst 22 hours (at $55 an hour) and a senior manager 8 hours (at $77 an hour) to meet these requirements for a cost estimate of $1,826. The total estimated cost burden is $93,126.

As discussed in § 153.330, States must submit a request to HHS for review and approval of an alternate risk adjustment methodology. We estimate that 5 States will request an approval for an alternate risk adjustment methodology. We presume all states requesting approval of an alternative risk adjustment methodology will update their methodology once. We presume that it will take an operations analyst 22 hours (at $55 an hour) and a senior manager 6 hours (at $77 an hour). Updating the methodology is expected to take an operations analyst 8 hours and a senior manager 2 hours. In total, we estimate that it will take approximately 38 hours for a State electing to establish an alternate risk adjustment methodology to meet the reporting requirements with a total estimated burden of 190 hours. We expect it will cost each state $2,266 to meet these requirements. The total estimated cost burden for five States is $11,330.

States choosing to run a risk adjustment program must validate their risk adjustment data annually. We estimate data collection and validation will take an operations analyst 25 hours (at $55 per hour) and a senior manager 5 hours (at $77 per hour). The cost estimate for validating the risk adjustment data annually is $1,760 per state and a total burden of $89,760.

D. ICRs Regarding Health Insurance Issuer Standards Related to the Transitional Reinsurance Program (§ 153.400 and § 153.410)

Within part 153, subpart E we discuss reporting requirements for health insurance issuers related to the transitional reinsurance program. We would require all health insurance issuers both inside and outside of the exchange to provide enrollment and premium data (covered lives and total expenses for the self-insured market) to the applicable reinsurance entity for the estimation and collection of contributions. We also would require that health insurance issuers of reinsurance-eligible plans submit data necessary in order to receive reinsurance payment.

For the purpose of this estimate and whenever we refer to burden requirements for issuers, we utilize estimates of the number of issuers provided by the *Healthcare.gov* Web site as this site provides the best estimate of possible issuers at this time. Based on preliminary findings there are approximately 1827 issuers in the individual and small group markets. While we recognize that not all issuers will offer QHPs, we use the estimate of 1827 issuers as the upper bound of participation and burden.

We further estimate that it will take each issuer approximately 12 hours to submit enrollment and premium data electronically on an annual basis and 12 hours to submit data for reinsurance payment on an annual basis. This estimate is similar to Medicare Part D estimates as discussed previously.

As such, we estimate that it will take each issuer approximately 24 hours to comply with these requirements for a total estimated annual burden of 43,848 hours. We presume that it will take a financial analyst 16 hours (at $57 an hour) and a senior manager 8 hours (at $72 an hour) to meet these requirements. The cost estimate for meeting these requirements for each issuer is of $1,488. The total burden cost estimate for all issuers is $2,718,576.

E. ICRs Regarding Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program (§ 153.520)

Within part 153, subpart F we discuss reporting requirements for qualified health plan issuers related to the risk corridors program. We would require all qualified health plan issuers to submit data on premiums collected and allowable costs. While we recognize that not all issuers will offer QHPs, we use the estimate of 1827 issuers as the upper bound of participation and burden. We further estimate that it will take each issuer approximately 12 hours to comply with this requirement on an annual basis. This estimate is similar to estimates for data submission in Medicare Part D as discussed previously with a slight increase due to the complexity of the risk corridor program. The total estimated annual burden is 21, 924 hours. We presume that it will take a financial analyst 8 hours (at $57 an hour) and a senior manager 4 hours (at

$72 an hour) for a cost estimate of $744. The total burden cost estimate for all issuers is $1,359,288.

F. ICRs Regarding Health Insurance Issuer Standards for the Risk Adjustment Program (§ 153.610–§ 153.630)

Within part 153, subpart G, we described reporting requirements for health insurance issuers related to the risk adjustment program. Health insurance issuers would be required to submit data required for risk adjustment. This data may include claims and encounter data for items and services rendered; enrollment and demographic information; issuer rate-setting rules; and prescription drug utilization data. While we do not specify the data collection timeframe for risk adjustment data, we provide an assumption on the timing of submission of this data. We estimate that it will take an issuer approximately 20 hours to submit this data electronically on an annual basis. This estimate is a slight increase from the Medicare Advantage requirements for submitting data for drug claims as described for § 423.329 for Medicare Part D and reflects the complexity of risk adjustment for the Exchange program.

Health insurance issuers would also submit data for validation and verification activities to HHS and States. Again, we estimate that it will take an issuer approximately 12 hours to submit this data electronically on an annual basis as this should be data they already collect for risk adjustment. Finally, health insurance issuers would maintain risk adjustment data for a period of ten years. We estimate that it will take approximately 2 hours annually for issuers to maintain this data.

We estimate that 1827 issuers must comply with these requirements. We further estimate that it will take each issuer approximately 34 hours to meet the reporting provisions in this subpart for a total of 62,118 hours. We presume that it will take a financial analyst 30 hours (at $57 an hour) and a senior manager 4 hours (at $72 an hour) for a cost estimate of $2,002 for each issuer. The total estimated annual burden cost for all issuers is $3,657,654.

Regulation section(s)	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting per response ($)	Total labor cost of reporting ($)
153.100	51	1	160	8,160	10,520	536,520
153.240	51	1	64	3,264	3,740	190,740
153.310 & 153.340	51	1	62	3,162	3,674	187,374
153.340(c)	5	1	17	85	979	4,895
153.330	5	1	38	190	2,266	11,330
153.350	51	1	30	1,530	1,760	89,760
153.400 & 153.410	1827	1	24	43,848	1,488	2,717,576
153.520	1827	1	12	21,924	744	1,359,288
153.610 & 153.630	1827	1	34	62,118	2,002	3,657,654

Note: Salaries and fringe benefit estimates were taken from the Bureau of Labor Statistics Web site (*http://www.bls.gov/oco/ooh_index.htm*).

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Officer, CMS–9975–P; *Fax:* (202) 395–5806; or *E-mail: OIRA_submission@omb.eop.gov*

IV. Summary of Preliminary Regulatory Impact Analysis

The summary analysis of benefits and costs included in this proposed rule is drawn from the detailed Preliminary Regulatory Impact Analysis, available at *http://cciio.cms.gov* under ''Regulations and Guidance.'' That preliminary impact analysis evaluates the impacts of this proposed rule and a second proposed rule ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans.'' The second proposed rule is published in this issue of the **Federal Register**. The following summary focuses on the benefits and costs of this proposed rule.

A. Introduction

HHS has examined the impacts of the proposed rule under Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits (both quantitative and qualitative) of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Few if any insurance issuers offering comprehensive health insurance policies fell below the size thresholds for ''small'' business established by the SBA. CMS tentatively concludes that this NPRM would not have a significant impact on a substantial number of small entities. We request comment on whether the small entities affected by this rule have been fully identified.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is approximately $136 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. Because States are not required to set up an Exchange or operate reinsurance and risk adjustment, the NPRM does not impose a mandate to incur costs above that $136 million UMRA threshold on State, local, or tribal governments.

B. Need for This Regulation

This proposed rule would implement standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), referred to collectively as the Affordable Care Act. These programs will mitigate the impacts of potential adverse selection and stabilize the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges (''Exchanges'') are implemented, starting in 2014. The transitional State-based reinsurance program serves to reduce the uncertainty of insurance risk in the individual market by making payments for high-cost cases. The temporary Federally-administered risk corridor program serves to protect against rate-setting uncertainty in the Exchange by limiting the extent of issuer losses (and gains). On an ongoing basis, the State-based risk adjustment program is intended to protect health insurance issuers that attract high-risk populations (such as individuals with chronic conditions).

C. Summary of Costs and Benefits of the Proposed Requirements

Two proposed regulations are being published simultaneously to implement components of the Exchange and health insurance premium stabilization policies in the Affordable Care Act. The detailed PRIA evaluates the impacts of both proposed rules, while this summary focuses on the benefits and costs of the proposed requirements in this NPRM.

Methods of Analysis

This preliminary impact analysis references the estimates of the CMS Office of the Actuary (OACT) (CMS, April 22, 2010), but primarily uses the underlying assumptions and analysis done by the Congressional Budget Office (CBO) and the staff of the Joint Committee on Taxation. Their modeling effort accounts for all of the interactions among the interlocking pieces of the Affordable Care Act including its tax policies, and estimates premium effects that are important to assessing the benefits of the NPRM. A description of CBO's methods used to estimate budget and enrollment impacts is available.[1] The CBO estimates are not significantly different than the comparable components produced by OACT; the Administration is working on developing an integrated modeling capacity that will estimate Federal spending, revenue, and private premium impacts comparable to those of CBO. Based on our review, we expect that the requirements in these NPRMs will not substantially alter the estimates of the budget impact of Exchanges or enrollment. The proposed requirements are well within the parameters used in the CBO modeling of the Affordable Care Act and do not diverge from assumptions embedded in the model. Our review and analysis of the proposed requirements indicate that the impacts are within the model's margin of error.

Summary of Costs and Benefits

CBO estimated program payments and receipts for reinsurance and risk adjustment. As Exchanges do not begin operation until 2014, there are no outlays for reinsurance and risk adjustment in 2012 and 2013. CBO estimates that risk adjustment payments and collections are equal in the aggregate, but that risk adjustment payments lag revenues by one quarter. CBO did not score the impact of risk corridors, but assumed collections would equal payments to plans in the aggregate. The payments and receipts in risk adjustment, reinsurance, and risk corridors are financial transfers between issuers.

TABLE 1—ESTIMATED OUTLAYS AND RECEIPTS FOR REINSURANCE AND RISK ADJUSTMENT PROGRAMS FY 2012–FY2016

[In billions of dollars]

Year	2012	2013	2014	2015	2016
Reinsurance and Risk Adjustment Program Payments [a]	.....	.....	11	18	18
Reinsurance and Risk Adjustment Program Receipts [a]	.....	.....	12	16	18

[a] Risk-adjustment payments lag receipts by one quarter.

Source: CBO. 2011. *Letter to Hon. Nancy Pelosi.* March 20, 2010. Available at *http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf*.

Benefits. Payments through reinsurance, risk adjustment, and risk corridors reduce the increased risk of financial loss that health insurance issuers might otherwise expect to incur in 2014 due to market reforms such as guaranteed issue and the elimination of medical underwriting. Insurers charge premiums for expected costs plus a risk premium, in order to build up reserve funds in case medical costs are higher than expected. Reinsurance, risk adjustment and risk corridors payments reduce the risk to the issuer and the issuer can pass on a reduced risk premium to beneficiaries.

Costs. There are administrative costs to States and Exchanges to set up and administer these risk mitigation programs. It is important to note that per section 1311 of the Affordable Care Act, States may use Exchange Planning and Establishment Grant funding to help with the development of these programs. For issuers not receiving payments, any contribution is an additional cost, which is typically passed on to beneficiaries through premium increases. There are also reporting costs for issuers to submit data and financial information.

Regulatory Options Considered

Options considered for reinsurance, risk adjustment and risk corridor programs parallel the options considered for Exchanges. These programs aim to mitigate the impacts of potential adverse selection and stabilize the individual and small group markets as insurance reforms and the Affordable Insurance Exchanges are implemented, starting in 2014. The Affordable Care Act structures reinsurance and risk adjustment as State-run programs with Federal guidelines on methodology, while it establishes risk corridors as a Federally-run program.

In addition to the proposed baseline, HHS has identified two regulatory options for this proposed rule as required by Executive Order 12866.

[1] CBO. ''CBO's Health Insurance Simulation Model: A Technical Description.'' (2007, October).

Uniform Standard for Operations of Exchange and Exchange-Related Programs

Under this option HHS would require a single standard for State operations of Exchanges, reinsurance, risk adjustment and risk corridors. This alternative model would restrict State flexibility, requiring a more uniform standard that States must enact in order to achieve certification.

State Flexibility for Operation of Exchange and Exchange-Related Programs

Under this option, States would have a great deal of flexibility around whether and how to implement Exchanges, reinsurance and risk adjustment. This alternative would allow States to develop these programs to fit their State-specific characteristics. The programs would be subject to few Federal standards.

Summary of Estimate Costs for Each Option

HHS notes that a single standard for State operations of Exchanges, reinsurance, risk adjustment and risk corridors could produce a benefit of reduced Federal oversight cost. However this option may reduce innovation and therefore limit diffusion of successful policies. HHS also notes that while State flexibility could allow for innovation for States, it would increase administrative burden on the Federal government and national issuers, as policies and procedures would vary between States. HHS proposes a middle approach that aims to limit administrative costs for temporary programs while also ensuring that the policy aims of these risk mitigation programs are met. These costs and benefits are discussed more fully in the detailed impact analysis.

D. Accounting Statement

Category	Primary estimate	Year dollar	Unit discount rate (percent)	Period covered
Benefits				
Annualized	Not estimated	2011	7	2012–2016
Monetized ($millions/year)	Not estimated	2011	3	2012–2016
Costs				
Annualized	Not estimated	2011	7	2012–2016
Monetized ($millions/year)	Not estimated	2011	3	2012–2016
Transfers				
Federal Annualized	9925	2011	7	2012–2016
Monetized ($millions/year)	9633	2011	3	2012–2016
Qualitative	Risk Adjustment transfers funds among individual and small group market health plan issuers. Reinsurance collects funds from all issuers and distributes it to individual market issuers.			

Note: For full documentation and discussion of these estimated costs and benefits see the detailed PRIA, available at *http://cciio.cms.gov* under ''Regulations and Guidance.''

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The Act generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed above, this proposed rule is necessary to implement standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with title I of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), referred to collectively as the Affordable Care Act. For purpose of the Regulatory Flexibility Analysis, we expect entities offering health insurance plans including fully insured health plan issuers, self-insured health plan issuers, TPAs and other organizations to be affected by this proposed rule. We believe that health insurers would be classified under the North American Industry Classification System (NAICS) Codes 524114 (Direct Health and Medical Insurance Carriers) According to SBA size standards, entities with average annual receipts of $7 million or less would be considered small entities for both of these NAICS codes. Health issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $10 million or less.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis, we determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for ''small'' business established by the SBA (currently $7 million in annual receipts for health insurers, based on North American Industry Classification System Code 524114).[2]

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), the Department used a data set created from 2009 National Association of Insurance Commissioners (NAIC) Health and Life Blank annual

financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and group markets. For purposes of that analysis, the Department used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. The Department estimated that there were 28 small entities with less than $7 million in A&H earned premiums offering individual or group comprehensive major medical coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business.

As discussed earlier in this summary of the preliminary RIA, the Department is seeking comments on the potential impacts of the requirements in this proposed regulation on issuers' administrative costs. The Department is also seeking comments relating to potential impacts on small issuers.

This rule proposes standards for premium stabilization programs required of health plan issuers including the risk adjustment program as well as the transitional reinsurance and risk corridors programs. Because health plan issuers are the only entities impacted by this rule and as evidenced above, few if any insurance firms offering comprehensive health insurance policies fell below the size thresholds for ''small'' business established by the SBA. We request comment on whether the small entities affected by this rule have been fully identified. We also request comment and information on potential costs for these entities and on any alternatives that we should consider.

VI. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing proposed rule (and subsequent final rule) that includes any Federal mandate that may result in expenditures in any one year by a State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. Because States are not required to set up an Exchange or operate reinsurance and risk adjustment, the NPRM does not impose a mandate to incur costs above the $136 million UMRA threshold on State, local, or tribal governments.

VII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, pre-empts State law, or otherwise has Federalism implications. Because States have flexibility in designing their Exchange and Exchange-related programs, State decisions will ultimately influence both administrative expenses and overall premiums. States are not required to operate an Exchange, risk adjustment, or reinsurance. For States electing to operate an Exchange, risk adjustment and reinsurance, much of the initial costs to the creation of Exchanges and Exchange-related programs will be funded by Exchange Planning and Establishment Grants. After this time, Exchanges will be financially self-sustaining with revenue sources at the discretion of the State. Current State Exchanges charge user fees to issuers.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, the Department has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this NPRM, the Department has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that CMS has complied with the requirements of Executive Order 13132 for the attached proposed regulation in a meaningful and timely manner.

VIII. Regulations Text

List of Subjects in 45 CFR Part 153

Administrative practice and procedure, Adverse selection, Consumer protection, Health care, Health insurance, Health records, Hospitals, Indians, Individuals with disabilities, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Reinsurance, Risk adjustment, Risk corridors, Risk mitigation, State and local governments.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR subtitle A, subchapter B, as set forth below:

SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

Part 153 is added as follows:

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

Subpart A—General Provisions

Sec.

Subpart B—State Notice of Insurance Benefits and Payment Parameters

Subpart C—State Standards for the Transitional Reinsurance Program for the Individual Market

Subpart D—State Standards for the Risk Adjustment Program

Subpart E—Health Insurance Issuer Standards Related to the Transitional Reinsurance Program

Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program

Authority: Title I of the Affordable Care Act, Sections 1321, 1341–1343.

Subpart A—General Provisions

§ 153.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act:

1321. State flexibility in operation and enforcement of Exchanges and related requirements.
1341. Transitional reinsurance program for individual market in each State.
1342. Establishment of risk corridors for plans in individual and small group markets.
1343. Risk adjustment.

(b) *Scope.* This part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors, and a permanent risk adjustment program.

§ 153.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Applicable reinsurance entity means a not-for-profit organization that carries out the reinsurance program established under this part.

Benefit year has the meaning given to the term in § 155.20.

Contributing entity means any health insurance issuer and, in the case of a self-insured group health plan, the third party administrator of the group health plan.

Enrollee has the meaning given to the term in § 155.20.

Exchange has the meaning given to the term in § 155.20.

Grandfathered health plan means coverage provided by a group health plan, or a health insurance issuer as provided in accordance with requirements under § 147.140.

Group health plan has the meaning given to the term in § 144.103.

Health insurance issuer or *issuer* has the meaning given to the term in § 144.103.

Health plan has the meaning given to the term in § 155.20.

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

Reinsurance-eligible plan means, for the purpose of the reinsurance program, any health plan offered in the individual market with the exception of grandfathered plans.

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any plan offered in the individual or small group market with the exception of grandfathered plans.

Small group market has the meaning given to the term in § 155.20.

State has the meaning given to the term in § 155.20.

Subpart B—State Notice of Insurance Benefits and Payment Parameters

§ 153.100 Establishment of State insurance benefits and payment parameters.

(a) *General requirement.* A State operating an Exchange, as well as a State establishing a reinsurance program, must issue an annual notice of benefits and payment parameters specific to that State if that State intends to modify any reinsurance or risk adjustment parameters from those specified in the forthcoming annual Federal notice of benefit and payment parameters.

(b) *State notice deadlines.* If a State elects to publish an annual notice of benefits and payment parameters, the State must issue the notice by early March of the year prior to the benefit year.

(c) *State failure to publish notice.* Any State operating an Exchange or establishing a reinsurance program that fails to publish a notice within the period specified in paragraph (b) of this section must adhere to the parameters, as specified in the forthcoming annual Federal notice of benefit and payment parameters.

§ 153.110 Standards for the State Notice.

(a) *Reinsurance content.* If a State operating an Exchange or establishing a reinsurance program intends to modify a Federal reinsurance payment parameter, the State notice must specify at least the following information:

(1) The data requirements and data collection frequency for health insurance issuers to receive reinsurance payment.

(2) The reinsurance attachment point, reinsurance cap, and coinsurance rate, as specified in § 153.230, if different from the corresponding parameters specified in the forthcoming annual Federal notice of benefit and payment parameters;

(3) If a State plans to use more than one applicable reinsurance entity, for each applicable reinsurance entity, the geographic boundaries for that entity and estimates of:

(i) The number of enrollees in group health plans, including the fully insured and self insured market;

(ii) The number of enrollees in the individual market;

(iii) The amount of reinsurance payments that will be made to issuers; and

(iv) The amount of all premiums in the geographic region that will be available for contributions for each reinsurance entity.

(b) *Risk adjustment content.* If a State operating an Exchange intends to modify a Federal risk adjustment parameter, the State notice must provide a detailed description of and rationale for any modifications, including:

(1) The methodology for determining average actuarial risk, including the establishment of risk pools and the Federally-certified risk adjustment model as specified in § 153.320; and

(2) The risk adjustment data validation methodology set forth in § 153.350.

Subpart C—State Standards for the Transitional Reinsurance Program for the Individual Market

§ 153.200 Definitions.

The following definitions apply to this subpart.

Attachment point means the threshold dollar amount of costs incurred by a health insurance issuer for payment of essential health benefits, as defined in section 1302(b) of the Affordable Care Act, provided for an enrolled individual, after which threshold, the costs for covered essential health benefits, as defined in section 1302(b) of the Affordable Care Act, are eligible for reinsurance payments.

Coinsurance rate means the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for costs incurred to cover essential health benefits, as defined in section 1302(b) of the Affordable Care Act, after the attachment point and before the reinsurance cap.

Contribution rate means the rate, based on a percent of premium, used to determine the dollar amounts each health insurance issuer and third party administrator, on behalf of a self-insured group health plan, must contribute to a State reinsurance program.

Percent of premium means the percent of total revenue, based on earned premiums as described in § 158.130(a), in a fully insured market or the percent of total medical expenses in a self-insured market.

Reinsurance cap means the threshold dollar amount for costs incurred by a

health insurance issuer for payment of essential health benefits, as defined in section 1302(b) of the Affordable Care Act, provided for an enrolled individual, after which threshold, the costs for covered essential health benefits, as defined in section 1302(b) of the Affordable Care Act, are no longer eligible for reinsurance payments.

Third party administrator means the claims processing entity for a self-insured group health plan.

§ 153.210 State establishment of a reinsurance program.

(a) *General requirement.* Each State that elects to operate an Exchange must establish a reinsurance program for the years 2014 through 2016.

(1) The State must enter into a contract with an existing applicable reinsurance entity or establish an applicable reinsurance entity to carry out the provisions of this subpart.

(2) If a State establishes or contracts with more than one applicable reinsurance entity, the State must:

(i) Ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity; and

(ii) Publish the geographic boundaries for each applicable reinsurance entity in a State notice described in § 153.110.

(3) Under authority granted by the State, an applicable reinsurance entity may subcontract specific administrative functions required under this subpart and part 156 subpart G.

(4) States must review and approve subcontracting arrangements to ensure efficient and appropriate expenditures of administrative funds collected under this subpart.

(5) States must ensure that the contract or establishment of the applicable reinsurance entity is of sufficient duration to cover completion of all reinsurance-related activities for benefit years commencing in 2014 through 2016 and any activities required to be undertaken in subsequent periods.

(b) *Multi-State reinsurance arrangements.* Multiple States may contract with a single not-for-profit entity to serve as the applicable reinsurance entity for each State. In such cases, each contractual arrangement between the not-for-profit entity and the individual State will be treated as an individual State applicable reinsurance entity separate and distinct from all other applicable reinsurance entities operated by the not-for-profit entity.

(c) *Special State circumstances for establishing a reinsurance program.* For each State that does not elect to establish an Exchange, the State may determine to operate its own reinsurance program and must carry out all of the provisions in this subpart.

(d) *Non-electing States.* For each State that does not elect to establish an Exchange and does not determine to operate its own reinsurance program, HHS will carry out all of the provisions of this subpart on behalf of the State and establish the reinsurance program to perform all the reinsurance functions for that State.

(e) *Oversight.* Each State that establishes an Exchange or operates a reinsurance program must ensure that each applicable reinsurance entity complies with all provisions of this subpart and subpart E throughout the duration of its contract or establishment.

§ 153.220 Collection of reinsurance contribution funds.

(a) *General requirement.* The State must ensure that the applicable reinsurance entity collects contributions to fund the following:

(1) Reinsurance contributions that will total, on a national basis, $10 billion in 2014, $6 billion in 2015, and $4 billion in 2016.

(2) U.S. Treasury contributions that will total, on a national basis, $2 billion in 2014, $2 billion in 2015, and $1 billion in 2016.

(b) *Contribution rate.* The State must adhere to a national contribution rate set by HHS for the amounts listed in paragraph (a)(1) and (a)(2) of this section.

(1) HHS will set the contribution rate as a percent of premium through a forthcoming annual Federal notice of benefit and payment parameters.

(2) At a minimum, the State must ensure that all applicable reinsurance entities operating in a State collect from all contributing entities the amount set forth by the national rate. The contributions allocated for—

(i) Reinsurance payments must be used for reinsurance payments.

(ii) Payments to the U.S. Treasury must be paid to the U.S. Treasury.

(3) An applicable reinsurance entity may collect more than the amounts collected from the set national rate to provide—

(i) Additional funding for reinsurance payments if the State believes the amount is not sufficient to fund required reinsurance payments; and

(ii) Funding for administrative expenses of the applicable reinsurance entity.

§ 153.230 Calculation of reinsurance payments.

(a) *General requirement.* A health insurance issuer of a non-grandfathered individual market plan becomes eligible for reinsurance payments when its expenses for items and services within the essential health benefits, as defined in section 1302(b) of the Affordable Care Act, of an individual enrollee exceed an attachment point.

(b) *Reinsurance payment.* States may use the payment formula and values for the attachment point, reinsurance cap, and coinsurance rate for each year commencing in 2014 and ending in 2016, established in the forthcoming annual Federal notice of benefit and payment parameters.

(1) States must ensure that the reinsurance payment represents the product of the coinsurance rate times all health insurance issuer costs for an individual's essential health benefits, as defined in section 1302(b) of the Affordable Care Act, which the health insurance issuer incurs between the attachment point and the reinsurance cap.

(2) The State, or the applicable reinsurance entity on behalf of the State, must remit the amounts in paragraph § 153.220(a)(2) of this section to the general fund of the U.S. Treasury at a frequency to be determined by HHS.

(c) *State modification of reinsurance payment formula.* States may modify the reinsurance payment formula to values determined appropriate by the State.

(1) States may use one or all of the following methods:

(i) Increasing or decreasing the attachment point;

(ii) Increasing, decreasing, or eliminating the reinsurance cap; and

(iii) Increasing or decreasing the coinsurance rate.

(2) States must publish any modification to the reinsurance payment formula and parameters in a State notice as described in § 153.110.

(3) States that develop a State formula for reinsurance payments must ensure that contributions toward reinsurance are sufficient to cover:

(i) All payments that the applicable reinsurance entity is obligated to make under that State formula for the given calendar year for the reinsurance program;

(ii) All contributions to the U.S. Treasury described in § 153.220(a)(2).

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* The State must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection

frequency specified by the State in the notice described in § 153.110 or in the forthcoming annual Federal notice of benefit and payment parameters.

(b) *Reinsurance entity payments.* The State must ensure that each applicable reinsurance entity make payments to health insurance issuers that do not exceed contributions.

(1) Payments must be made to health insurance issuers of reinsurance-eligible plans based on the applicable payment notice identified in § 153.230(b) or the payment parameters set pursuant to § 153.230(c).

(2) Payments may be reduced on a pro rata basis to match the amount of contributions received by the State in a given reinsurance year. Any pro rata reductions that the State determines are necessary must be fair and equitable for all health insurance issuers in the individual market.

(3) The State must ensure that an applicable reinsurance entity makes payment as specified in § 153.410(b) to the health insurance issuer of a reinsurance-eligible plan after receiving a valid claim for payment from that health insurance issuer.

(c) *Maintenance of Records.* The State must maintain books, records, documents, and other evidence of accounting procedures and practices of the reinsurance program for each benefit year for at least 10 years.

§ 153.250 Coordination with high-risk pools.

(a) *General requirement.* The State shall eliminate or modify any State high risk pool to the extent necessary to carry out the reinsurance program established under this subpart.

(b) *Coordination with high-risk pools.* The State may coordinate the State high risk pool with the reinsurance program to the extent it conforms to the provisions of this subpart.

Subpart D—State Standards for the Risk Adjustment Program

§ 153.300 Definitions.

The following definitions apply to this subpart:

Alternate risk adjustment methodology means a risk adjustment methodology proposed by a State for use instead of existing Federally-certified risk adjustment models, but not yet certified by HHS.

Federally-certified risk adjustment methodology means a risk-adjustment methodology that has been either developed and promulgated by HHS or has been certified by HHS.

Risk adjustment methodology means the specific procedures used to determine average actuarial risk.

Risk adjustment model means an actuarial tool used to predict health plan costs based on the relative actuarial risk of enrollees in risk adjustment covered plans.

Risk pool means the population across which risk is distributed in risk adjustment.

§ 153.310 Risk adjustment administration.

(a) *State eligibility to establish a risk adjustment program.* (1) A State that elects to operate an Exchange is eligible to establish a risk adjustment program.

(2) Any State that does not elect an Exchange, or that HHS has not approved to operate an Exchange, will forgo implementation of all State functions in this subpart and HHS will carry out all of the provisions of this subpart on behalf of the State.

(3) Any State that elects to establish an Exchange but does not elect to administer risk adjustment will forgo implementation of all State functions in this subpart and HHS will carry out all of the provisions of this subpart on behalf of the State.

(b) *Entities eligible to carry out risk adjustment activities.* A State may elect to have an entity other than the Exchange perform the risk adjustment functions of this subpart provided that the entity selected meets the requirements proposed in § 155.110 of the notice of proposed rulemaking entitled, ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans,'' published in this issue of the **Federal Register.**

(c) *Timeframes.* A State, or HHS on behalf of the State, must commence calculating payment and charges with the 2014 benefit year.

§ 153.320 Federally-certified risk adjustment methodology.

(a) *General requirement.* Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be established as a Federally-certified risk adjustment methodology. A risk adjustment methodology may become Federally-certified by one of the following processes:

(1) A risk adjustment methodology developed by HHS, with its use authorized and published in a forthcoming annual Federal notice of benefits and payment parameters; or

(2) An alternative risk adjustment methodology submitted by a State in accordance with § 153.330, and reviewed and certified by HHS. After HHS approves a State alternative risk adjustment methodology, that methodology is considered a Federally-certified risk adjustment methodology.

(b) *Publication of methodology in notices.* A State must use one of the Federally-certified risk adjustment methodologies that will be published by HHS in a forthcoming annual Federal notice of benefits and payment parameters or that has been published by the State in the annual State notice described in § 153.110(b). Each methodology will include:

(1) A complete description of the risk adjustment model, including—

(i) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for collection of risk adjustment data and determination of factors; and

(2) Any adjustments made to the risk adjustment model weights to determine average actuarial risk.

(c) *Use of methodology for States that do not elect an Exchange.* HHS will specify in the forthcoming annual Federal notice of benefits and payment parameters the Federally-certified risk adjustment methodology that will apply in States that do not elect to operate an Exchange.

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.*

(1) The State request to HHS for the certification of an alternative risk adjustment model must include:

(i) A description of specific risk pools to which the methodology will be applied;

(ii) A complete description of the risk adjustment model, including—

(A) Factors to be employed in the methodology, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(B) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(C) Weights assigned to each factor;

(D) The schedule for collection of risk adjustment data and the method of data collection;

(E) Calibration methodology and frequency of calibration; and

(F) Statistical performance metrics, as specified by HHS; and

(iii) Any adjustments made to the base risk adjustment model weights to determine average actuarial risk.

(2) The request must include the extent to which the methodology:

(i) Accurately explains the variation in the expenses of a given population;

(ii) Links risk factors to daily clinical practice and are clinically meaningful to providers;

(iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

(iv) Uses data that is complete, high in quality and available in a timely fashion;

(v) Is easy for stakeholders to understand and implement;

(vi) Provides stable risk scores over time and across plans; and

(vii) Minimizes administrative costs.

(b) *State renewal of alternate methodology.* The State may not implement a recalibrated risk adjustment model or otherwise altered methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii)(E);

(2) Request must include any changes to the parameters described in paragraph (a)(1).

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* The State, or HHS on behalf of the State, must collect risk-related data to determine individual risk scores that form the basis for risk adjustment.

(b) *Minimum standards.* The State, or HHS on behalf of the State, may vary the amount and type of data collected provided that the State, or HHS on behalf of the State, uses the following standards for risk adjustment data collection:

(1) The NCPDP claims transaction or the HIPAA standard ASC X12N 837 Health Care Claim transaction for all claims and encounter data;

(2) The HIPAA standard ASC X12N 834 Benefit Enrollment and Maintenance transaction for all demographic and enrollment data; and

(3) To ensure adequate data privacy standards, the State, or any official, employee, agent or representative of the State must use individually identifiable information only as specifically required or permitted by this part and must not disclose individually identifiable information except as provided in paragraph (d) of this section.

(i) The State should interpret this provision as separate from the authority of other applicable laws for disclosing individual identifiable information under paragraph (d) of this section.

(ii) The State must implement security standards that provide administrative, physical, and technical safeguards for the individually identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

(iii) The State must establish privacy standards that set forth approved uses and disclosures of individually identifiable information.

(c) *Exception for States with all payer claims databases.* Any State with an all payer claims database that is operational on or before January 1, 2013 may request an exception from the data collection minimum standards described in paragraph (b) of this section by submitting:

(1) Technical specifications for the all payer claims database including data formats;

(2) Proposed system modifications to support risk adjustment activities;

(3) Proposed system modifications to meet requirements set forth in paragraph (d) of this section and other Exchange-related activities.

(d) *Uses of risk adjustment data.* The State, or HHS on behalf of the State, must make relevant claims and encounter data collected under risk adjustment available to support claims-related activities as follows:

(1) Provide HHS with de-identified claims and encounter data for use in recalibrating Federally-certified risk adjustment models;

(2) Provide HHS with summarized claims cost for use in verifying risk corridor submissions; and

(3) Provide the reinsurance entity with summarized claims and encounter data from reinsurance-eligible plans for payment verification purposes and individual-level from reinsurance-eligible plans for audit purposes.

§ 153.350 Risk adjustment data validation standards.

(a) *General requirement.* The State, or HHS on behalf of the State, must validate a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State.

(b) *Use of data validation to adjust risk.* The State, or HHS on behalf of the State, may adjust the average actuarial risk calculated in § 153.310 for all risk adjustment covered plans offered by an issuer based on the risk score error determined in the data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments.* The State may adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.

(d) *Appeals.* The State must provide an administrative process to appeal data validation findings.

Subpart E—Health Insurance Issuer Standards Related to the Transitional Reinsurance Program

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make payments of contributions, in a frequency and manner determined by the State or HHS, to the applicable reinsurance entity for each State in which the contributing entity issues health insurance for the contributions specified pursuant to § 153.220(b).

(b) *Multiple reinsurance entities.* If the State establishes or contracts with more than one reinsurance entity, the contributing entity must make payments to each applicable reinsurance entity that covers each geographic area in which the contributing entity issues health insurance.

(c) *Data requirements.* Each contributing entity must submit to each applicable reinsurance entity data required to substantiate the contribution amounts for the contributing entity.

(1) Each contributing entity in the individual and fully insured market must submit enrollment and premium data.

(2) Each contributing entity in the self-insured market must submit data on covered lives and total expenses.

§ 153.410 Requests for reinsurance payment.

(a) *General requirement.* A reinsurance-eligible plan issuer may make a request for payment when an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment.

(b) *Manner of request.* Reinsurance-eligible plan issuers must make requests for payment in a manner that will be specified by the State as described in § 153.110 or in the forthcoming annual Federal notice of benefit and payment parameters.

Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program

§ 153.500 Definitions.

Allowable administrative costs means the total non-medical costs as defined in § 158.160(b), including costs for the administration and operation incurred by the plan as set forth in § 158.160(b)(2).

Allowable costs means an amount equal to the total medical costs, which include clinical costs, excluding allowable administrative costs, paid by the QHP issuer in providing benefits covered by the QHP.

Charge means the flow of funds from QHP issuers to HHS.

Direct and indirect remuneration means prescription drug price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by a QHP issuer or an intermediary contracting organization with which a QHP issuer has contracted. Such concessions include but are not limited to: Discounts, charge backs, rebates, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, and grants. We further specify that the term applies regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the QHP issuer and regardless of the terms of the contract between the issuer and the intermediary contracting organization.

Payment means the flow of funds from HHS to QHP issuers.

Qualified Health Plan, or QHP, has the meaning given to the term proposed in the general definitions section of the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, published in this issue of the **Federal Register.**

Risk corridor means any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount.

Target amount means an amount equal to the total premiums incurred by a QHP, including any premium tax credit under any governmental program, reduced by the allowable administrative costs of the plan.

§ 153.510 Risk corridor establishment and payment methodology.

(a) *General requirement.* A QHP issuer must adhere to the requirements set by HHS in this subpart and in the forthcoming annual Federal notice of benefits and payment parameters for the establishment and administration of a program of risk corridors for calendar years 2014, 2015, and 2016.

(b) *HHS payments to health insurance issuers.* QHP issuers will receive payment from HHS in the following amounts under the following circumstances:

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, HHS pays the QHP issuer an amount equal to 50 percent of the target amount in excess of 103 percent of the target amount; and

(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, HHS pays to the QHP issuer an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

(c) *Health insurance issuers' remittance of charges.* QHP issuers must remit charges to HHS in the following amounts under the following circumstances:

(1) If a QHP's allowable costs for any benefit year are less than 97 percent but not less than 92 percent of the target amount, the QHP issuer must remit charges to HHS an amount equal to 50 percent of the difference between 97 percent of the target amount and the allowable costs; and

(2) When a QHP's allowable costs for any benefit year are less than 92 percent of the target amount, the QHP issuer must remit charges to HHS an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

§ 153.520 Risk corridor standards for QHP issuers.

(a) *Adjusted premium data.* QHP issuers must submit to HHS data on the premiums collected for each QHP that the issuer offers in a format specified by HHS. These premium amounts must be adjusted in the following manner:

(1) Increased by the amount of any payments received for—

(i) Risk adjustment, and

(ii) Reinsurance as described in § 153.230; and

(2) Reduced for any—

(i) Risk adjustment charges assessed,

(ii) Reinsurance contributions made as described in § 153.220, and

(iii) User fees paid.

(3) *Accounting for reinsurance payments.* QHP issuers must attribute reinsurance payments to risk corridors based on the date, to be determined by HHS, on which the valid reinsurance claim was submitted.

(b) *Allowable costs.* All QHP issuers offering QHP's must submit to HHS the allowable costs incurred for each QHP that the QHP issuer offers in a format to be specified in the forthcoming annual Federal notice of benefits and payment parameters.

(1) Allowable costs must be net of direct and indirect remuneration.

(2) Allowable costs must be reduced for any cost-sharing reductions payments received from HHS.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

§ 153.600 Definitions.

Risk adjustment data means all data that are used in the application of a risk adjustment payment model.

§ 153.610 Risk adjustment issuer requirements.

(a) *Data submission.* All issuers that offer risk adjustment covered plans must submit all required risk adjustment data for those risk adjustment covered plans in the manner and timeframes established by the State, or by HHS on behalf of the State. This data may include but is not limited to:

(1) Claims and encounter data for items and services rendered;

(2) Enrollment and demographic information; and

(3) Prescription drug utilization data.

(b) *Issuer contracts.* Issuers that offer risk adjustment covered plans may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframes established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(c) *Assessment of charges.* After charges and payments for all risk adjustment covered plans have been calculated, issuers that offer risk adjustment covered plans with a net balance of risk adjustment charges payable will be notified by the State, or by HHS on behalf of the State, for those net charges and must remit those risk adjustment charges to the State, or to HHS on behalf of the State.

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* All issuers that offer risk adjustment covered plans must make available to HHS and the State any data requested to support validation of risk adjustment data reported under this subpart of this part.

(b) *Issuer records maintenance requirements.* All issuers that offer risk adjustment covered plans must retain any risk adjustment data reported under this subpart of this part for a period of at least ten years after the date of the report.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 29, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 7, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–17609 Filed 7–11–11; 11:15 am]

BILLING CODE 4120–01–P