

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 153

[CMS-9975-F]

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: Final rule.

SUMMARY: This final rule implements 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 uncertainty by sharing risk in the individual market through making payments for high claims costs for enrollees. The temporary Federally administered risk corridors program serves to protect against uncertainty in rate setting by qualified health plans sharing risk in losses and gains with the Federal government. The permanent State-based risk adjustment program provides payments to health insurance issuers that disproportionately attract high-risk populations (such as individuals with chronic conditions).

DATES: *Effective Date:* These regulations are effective on May 22, 2012.

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SUPPLEMENTARY INFORMATION:

Abbreviations

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

PCIP Pre-existing Condition Insurance Plan

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

QHP Qualified Health Plan

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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. In addition, Exchanges will give individuals and small businesses the same purchasing power as big businesses. The Departments of Health and Human Services, Labor, and the Treasury are working in close coordination to release guidance related to Exchanges in several phases. A Request for Comment relating to Exchanges was published in the **Federal Register** on August 3, 2010. An Initial Guidance to States on Exchanges was issued on November 18, 2010. 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. Two proposed rules, including the proposed form of this rule, were published in the **Federal Register** on July 15, 2011 to implement

components of Exchanges and health insurance premium stabilization programs (that is, reinsurance, risk corridors, and risk adjustment) from the Affordable Care Act. A proposed rule regarding eligibility for Exchanges was published in the **Federal Register** on August 17, 2011. A proposed rule on the Health Insurance Premium Tax Credit was published in the **Federal Register** on August 17, 2011. A proposed rule making changes to eligibility for the Medicaid program was published in the **Federal Register** on August 17, 2011. The final versions of the Exchange Establishment and Eligibility rules were made available for public inspection at the Office of the Federal Register on March 12, 2012. A final version of the Medicaid rule is being made available for public inspection at the Office of the Federal Register on the same date as this rule.

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 through 2016). Section 1342 provides that HHS must establish a temporary risk corridors program that will apply to QHPs in the individual and small group markets for the first three years of Exchange operation (2014 through 2016). Section 1343 provides that each State must establish a permanent program of risk adjustment for all non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges. These risk-spreading mechanisms, which will be implemented by HHS 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. If a State chooses not to establish a transitional reinsurance program or a risk adjustment program, this final rule provides that HHS will do so on its behalf.

Section 1321(a) also provides broad authority for HHS to establish standards and regulations to implement the statutory requirements related to reinsurance, risk adjustment, and the other components of title I of the Affordable Care Act. Section 1321(a)(2) requires, in issuing such regulations, HHS to engage in stakeholder consultation in a way that ensures balanced representation among interested parties. We describe the consultation activities HHS has undertaken later in this introduction. Section 1321(c)(1) authorizes HHS to establish and implement reinsurance,

risk adjustment, and the 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 results when a health insurance purchaser understands his or her own potential health risk better than the health insurance issuer does, resulting in a health plan having higher costs than anticipated.

To protect themselves from adverse selection, issuers may include a margin in their pricing (that is, set premiums higher than necessary) in order to offset the potential expense of high-cost enrollees. The uncertainty resulting from adverse selection could also lead an issuer to be more cautious about offering certain plan designs in the Exchange. This risk will likely be greatest in the first years of the Exchange; however, the risk should decrease as the new market matures and issuers gain actual claims experience with this new population.

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 regardless of their current need for health care. In addition, to further minimize the negative effects of adverse selection and foster a stable marketplace from year one of implementation, the Affordable Care Act establishes transitional reinsurance and temporary risk corridors 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 the temporary risk corridors 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 partially offsetting

risk for high-cost enrollees. By limiting issuers' exposure to high-cost enrollees, this program will attenuate individual market rate increases that might otherwise occur because of the immediate enrollment of individuals with unknown health status. The risk corridors program, which is a Federally administered program, will protect against uncertainty in rates for QHPs by limiting the extent of issuer losses (and gains). On an ongoing basis, the risk adjustment program is intended to provide increased payments to health insurance issuers that attract higher-risk populations (such as those with chronic conditions) and reduce the incentives for issuers to avoid higher-risk enrollees. Under this program, funds are transferred from issuers with lower-risk enrollees to issuers with higher-risk enrollees. Section 1343 of the Affordable Care Act authorizes HHS to utilize criteria and methods similar to those utilized under Parts C or D of title XVIII of the Social Security Act to implement risk adjustment. Standards for the reinsurance, risk corridors, and risk adjustment programs are addressed in this final rule. The following chart summarizes these programs:

Program	Reinsurance	Risk corridors	Risk adjustment
What	Provides funding to issuers that incur high claims costs for enrollees.	Limits issuer losses (and gains)	Transfers funds from lower risk plans to higher risk plans.
Program Operation	State option to operate, regardless of whether the State establishes an Exchange.	HHS	State option to operate if the State establishes an Exchange.
Who Participates	All issuers and third party administrators on behalf of group health plans contribute funding; non-grandfathered individual market plans (inside and outside the Exchange) are eligible for payments.	Qualified health plans	Non-grandfathered individual and small group market plans, inside and outside the Exchange.
Why	Offsets high cost outliers	Protects against inaccurate rate-setting.	Protects against adverse selection.
When	Throughout the year	After reinsurance and risk adjustment.	Before June 30 of the calendar year following the benefit year.
Time Frame	3 years (2014–2016)	3 years (2014–2016)	Permanent.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

As indicated in our proposed rule, HHS published a Request for Comment (RFC) on August 3, 2010, inviting the public to provide input regarding the rules that will govern the Exchanges. The comment period closed on October 4, 2010. Comments were submitted by consumer advocacy organizations, medical and health care professional trade associations and societies, medical and health care professional entities, health insurance issuers, insurance trade associations, members of the general public, and employer

organizations. The RFC comments were considered in the development of the proposed rule.

Leading up to the issuance of the Premium Stabilization proposed rule, HHS consulted with stakeholders through weekly meetings with the National Association of Insurance Commissioners (NAIC), regular contact with States through the Exchange grant process, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We continue to consult with these stakeholders on the development of guidance related to the reinsurance, risk adjustment, and risk

corridors programs. In this final rule, we have responded to comments submitted in response to the Premium Stabilization proposed rule and the RFC, where relevant.

On July 15, 2011, we published in the **Federal Register** (76 FR 41950–41956) the proposed Standards related to Reinsurance, Risk Corridors, and Risk Adjustment. We received approximately 700 comments on the proposed rule. Of the comments received, approximately 200 were submitted as part of letter campaigns related to women's and mental health services, or were general comments on the Affordable Care Act and the government's role in health

care, but were not specific to the proposed rule.

Comments that were specific to the proposed rule represented a wide variety of stakeholders, including States and tribal organizations, health insurance issuers, consumer groups, healthcare providers, industry experts, and members of the public. Many commenters emphasized the importance of the premium stabilization programs as Exchanges and insurance reforms are implemented and addressed the balance between flexibility for States and standardization and predictability for consumers nationwide.

A. Subpart A—General Provisions

1. Basis and Scope (§ 153.10)

Section 153.10(a) of subpart A specified 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) specified that this part establishes standards for the establishment and operation of a transitional reinsurance program, a temporary risk corridors program, and a permanent risk adjustment program. We received a number of supportive comments on these provisions and we are finalizing them without modification.

2. Definitions (§ 153.20)

In § 153.20, § 153.200, § 153.300, and § 153.600 of the proposed rule, we set forth definitions for terms that are critical to the reinsurance, risk adjustment, and risk corridors programs. Many of the definitions presented in § 153.20 were taken directly from the Affordable Care Act or from existing regulations. New definitions were created to carry out the regulations 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 § 153.20 is limited to part 153.

Considering the comments received, we are finalizing this section as proposed, with the following modifications:

We are moving a number of definitions that previously appeared in subparts C, D, and G of the proposed rule to subpart A of this final rule. We are revising the definition of “attachment point” to clarify that reinsurance payments will apply to claims costs accumulated on an incurred basis in a benefit year, and to specify that reinsurance payments are payable on all covered benefits. We are

making conforming revisions to the definitions of “coinsurance rate” and “reinsurance cap.” We are revising the definition of “contribution rate” to be a per capita amount payable with respect to reinsurance contribution enrollees who reside in a State. We are adding a new defined term, “reinsurance contribution enrollee,” which means an individual covered by a plan for which reinsurance contributions must be made pursuant to § 153.400(b). We are removing the definition of “percent of premium” because this definition is no longer used.

We are modifying the definition of “risk adjustment methodology” to mean all parts of the risk adjustment process—the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program. We are doing so to clarify the distinct parts of the risk adjustment process. The risk adjustment model calculates individual risk scores. The calculation of plan average actuarial risk adjusts those individual risk scores for rating variation, and calculates average actuarial risk at the plan level. The plan average actuarial risk is used for the calculation of payments and charges for risk adjustment covered plans. The risk adjustment data collection approach specifies how risk adjustment data will be stored, collected, accessed, transmitted, and validated, and the timeframes, data format, and privacy and security standards associated with each. The schedule for the risk adjustment program is the schedule for calculating payments and charges, invoicing issuers for charges, and disbursing payments. We are modifying the definition of “risk adjustment data” to mean all data that are used in a risk adjustment model, the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data. We have added several new definitions—“individual risk score,” “calculation of plan average actuarial risk,” “calculation of payments and charges,” and “risk adjustment data collection approach.”

Finally, we are making a number of clarifying modifications throughout this section.

Comment: We received one comment suggesting that HHS define the benefit year as a calendar year and that the reinsurance program would be best operated on a calendar year basis.

Response: The benefit year was defined as the calendar year in the Exchange Establishment rule. We have

cross-referenced this definition in this final rule.

Comment: Although a few commenters supported the proposal that reinsurance be payable only on essential health benefits, the majority of commenters urged that reinsurance be payable on all covered benefits, with several citing the administrative complexity of distinguishing between claims for essential health benefits and claims for other covered benefits.

Response: Because it would be administratively burdensome for issuers to distinguish claims for covered essential health benefits from other claims, we are revising the definitions so that reinsurance is payable on all covered benefits.

Comment: We received several comments disagreeing with the inconsistency in the proposed definition of percent of premium, which would include administrative costs for the fully insured market, but not the self-insured market.

Response: We believe that the statute intended for self-insured plans also to pay administrative costs. However, since we have modified the policy for the collection of contributions as discussed in the preamble to § 153.220, we are no longer proposing a definition for percent of premium.

Comment: We received a number of comments requesting clarification of the definition of a contributing entity for the reinsurance program. Several commenters suggested that HHS clarify that third-party administrators are not financially liable for contributions to be made by group health plans for which they administer benefits.

Response: The Affordable Care Act requires that health insurance issuers and third party administrators on behalf of group health plans make contributions. We are including text in § 153.400 that clarifies which issuers must make reinsurance contributions and which are exempt.

Comment: A few commenters expressed support for the differentiation between the defined terms “risk adjustment model” and “risk adjustment methodology.” Another commenter suggested an expanded set of definitions to capture more of the steps in the risk adjustment process, including a term to define the methodology for transferring money between plans, and a term to describe an individual enrollee’s relative cost compared to that of an average enrollee.

Response: We are adding a definition of “individual risk score” to describe a relative measure of predicted health care costs for a particular enrollee. We are adding a definition of “calculation

of plan average actuarial risk” to describe the specific calculations used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including the specification of the risk pool from which average actuarial risk will be calculated. We are adding a definition of “calculation of payments and charges” to describe the specific procedures used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including adjustment for variable rating factors and the specification of the risk pool from which average actuarial risk is to be calculated. We are adding a definition of “risk adjustment data collection approach” to describe the specific procedures by which risk adjustment data is to be stored, collected, accessed, and transmitted, and the timeframes, data format, and privacy and security standards with respect thereto.

Comment: We received two comments about the definition of “risk adjustment data.” One commenter suggested that the definition be expanded to encompass all aspects of the risk adjustment process. Another commenter requested that HHS not adopt language that would curtail the use of a prospective risk adjustment model.

Response: We are aligning the definition with a number of the other new definitions encompassed in “risk adjustment methodology.” We do not intend to curtail the use of a prospective risk adjustment model.

Comment: We received a few comments requesting clarification as to the types of plans that are subject to risk adjustment. Commenters asked specifically about Medicaid managed care plans and multi-State plans.

Response: Section 1343 of the Affordable Care Act requires that health plans (except grandfathered plans) in the individual or small group markets participate in the risk adjustment program. We are modifying the definition of “risk adjustment covered plan” in response to comments. This modification clarifies that all health insurance coverage, including multi-State plans and Consumer Operated and Oriented Plans, are risk adjustment covered plans. The risk adjustment program does not apply to Medicare Advantage plans or Medicare Prescription Drug Plans, under which private health plans contract with Medicare to provide Medicare-covered benefits, or to contracts with State Medicaid agencies to provide Medicaid benefits, as payments for such coverage are regulated under provisions of the Social Security Act.

Insurance coverage solely for excepted benefits under title XXVII of the PHS Act will be excluded from risk adjustment. Excepted benefit plans cover a specific set of services, such as vision benefits, while “major medical” plans cover a broader set of benefits such as physician and hospital visits. These differences make fair enrollee risk comparison between excepted benefit plans and major medical plans difficult. We are modifying the definition of risk adjustment covered plan to exclude plans determined not to be risk adjustment covered plans in the annual HHS notice of benefit and payment parameters.

B. Subpart B—State Notice of Benefit and Payment Parameters

In this subpart, we proposed a process by which the States that are operating a risk adjustment program or establishing

a reinsurance program issue an annual notice of benefit and payment parameters to disseminate information to issuers and other stakeholders about specific requirements to support payment-related functions. This provides a practical way to update certain payment and benefit parameters that may change annually, such as reinsurance contribution rates that are based on annually changing thresholds. This notice will also serve as a mechanism to address other Exchange-related provisions.

1. State Notice of Benefit and Payment Parameters (§ 153.100)

In § 153.100(a), we proposed that a State operating an Exchange, as well as a State establishing a reinsurance program, be required to issue a 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 annual HHS notice of benefit and payment parameters. In paragraph (b) (now paragraph (c)), we proposed specific deadlines for the State notice of benefit and payment parameters. We proposed that those deadlines be tied to the publication of the annual HHS notice of benefit and payment parameters, upon which the public will have an opportunity to comment. Below is a chart detailing the schedules for the annual HHS notice of benefit and payment parameters for benefit year 2014 and subsequent years, with the first two milestones occurring in the calendar year two years before the effective date.

ANNUAL HHS NOTICE OF BENEFIT AND PAYMENT PARAMETERS

HHS publishes advance notice	Mid-October two calendar years before the benefit year.
Comment period ends	Mid-November two calendar years before the benefit year.
HHS publishes final notice	Mid-January of the calendar year before the benefit year.

We proposed that a State that plans to modify Federal parameters issue its notice by early March in the calendar year before the benefit year. We proposed that this requirement set an outer bound for the date by which the final notice is to be issued by a State that intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the annual HHS notice of benefit and payment parameters.

We also proposed in paragraph (c) (now paragraph (d)), 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 within the period specified, the parameters set forth in the annual HHS notice of benefit and payment parameters will serve as the State parameters.

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 153.100 of the proposed rule, with the following modifications: We are clarifying that a State must publish a notice of benefit and payment parameters if it intends to

modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, or modify any reinsurance parameters. We are directing a State that operates a risk adjustment program to publish a notice of benefit and payment parameters setting forth the risk adjustment methodology and data validation standards it will use. We are specifying that State notices be issued by March 1 of the calendar year prior to the first benefit year for which the notice applies. We are clarifying that a

State that does not publish a notice of benefit and payment parameters forgoes its right to modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, or use any risk adjustment methodology or data validation standards other than those published in the annual HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of a State. We are also making a number of clarifying modifications throughout this section.

Comment: We received a number of comments in support of a requirement that States publish a State notice of benefit and payment parameters. One commenter suggested that we include a requirement that all notices be made public with a period for comment. Another commenter proposed that States be required to justify deviation from any methodologies or parameters set forth in the annual HHS notice of benefit and payment parameters.

Response: While we recognize the value of requiring a public comment period for State notices, we believe that such a requirement should be left to State law and practice. HHS will provide an opportunity for public comment when HHS administers risk adjustment or reinsurance. State law will govern what administrative process is necessary when a State adopts a risk adjustment methodology, or modifies reinsurance parameters, subject to the limits of this final rule and the HHS notice of benefit and payment parameters. We are clarifying the content of the justification to be published by a State that seeks to use a risk adjustment methodology other than the methodology used by HHS when operating risk adjustment on behalf of a State. However, we are not requiring that a State must provide justification for changes to reinsurance payment parameters. As discussed in the preamble in subpart C, we believe a State may have many reasons to make adjustments to the HHS reinsurance payment parameters. As such, we believe that each State should have the flexibility to determine the parameters that best suit the administration of its reinsurance program.

Comment: A number of commenters expressed support for the timing of notice releases as proposed. However, we received a number of comments stating that the proposed timeframe did not allow sufficient time for issuers to prepare their applications for certification for participation in the Exchange in time for the October 2013 open enrollment period. Commenters

proposed alternative timeframes for the release of the HHS notice that ranged from January 2012 to June 30, 2012. A number of commenters also stated that, particularly in the initial years, more advanced notice of Federal and State program parameters will be necessary in order for issuers to prepare premiums for the 2014 benefit year.

Response: The timeframe for implementation of the Affordable Care Act makes it difficult for the Federal and State governments to provide more notice than was proposed in the proposed rule. To accommodate States' and issuers' desire for further information with respect to risk adjustment, HHS is planning a number of working sessions with issuers and States. We believe these sessions will provide sufficient information to issuers and States, while providing HHS the time necessary to more fully develop the Federal parameters for the reinsurance and risk adjustment programs. For these reasons, we are clarifying and finalizing the proposed requirement that State notices of benefit and payment parameters be published by March 1 of the calendar year prior to the benefit year.

Comment: We received a comment supporting the requirement that, if a State establishing a reinsurance program does not provide public notice of its intent to have State-specific parameters, the parameters set forth in the annual HHS notice of benefit and payment parameters will serve as the State parameters.

Response: We are finalizing our policy that a State that elects to establish a reinsurance program that does not publish a State notice of benefit and payment parameters by March 1 must adhere to the parameters set forth in the HHS notice of benefit and payment parameters.

2. Standards for the State Notice of Benefit and Payment Parameters (§ 153.110)

We proposed in paragraph (a)(1) (now paragraph (a)), that content related to the reinsurance program include the data requirements and data collection frequency for health insurance issuers to receive reinsurance payments. In paragraph (a)(2) (now paragraph (e)), we proposed that a State that establishes a reinsurance program must specify the attachment point, reinsurance cap, and coinsurance rate if the State plans to use values different from those set forth in the annual HHS notice of benefit and payment parameters. In paragraph (a)(3) (now paragraph (d)), we proposed that if a State plans to use more than one applicable reinsurance entity, the State

must include in its State notice of benefit and payment parameters 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.

In paragraph (b) (now paragraph (f)), we proposed content related to the risk adjustment program if the State intends to modify the risk adjustment parameters set forth in the annual HHS notice of benefit and payment parameters, including a detailed description of and rationale for any modification.

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 153.110 with the following modifications: We are specifying that a State establishing a reinsurance program that elects to collect reinsurance contributions from the fully insured market must announce its intention to do so, and must set forth the data requirements for reinsurance payments in the State notice of benefit and payment parameters. We are clarifying that a State must apply any modified reinsurance parameters uniformly throughout the State. However, as discussed in Subpart C, a State must inform HHS by December 1, 2012, of its intent to collect reinsurance contributions for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if the State elects to collect reinsurance contributions for any benefit year after 2014. A State that elects to collect additional reinsurance contributions must describe the purpose of the additional collection and the additional contribution rate. We are making a number of clarifying modifications throughout this section.

Comment: One commenter supported affording States the flexibility to provide higher reinsurance payments to plans.

Response: We believe that States should have the flexibility to vary reinsurance payments, so long as the reinsurance parameters are uniform throughout the State. However, a State electing to change reinsurance parameters must publish those changed parameters in the State notice of benefit and payment parameters. A State electing to make higher reinsurance payments will be required to collect any additional reinsurance contributions required to fund those higher payments through a State applicable reinsurance entity.

Comment: We received a comment asking that States be provided the

flexibility to use multiple coinsurance rates.

Response: We believe that States generally should have flexibility in setting payment parameters, but we do not believe that the Affordable Care Act intended for a State to allow an applicable reinsurance entity to set multiple payment parameters in the State, or for multiple applicable reinsurance entities in a State to set different payment parameters. We believe that payment parameters set by the State or HHS on behalf of the State should be uniform throughout the State.

Comment: Several commenters supported the requirement that if there are multiple applicable reinsurance entities in a State, these entities must be required to operate in distinct geographic areas.

Response: We are finalizing that requirement in § 153.210(a)(2).

Comment: Several commenters asked for clarification or changes in the content that a State must provide in its notice of benefit and payment parameters. In particular, commenters stated that the proposed rule did not define the term “risk adjustment data validation methodology.”

Response: We believe our proposed rule struck a balance between providing minimal baselines for States and providing States with flexibility for their State notices. We are clarifying the provisions related to risk adjustment data validation by requiring that § 153.110(f) align with § 153.330(a) and § 153.350.

C. Subpart C—State Standards Related to the Reinsurance Program

Section 1341 of the Affordable Care Act directs that a transitional reinsurance program be established in each State to help stabilize premiums for coverage in the individual market during the benefit 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 support reinsurance payments to non-grandfathered plans of individual market issuers that cover high-cost individuals. As a basis for reinsurance payments, the law directs HHS 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.

In subpart C of the proposed rule, we proposed to codify in regulation 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 were proposed in subpart E of the proposed rule.

1. Reserved (§ 153.200)

Section 153.200 of the proposed rule defined a number of terms used in this subpart. Those definitions have been moved to subpart A. We are reserving this section for future use.

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

In § 153.210 of the proposed rule, we described standards for States regarding the establishment of a reinsurance program. We proposed 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 proposed to codify in regulation section 1341(a) of the Affordable Care Act, which requires that 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. We believe the statute allows State flexibility in selecting an applicable reinsurance entity and did 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 proposed 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 of benefit and payment parameters, described in subpart B, 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 proposed to allow the State to permit a reinsurance entity to subcontract for administrative functions, provided that the State reviews and approves these subcontracted arrangements as described in paragraph (a)(4). We interpreted 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 proposed in paragraph (a)(5) that the establishment of, or contract with, an applicable reinsurance entity must extend for a sufficient period to ensure that the entity can fulfill all reinsurance requirements for the benefit years 2014 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 such additional periods. Section 1341(b)(4) of the Affordable Care Act requires that these payments be completed by December 31, 2018.

We clarified in paragraph (b) that there may be situations in which an applicable reinsurance entity operates a reinsurance program for more than one State. In such cases, we consider each contract to be an individual reinsurance arrangement between a specific State and the applicable reinsurance entity.

We proposed 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 proposed that if a State does not elect to establish an Exchange and does not elect to establish its own reinsurance program, HHS will establish the reinsurance program and will 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 proposed that each State that establishes a reinsurance program must ensure that each applicable reinsurance entity within the State complies with all provisions of this subpart and with subpart E.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions with the following modifications:

In paragraph (a), we are clarifying that because reinsurance is no longer a required Exchange function, each State is eligible to establish a reinsurance program regardless of whether the State establishes an Exchange; we are removing proposed paragraph (c) to conform to this change. We are clarifying in paragraph (a)(2) that each State is required to notify HHS in the manner and timeframe specified by HHS of the percentage of reinsurance contributions received by HHS for the State to be allocated to each applicable reinsurance entity, if applicable. We are moving the requirement that a State publish the geographic boundaries for each applicable reinsurance entity, if it elects to have more than one, to subpart B. Finally, we are making a number of clarifying modifications to this section.

Comment: We received a comment suggesting a number of entities that could serve as a not-for-profit reinsurance entity for a State. We received a few comments urging that we provide more guidance on entities eligible to be State applicable reinsurance entities. One commenter suggested that the State reinsurance entity be subject to both Federal and State oversight.

Response: We believe that a State should have the discretion to select the entity that will administer its reinsurance program, and do not establish specific standards for that selection. We understand the commenter's concern about oversight, and note that § 153.210(d) requires States to ensure compliance with subpart C when the State is operating the reinsurance program. When HHS is operating a reinsurance program on behalf of the State, HHS will also ensure such compliance. Because we believe that States should have flexibility in selection and oversight over the applicable reinsurance entity, we are not proposing further guidance on those matters.

Comment: We received a comment suggesting that HHS provide options for States to terminate an entity for cause.

Response: We believe that nothing in this final rule precludes States from terminating a contract with an applicable reinsurance entity in a manner consistent with State law (including regulations governing contracting). In such an event, the State should ensure a seamless transition of reinsurance functions to another applicable reinsurance entity to prevent any disruption in the program.

Comment: We received many comments suggesting that a State establishing an Exchange not be required to operate a reinsurance program. Commenters stated that it would be difficult for a State to identify a not-for-profit entity to operate the transitional reinsurance program. One commenter suggested that HHS execute a master contract with a single reinsurance entity that satisfies all of the requirements in this final rule and permit States to use that entity. Another commenter stated that a State's options for establishing a reinsurance program should be similar to those it has with respect to establishing a risk adjustment program.

Response: We are no longer requiring that States that establish an Exchange also establish a reinsurance program. We believe that this flexibility is appropriate because some States have previously established reinsurance programs, and may feel they are

prepared to operate a reinsurance program for their State. If a State chooses not to establish a reinsurance program, HHS will establish a reinsurance program for that State.

Comment: We received one comment asking HHS to publish a white paper on draft methodologies for reinsurance.

Response: We are describing the general methodology for collecting reinsurance contributions and making reinsurance payments in subpart C of this final rule. We plan to provide further details on this methodology, including the national rate for contributions and State-based reinsurance payment parameters, in the HHS notice of benefit and payment parameters.

Comment: We received a comment seeking clarification on the use of unexpended contribution funds collected in calendar years 2014 through 2016, and funds that may remain after 2016.

Response: We believe that unused reinsurance funds should be used by the State until expended or by December 31, 2018, whichever date comes first, to make reinsurance payments. States are not prohibited from continuing a reinsurance program, but may not use reinsurance contribution funds collected under the reinsurance program in calendar years 2014 through 2016 to fund the program in years after 2018. If contribution funds collected for a calendar year between 2014 and 2016 remain unspent by December 31 of the year, those funds may be carried into the next year to make payments for the next year or to make retroactive payments for prior years.

Comment: We received a comment asking that existing State reinsurance programs be permitted to serve as a combined reinsurance program. The commenter further suggested permitting the use of reinsurance contributions collected under the transitional reinsurance program for an existing State reinsurance program.

Response: We believe that a State with an existing reinsurance program in place can modify that program to comply with the standards for the transitional reinsurance program. The State would be required to contract with a not-for-profit reinsurance entity to administer the program, and the applicable reinsurance entity must comply with the standards.

Contributions collected for the transitional reinsurance program must be used to make reinsurance payments pursuant to the transitional reinsurance program based on the payment parameters established by the State or HHS on behalf of the State, and may not

be used to fund a separate State reinsurance program.

3. Collection of Reinsurance Contribution Funds (§ 153.220)

In § 153.220 of the proposed rule, we described standards for the collection of reinsurance contribution funds. In paragraph (a)(1) (now paragraph (c)), we proposed to codify in regulation the aggregate contribution amounts required under the Affordable Care Act for reinsurance. The Affordable Care Act requires that the reinsurance entity collect specified additional contribution funds for deposit into the general fund of the U.S. Treasury. In paragraph (a)(2), we proposed to codify in regulation these additional contribution amounts.

Although the transitional reinsurance program is State-based, section 1341(b)(3) sets contribution amounts for the program on a national basis. We considered two approaches to collecting 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 the Affordable Care Act. In paragraph (b), we proposed using a national contribution rate. Use of a national contribution rate is a simpler approach. Further, since there is significant uncertainty about individual market enrollment, the overall health of the enrolled population, and the cost of care for new enrollees, we believed 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 under the national contribution rate would stay in that State and be used to make reinsurance payments on valid claims submitted by reinsurance-eligible plans in that State. 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) (now paragraph (e)), we proposed the percent of premium method as the fairest method by which to collect these contributions.

In paragraph (b)(2) (now paragraph (e)), we also proposed requiring that all contribution funds collected for reinsurance payments be used for reinsurance, and all contribution funds collected for the U.S. Treasury be paid to the U.S. Treasury. In paragraph (b)(3)(i), we proposed that a State may collect more than would be collected under the national rate, if the State believes that these amounts are not sufficient to cover the payments it will

make under the payment formula. In paragraph (b)(3)(ii) (now paragraph (g)), we proposed permitting a State to collect more than the amount collected at the national rate to cover the administrative costs of the applicable reinsurance entity.

We also considered the frequency with 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.

Considering the comments received, we are finalizing these provisions with the following modifications:

In paragraph (a), we are revising the proposed provisions so that HHS would collect contribution funds from self-insured plans and third-party administrators on their behalf, whether or not a state elects to establish a reinsurance program. This policy is consistent with traditional Federal oversight of self-insured plans. States that establish a reinsurance program would have the option, but not the obligation, to collect contributions from issuers in the fully insured market. If a State does not elect to collect from the fully insured market, HHS would collect contributions from both fully insured and self-insured plans.

In paragraph (b), we are clarifying that a State that elects to establish a reinsurance program must generally notify HHS by September 1 of the calendar year that is two years prior to the applicable benefit year if the State plans to collect reinsurance contributions from fully insured plans. However, due to States' anticipated workload in establishing Exchanges in the fall of 2012, we are postponing the deadline for notifying HHS of a State's intent to collect reinsurance contributions from fully insured plans to December 1, 2012, for the 2014 benefit year (with the notification being required by September 1 of the calendar year two years prior to the applicable benefit year for any benefit year after 2014). The State's notification will be effective for the applicable benefit year and each subsequent benefit year during which reinsurance-related activities continue.

Paragraph (d) describes how contribution funds collected by HHS will be distributed: HHS will distribute the reinsurance contributions collected to the applicable reinsurance entity for a State, net of the State's share of the U.S. Treasury contribution and

administrative expenses incurred when performing reinsurance functions under this subpart.

In paragraph (e), we are clarifying that HHS will set the national contribution rate in the annual HHS notice of benefit and payment parameters along with the proportion of the national contribution rate that will be allocated to reinsurance payments, payments to the U.S. Treasury, and administrative expenses of the applicable reinsurance entity for the State or HHS when performing reinsurance functions under this subpart.

In paragraph (g), we are clarifying that a State may elect to collect more than the amounts that would be collected based on the contribution rate to provide funding for administrative expenses or additional reinsurance payments. This policy was proposed in paragraph (b)(3) of the proposed rule. In paragraph (h), we describe the administration of additional State collections. If a State establishes a reinsurance program and elects to collect more than the amounts that would be collected based on the national contribution rate for administrative expenses, then the State must notify HHS within 30 days after publication of the proposed annual HHS notice of benefit and payment parameters of the additional contribution rate that it elects to collect for administrative expenses. Further, the State must ensure that the State's applicable reinsurance entity collects any additional amount for administrative expenses, or accepts additional amounts from HHS in accordance with the State's election under paragraph (a)(1). For reinsurance payments, notwithstanding paragraphs (a)(1) and (a)(2), the State must ensure that the State applicable reinsurance entity collects all additional reinsurance contributions from contributing entities for the purpose of reinsurance payments. In sum, HHS will only collect additional amounts for administrative expenses for a State, and will not collect additional amounts for reinsurance payments for a State. The collection of additional amounts for reinsurance payments must be carried out by the State's applicable reinsurance entity. We are also making a number of clarifying modifications throughout this section.

Comment: We received many comments expressing concern that States may lack the ability to collect contributions from self-insured plans, due to the States' lack of authority and oversight of self-insured plans.

Response: We are revising the proposed collection process so that HHS

collects from the self-insured market in all States. We believe that this change in collection process will create a more efficient, centralized collection from self-insured plans that is beneficial to both States and third party administrators on behalf of group health plans. This collection is authorized under HHS' authority under section 1321(c)(1) of the Affordable Care Act to "take such actions as are necessary to implement" the requirements of title I of the Affordable Care Act.

Comment: We received overwhelming support for the proposed use of a national uniform contribution rate. However, one commenter expressed concern with this approach, and suggested a State-level allocation to make the redistribution of contribution funds proportional to the size of the State's individual market.

Response: Consistent with the majority of comments, we believe that a national uniform contribution rate is the better approach because it is simpler and more easily implemented for a transitional program. The statute does not specify the approach for collection of contributions, but requires HHS to consult with the NAIC in determining provisions for the reinsurance program. NAIC supported the use of a national contribution rate because it minimizes the burden on States and issuers and is more equitable. NAIC also stated in its official response to the proposed rule that a State-level allocation would be more administratively burdensome for issuers and States and would not guarantee fairness in the collection of contributions. While one commenter expressed concern that use of a national contribution rate would result in underfunding of reinsurance, we believe that a State's right to increase the contribution rate addresses this concern.

Comment: Many commenters supported the proposed percent of premium method, arguing that a percent of premium method better allocates contributions to States with higher premium and healthcare costs. A few commenters opposed use of a percent of premium method due to its complexity and a concern that it could adversely impact the market.

Response: HHS has considered the advantages and disadvantages of both methods, along with the overarching goals for the transitional reinsurance program, which are to (1) Stabilize premiums by offering protection to health insurance issuers against medical cost overruns for high-cost enrollees in the individual market; (2) provide early and prompt payment of reinsurance funds during the benefit year; (3) minimize administrative burden; and (4)

allow contributions collected by or on behalf of a State to remain in that State. Given these goals and the time-limited nature of the program, we believe that the per capita approach will be less complex to administer, particularly with regard to the self-insured market. Further, the per capita approach will better enable us to maintain the goals of the reinsurance program by providing issuers with a more straightforward approach in making contributions to the reinsurance program with minimal administrative burden. A State would still be allowed to collect additional contributions towards reinsurance payment.

While several commenters expressed support for our original proposal of a percent of premium method, these same stakeholders also support timely collection and payment in the reinsurance program, which is an important component of the premium stabilization provided by the reinsurance program. We believe that the per capita approach will best achieve this goal.

4. Calculation of Reinsurance Payments (§ 153.230)

In § 153.230 of the proposed rule, we set the payment policy for the reinsurance program based upon consultation with the American Academy of Actuaries. The reinsurance payment policy must address 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 prefer to use reliable and readily accessible data sources that will allow health insurance issuers to receive prompt payment. We proposed in paragraph (a) that coverage be based on items and services within the essential health benefits for an individual enrollee that exceeds an attachment point.

In paragraph (b), we proposed to announce the reinsurance payment formula and State-specific values for the attachment point, reinsurance cap, and coinsurance rate in the annual HHS notice of benefit 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 calendar 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 proposed establishing a reinsurance cap set at a level approximately equal to the attachment point for traditional commercial reinsurance.

In paragraph (b)(1) (now paragraph (c)), we proposed 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 will permit a State that establishes a reinsurance program to establish its own payment formula by varying the attachment point, coinsurance rate, and reinsurance cap. The preamble to the proposed rule contains a further discussion of the reasoning and background behind the policy proposed in paragraph (b)(1).

We proposed using medical cost experience to identify eligible enrollees for which health insurance issuers would receive reinsurance. This approach for calculating reinsurance payments considers costs only for high-risk individuals. However, use of a reinsurance cap, as well as the fact that a health insurance issuer pays only a portion of costs above the attachment point and below the cap, may incentivize health insurance issuers to control costs.

We proposed in paragraph (b)(2) (now moved to § 153.220(f)(2)(ii)), that all payments to the general fund of the U.S. Treasury be made on a frequency to be determined by HHS. We have also considered the frequency with 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 and continuing through January 31, 2017 or until States have remitted the full amount of all payments. We proposed in paragraph (c) (now paragraph (d)), to allow some degree of State variation from the reinsurance parameters proposed by HHS. We proposed in paragraph (c)(1) (now paragraph (d)(1)), that the State may alter the attachment point, reinsurance cap, including elimination of the cap, and coinsurance rate. We proposed in paragraph (c)(2) (now paragraph (d)(2)), that States must publish any modification to the reinsurance payment formula and parameters in a State notice of benefit and payment parameters as described in subpart B of this part. We proposed in paragraph (c)(3) (now paragraph (d)(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 all of its obligations for payments. These 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 decide to increase reinsurance payments above the levels 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. Finally, the State may elect to pay the same amounts recommended by HHS, but may wish to modify the frequency of those payments.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with the following modifications:

In paragraph (a), we are no longer requiring that payment be linked to the coverage of essential health benefits. In paragraph (b), we are clarifying that the States must use, subject to any modifications made pursuant to paragraph (d), 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 annual HHS notice of benefit and payment parameters for the applicable benefit year. We are removing paragraph (b)(2) due to the new policy on collections and payments to the U.S. Treasury set forth in § 153.220. We are revising paragraph (c)(3) (now paragraph (d)(3)), to clarify that any State modification to the reinsurance payment formula pursuant to paragraph (d)(1) must be reasonably calculated to ensure that contributions received toward reinsurance are sufficient to cover payments that the applicable reinsurance entity is obligated to make under that State formula for the given benefit year for the reinsurance program. We are making a number of clarifying modifications throughout this section.

Comment: We received a number of comments that emphasized that reinsurance programs typically are tied not to underlying conditions that lead to high enrollee medical costs, but to claims costs beyond a specific dollar threshold within a coverage period, regardless of enrollees' health condition. Several commenters stated 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 would require more extensive verification than usually required by traditional reinsurance. Another commenter stated that reinsurance that makes payments based solely on incurred costs does not encourage efficient and effective care.

Response: We are finalizing the provisions that base reinsurance payments on total claims costs, rather than specific diagnoses. We believe that because reinsurance payments are likely to only reimburse a portion of claims costs above the attachment point and will pay no costs above the reinsurance cap, there will still be incentives for an issuer to encourage efficient and effective care.

Comment: We received a few comments suggesting that States be permitted to use one of the other approaches proposed by the American Academy of Actuaries for determining eligible individuals for reinsurance.

Response: In consultation with HHS, the American Academy of Actuaries proposed four approaches for determining eligible individuals for the reinsurance program, described in the preamble to the proposed rule. From those proposals, we selected the approach based on total claims costs. We believe that permitting States the flexibility to select one of the other American Academy of Actuaries approaches would unnecessarily burden issuers operating in multiple States. Because reinsurance is a transitional program, we wish to avoid that additional burden on issuers, and are finalizing the proposed policy that uses total claims cost.

Comment: We received many comments supporting our proposed approach for calculating reinsurance payments based on the use of an attachment point, coinsurance rate, and reinsurance cap. One commenter expressed concern that the proposed approach may reduce the incentive to control costs.

Response: We understand the concerns regarding cost control. However, since issuers are likely to not be fully reimbursed under the reinsurance program for claims costs above the attachment point, we believe that they will continue to have an incentive to control costs.

Comment: We received a comment asking for clarification on whether reinsurance payments are made on an incurred basis.

Response: As indicated in the proposed definitions for "attachment point," "coinsurance rate," and "reinsurance cap," we intend for claims costs to be measured on an incurred

basis for purposes of calculating reinsurance payments.

5. Disbursement of Reinsurance Payments (§ 153.240)

In § 153.240, we proposed parameters for the timing of reinsurance payments. In paragraph (a) of this section, we proposed 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 State notice of benefit and payment parameters described in subpart B, or in the annual HHS notice of benefit and payment parameters.

In paragraph (b), we proposed that a 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 proposed in paragraph (b)(2) (now paragraph (b)(1)), to allow a State to reduce payments on a pro rata basis to match the amount of contributions received by the State in a given reinsurance year, and to require that pro rata reductions made by the State be made in a fair and equitable manner for all health insurance issuers in the individual market.

In paragraph (b)(3) (now paragraph (b)(2)), we proposed that a State be required to ensure that an applicable reinsurance entity make payments as specified in § 153.410(b) to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment. Finally, in paragraph (c), we proposed that for each benefit year, the State be required to maintain all records related to the reinsurance program for 10 years, consistent with requirements for record retention under the False Claims Act.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions with the following modifications:

We are clarifying in paragraph (b) that the State must ensure that each applicable reinsurance entity does not make reinsurance payments that exceed contributions received to date. We are removing paragraph (b)(1) because those requirements are covered in § 153.230 and paragraph (b)(2) (formerly paragraph (b)(3)). We are clarifying in paragraph (b)(1) (formerly paragraph (b)(2)), that if a State, or HHS on behalf of the State, determines that reinsurance payments requested for a calendar year will likely exceed the reinsurance contributions that will be received for

the year, the State, or HHS on behalf of the State, may reduce reinsurance payments, so long as the manner in which payments are reduced is fair and equitable for all health insurance issuers in the individual market. We are making a number of clarifying modifications throughout this section.

Comment: We received many comments related to the timing of reinsurance payments. Some commenters asked that States be provided flexibility in determining payment timeframes. A few commenters suggested that contributions be collected monthly, but that payments be made quarterly. One commenter suggested providing early funds to small carriers to cover potential cash flow shortfalls.

Response: We recognize the importance of providing issuers with reinsurance payments in a timely manner, but we believe it is prudent to maintain flexibility in payment timing to ensure that sufficient contributions are available to fund those payments. We are finalizing the proposal permitting States to establish the payment timeframe in the State notice of benefit and payment parameters described in subpart B. For reinsurance programs established by HHS on behalf of the State, HHS will publish the payment timeframe in the HHS notice of benefit and payment parameters. We anticipate that States will take into account the cash flow needs of small issuers in setting the reinsurance payment timeframes.

Comment: We received several comments suggesting that HHS prohibit health insurance issuers from passing reinsurance payment shortfalls on to providers.

Response: We understand the concern raised by the commenters, and we encourage providers to work with plan issuers concerning this matter.

Comment: We received several comments on the duration of the record maintenance requirement. Commenters suggested retention requirements ranging from two to fifteen years, with many commenters suggesting a five-year period.

Response: We believe that the record retention requirements for reinsurance should be consistent with other Federal record retention requirements, and are finalizing the proposed provision that requires records to be retained for ten years, as explained above.

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

In § 153.250(a) of the proposed rule, we proposed to codify in regulation section 1341(d) of the Affordable Care

Act, which requires that States eliminate or modify high-risk pools to the extent necessary to carry out the reinsurance program. In paragraph (a), we proposed to codify in regulation the above-referenced section. In paragraph (b), we proposed to permit a State that continues its high-risk pool to coordinate its high-risk pool with its reinsurance program to the extent it conforms with the provisions of this subpart.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions with no modifications.

Comment: We received several comments recommending that high-risk pools be permitted to be offered as individual market plans eligible for reinsurance. One commenter requested that reinsurance contributions be used to fund the costs of operating State high-risk pools during the three-year period. Several commenters suggested not combining reinsurance funds with funds for high-risk pools, and opposed permitting high-risk pools to receive reinsurance payments.

Response: We clarify in § 153.400 that State high-risk pools are excluded from contributions and payments. We clarify, as we did in the proposed rule, that none of the funds collected for reinsurance can be used for any purpose other than for making payments under the reinsurance program or for administering that program. We understand the concerns of some commenters regarding the transition of high-risk pool participants and point out that the Exchanges will work with State high-risk pools to ensure a smooth transition and continuity of care for these enrollees. We believe that the reinsurance program, along with the risk adjustment and risk corridors programs, were designed in anticipation of new high-cost enrollees, some of whom may currently be receiving coverage through State high-risk pools.

Comment: We received a comment suggesting coordination between PCIP and the transitional reinsurance program.

Response: Section 1101 of the Affordable Care Act requires coordination between PCIP and the Exchanges. To the extent that individuals previously enrolled in PCIP enroll in reinsurance-eligible plans, issuers will have access to the reinsurance program for these enrollees.

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

In subpart D, we proposed standards for States with respect to the risk adjustment program required under

section 1343 of the Affordable Care Act. Parallel provisions for health insurance issuers were proposed in subpart G of this part. 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. 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 interpret section 1343 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 within each State.

1. Reserved (§ 153.300)

Section 153.300 of the proposed rule defined a number of terms used in this subpart. Those definitions have been moved to subpart A. We are reserving this section for future use.

2. Risk Adjustment Administration (§ 153.310)

In this section, in paragraph (a)(1), we specified that any State electing to establish an Exchange is eligible to establish a risk adjustment program. Pursuant to section 1321(c)(1) of the Affordable Care Act, we proposed in paragraph (a)(2) that for States that do not operate an Exchange, HHS will establish a risk adjustment program. We also clarified in paragraph (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. We are finalizing this provision, with a number of clarifying modifications.

Comment: Many commenters supported permitting States to defer operation of a risk adjustment program to HHS. One commenter recommended that any State should be eligible to operate a risk adjustment program, whether or not the State is establishing an Exchange.

Response: An effective risk adjustment program is critical to prevent adverse selection and stabilize premiums inside and outside the Exchanges. Developing a risk adjustment program is methodologically and operationally complex. We believe that, particularly in the initial years, States may wish to defer risk adjustment operation to HHS in order to focus resources on establishing Exchanges. We are therefore finalizing these provisions to provide States the option to operate risk adjustment if they establish Exchanges. Because we believe that the Federally Facilitated Exchange should be operated in coordination with a risk adjustment program that is closely tied to its implementation, States not operating Exchanges and States entering into a partnership with or relying entirely on the Federally Facilitated Exchange will not be permitted to operate a risk adjustment program. We will clarify in future guidance the process through which a State will notify HHS of its choice to operate risk adjustment if it establishes an Exchange beginning in 2014 or any subsequent year.

In paragraph (b), we clarified that a 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 an Exchange set forth in § 155.110 of the proposed Exchange Establishment rule. Considering the comments received, we are finalizing this provision, noting that the definition of an entity eligible to serve as an Exchange has been modified from the proposed definition.

Comments: Commenters offered varying opinions regarding the requirements for entities to be eligible to administer risk adjustment. Several commenters urged HHS to include stronger provisions prohibiting conflicts of interest. Those commenters stated that all members of the board of a risk adjustment entity should be free of financial ties to issuers, and that consumer representation on the board should be required. One commenter believed that an entity's eligibility to be a risk adjustment entity should be based on the entity's experience, and not on the requirements governing entities carrying out Exchange functions. Other commenters stated that the requirements on entities eligible to administer risk adjustment and carry out Exchange functions were overly restrictive, noting that the requirements would exclude State regulators, such as a State Department of Insurance. This commenter asked that the regulator in

each State be eligible to administer risk adjustment. Two commenters suggested that entities be eligible to administer both risk adjustment and reinsurance.

Response: We believe that a State may have a single entity administer reinsurance and risk adjustment, provided that the entity meets the separate requirements to administer both programs. We note that to be eligible to administer reinsurance, an entity must meet the definition outlined in § 153.20. We also appreciate concerns that risk adjustment entities may have board members with conflicts of interest and, further, that because risk adjustment involves the transfer of money between plans, these concerns may be especially relevant for this program. We encourage States to weigh these concerns when establishing a risk adjustment entity. However, we seek, to the extent possible, consistency between the requirements to serve as a risk adjustment entity and the requirements to serve as an entity performing other Exchange functions.

In paragraph (c), we proposed timeframes for the risk adjustment process. We proposed that all payment calculations commence with the 2014 benefit year. We sought comment on the appropriate deadline by which risk adjustment must be completed each year. In response to comments, we are finalizing the standard that risk adjustment be implemented beginning with the 2014 benefit year, and are including a requirement that each issuer be notified of risk adjustment payments owed to, or charges owed by, the issuer by June 30 of the year following the benefit year. We believe that this deadline best balances the need to coordinate risk adjustment payments and charges with other programs, and the need to ensure that high quality risk adjustment data is available to support the program.

Comments: We received a number of comments recommending that risk adjustment be performed before completion of the MLR calculation process. Two commenters specified that risk adjustment should be completed by late May of the year following the benefit year in order to accommodate the Federal MLR reporting deadline of June 1. Other commenters stated that it would be difficult to coordinate risk adjustment payments with MLR reporting. Two commenters suggested extending the MLR deadline for 2014 through 2016. One commenter suggested delaying the implementation of risk adjustment until 2016.

Response: The risk adjustment process relies in part on high quality claims data. Allowing for claims run-out

after the benefit year increases the amount and quality of claims data because issuers will have more time to receive, review and pay claims made during the benefit year. Better quality data will lead to more accurate risk scores, which ultimately feed into the calculation of plan average actuarial risk and the calculation of payments and charges.

In the preamble to the proposed rule, we discussed requiring that States complete the risk adjustment process by June 30 of the year following the benefit year, or June 30, 2015 for the benefit year 2014. States would be free to set a payment schedule (including interim payments throughout the benefit year), but would be required to comply with the June 30 deadline. Many commenters agreed that June 30 was a reasonable deadline for completion of the risk adjustment process. We have included in the final rule a June 30 deadline for the completion of the risk adjustment process. We believe that 6 months following the benefit year is a reasonable timeframe to complete the risk adjustment process.

The deadline to submit MLR reports to the Federal government is June 1 of the year following the calendar year experience being reported. MLR calculations must take into account risk adjustment payments and charges. We recognize that our proposed deadline is inconsistent with the current Federal MLR reporting deadline, but believe that allowing sufficient time to collect quality data to support risk adjustment is extremely important and would be extremely difficult to complete within current MLR timeframes. We will work to resolve this issue prior to 2014.

Comments: A few commenters suggested that risk adjustment payments be made quarterly, with the final payment to be made after the first quarter of the year following the benefit year.

Response: We believe that States should have the flexibility to set a payment schedule that best suits their program administration. Therefore, we did not include a requirement that States adhere to a specific payment schedule.

In the preamble to the proposed rule, we discussed our belief 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 final rule directs States to submit an annual summary report of their program. We believe that this report will permit States to learn from other States' experience and will help HHS evaluate the implementation of the risk

adjustment program. We will specify the contents of the report in future guidance, but expect the report would include information such as plan average actuarial risk score and the risk adjustment payment or charge for each risk adjustment covered plan in the State, trends in risk scores over time, evidence of upcoding, and other risk adjustment-related elements. We expect that States will make summary reports publicly available. We believe this report will facilitate periodic evaluation, oversight, and continuous improvement of the risk adjustment program.

Comment: Several commenters supported the concept of providing summary reports. However, one commenter was unwilling to fully support the requirement until knowing the content that would be required in the report. Two commenters suggested that the report include the average actuarial risk for each plan, the risk adjustment charge or payment for each plan, and information on risk scores and cost trends, including evidence of upcoding and error rates determined under the most recently completed risk adjustment data validation audits. We also received comments requesting that HHS require that State risk adjustment entities report information about their States' risk adjustment program to issuers. Finally, we received one comment suggesting that all funds collected by the risk adjustment entity be required to be used only in connection with the risk adjustment program.

Response: Annual summary reports can serve as a tool for States and HHS to monitor and evaluate State programs across the country. HHS will also be able to use the reports to provide technical assistance to States administering risk adjustment programs when needed. The technical assistance will serve not only to improve a State's risk adjustment program, but will reduce the burden on each State to evaluate and improve its risk adjustment program. The information in the annual reports will also be useful in evaluating the implementation of the Federally developed risk adjustment methodology and other Federally certified risk adjustment methodologies. For these reasons, we have added paragraph (d) to this final rule to ensure that States submit annual risk adjustment program reports to HHS.

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 plan average actuarial risk. In § 153.300 of the proposed rule, we defined the risk adjustment methodology as encompassing the risk adjustment model, the calculation of plan average actuarial risk, and the calculation of payments and charges.

We proposed in paragraph (a)(1) that a Federally certified risk adjustment methodology be developed by HHS. We proposed in paragraph (a)(2) that a State-submitted alternate risk adjustment methodology may become a Federally certified risk adjustment methodology through HHS certification. For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with certain clarifying modifications.

Comments: One commenter requested clarification on when State alternate methodologies would be required to be submitted and would be evaluated. Multiple commenters expressed a preference that State and Federal methodologies be announced early enough to give sufficient time for issuers to incorporate anticipated risk adjustment payments or charges into their rates.

Response: While the proposed timing necessitates a short window for submission and evaluation of the alternate risk adjustment methodologies, the timeframe permits a State to evaluate the methodology proposed by HHS in the proposed annual HHS notice of benefit and payment parameters. This timeframe also permits HHS to publish all certified methodologies at one time in the final annual HHS notice of benefit and payment parameters. In future years, HHS will evaluate whether it should accept and evaluate applications for alternate risk adjustment methodologies on an earlier timeframe. However, in the initial year, the HHS methodology will likely not have been fully developed in time to benchmark alternate risk adjustment methodologies on an earlier timeframe.

We proposed in paragraph (b)(1) 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 an annual HHS notice of benefit and payment parameters. We proposed that State notices of benefit and payment parameters include a full description of the risk adjustment model, including, but not limited to: (1) Demographic factors, diagnostic factors, and utilization factors (if any); (2) the

qualifying criteria for establishing that an individual is eligible for a specific factor; (3) the weights assigned to each factor; and (4) the schedule for the calculation of individual risk scores. We sought comments on other information that should be included in this notice. In paragraph (b)(2), we proposed 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.

Considering the comments received, we are finalizing this provision, with the following modifications: We are clarifying that notices must also include a description of the calculation of plan average actuarial risk, a description of the calculation of payments and charges, and a description the risk adjustment data collection approach. We are also including a number of other clarifying modifications.

Comments: We received several comments supporting a structure in which HHS will develop a risk adjustment methodology but States have the option to submit alternate methodologies for approval by HHS. Several commenters preferred that HHS establish one national methodology. Other commenters suggested that States be required to justify deviation from the methodology developed by HHS. Two commenters believed that HHS approval of State methodologies was unnecessary, and that any State alternate methodology should be deemed certified and available to all States. Some commenters suggested that all methodologies be subject to notice and comment.

Response: We recognize that States may wish to employ alternate risk adjustment methodologies, and believe that alternate approaches could achieve results similar to those that will be achieved by the methodology developed by HHS. We agree that States should submit a rationale for their proposed alternate methodology for certification. We are therefore finalizing the proposed rule, which required publication of a rationale, with a number of clarifying modifications. HHS will develop a Federal risk adjustment methodology, and States that wish to deviate from that methodology may submit an alternate methodology to HHS for approval. States must specify in their State notice of benefit and payment parameters which of the Federally certified methodologies published in the annual HHS notice of benefit and payment parameters they will use. We believe that the publication of the Federal methodology in a notice of benefit and payment parameters addresses certain

commenters' desire that interested parties be given opportunity to comment on the methodology proposed by HHS. HHS will provide an opportunity for public comment when it administers risk adjustment on behalf of a State. State law will govern what administrative process is necessary when a State adopts a risk adjustment methodology, subject to the limits of this final rule and the annual HHS notice of benefit and payment parameters.

In paragraph (c), we proposed that HHS will specify in the annual HHS notice of benefit and payment parameters the Federally certified risk adjustment methodology that will apply when HHS operates the risk adjustment program. We are finalizing this provision, with a number of clarifying modifications.

The statute is not specific with respect to the method by which States are expected to determine the precise value of payments and charges, so we requested comment on two payments and charges methodologies and whether there are alternate methodologies that might be used. We received a number of comments requesting consistency in methodology from State to State. Therefore, we plan to establish a national method for the calculation of payments and charges that States may not vary. A national method for the calculation of payments and charges ensures a degree of consistency in the risk adjustment program from State to State while allowing States to vary certain elements of the program.

Comments: Many commenters recommended that HHS establish one national methodology or limit States' ability to deviate from the methodology developed by HHS. Other commenters supported giving States the flexibility to propose alternate methodologies so long as those methodologies are as robust as the one proposed by HHS.

Response: The calculation of payments and charges requires selection of a baseline premium, for example, a plan average or State average premium. That premium basis is multiplied by the plan average actuarial risk to calculate risk adjustment payments or charges, and requires balancing if payments do not equal charges. Thus, the calculation of payments and charges affects the amount of funds transferred from low-risk to high-risk plans, and can affect premiums in low-risk and high-risk plans.

Although a national standard methodology for calculating payments and charges provides a degree of consistency from State to State, we recognize it may also limit States' ability

to implement novel methodologies. We believe that there may be potential to introduce State variation in the calculation of payments and charges in the future. We also believe that requiring a national methodology for calculating payments and charges initially, and leaving open the possibility of permitting State variation in later years, relieves States from the burden of developing such a methodology in the first year, and provides a starting point for States seeking to create alternate methodologies in later years.

4. State Alternate Risk Adjustment Methodologies (§ 153.330)

We proposed allowing States to utilize alternate risk adjustment methodologies, provided that States taking advantage of this flexibility submit their proposed alternate risk adjustment methodologies for HHS review and certification. We proposed in paragraph (a)(1) the information about the State's proposed risk adjustment methodology that the State must include in its request for certification. In paragraph (a)(2), we proposed that all requests include information relating to certain criteria to be used in the evaluation of the request.

For the reasons described in the proposed rule, and considering the comments received, we are finalizing these provisions with the following modifications: We are including new language requiring States to provide a description of the risk adjustment methodology. This change aligns this provision with changes made to § 153.320 discussed above. We are also making a number of clarifying modifications throughout this section.

Comments: Several commenters requested greater specificity about the validation requirements for the proposed alternate risk adjustment methodologies. One commenter requested that HHS permit States to vary payments based on whether a plan participates in the Exchange or the Small Business Health Options Program. Another commenter suggested that States be permitted to vary payments based on whether the issuer implements programs to improve population health. Other commenters suggested other requirements for certification of alternate risk adjustment methodologies. For example, one commenter recommended requiring that an alternate methodology include either a separate model for pediatrics or demonstrate the model's effectiveness in pediatric populations. Another commenter recommended requiring States to specify how they will move

from a retrospective to a prospective risk adjustment approach. A number of commenters supported use of a prospective approach, while others favored a retrospective approach. Some commenters supported a diagnosis-based risk adjustment model, while others favored a demographic approach. One commenter suggested that a survey-based approach be utilized.

Response: We anticipate that a number of different approaches could receive Federal certification. HHS will provide further details on the process for receiving Federal certification for alternate risk adjustment methodologies in the draft annual HHS notice of benefit and payment parameters. State alternate methodology requests will be accepted up to 30 days after publication of the draft annual HHS notice of benefit and payment parameters, and alternate methodologies that are certified by HHS will be published in the final HHS notice of benefit and payment parameters.

In paragraph (b), we proposed that a State that operates 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. Considering the comments received, we are finalizing this provision with the following modifications: We are including language clarifying that the need to obtain recertification of a recalibrated risk adjustment model applies to any alteration to the Federally certified risk adjustment methodology.

Comment: We received two comments supporting a requirement that States wishing to recalibrate or otherwise change their methodology submit that change to HHS for approval.

Response: We are finalizing this policy.

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 plan and State average actuarial risk. In paragraph (a), we proposed that a State, or HHS on behalf of the State, be responsible for collecting data for use in the risk adjustment program. 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 individual risk scores to the entity responsible for assessing risk adjustment charges and payments.

Considering the comments received, we are modifying this paragraph as follows: Rather than specify an intermediate risk adjustment data collection approach, we are permitting States that elect to operate a risk adjustment program to choose the risk adjustment data collection approach that best suits their program. HHS will use a distributed approach when operating risk adjustment on behalf of a State. Because a distributed approach to data collection has not been implemented on this scale, we plan to evaluate the implementation and may make changes to the approach based on that evaluation. We are including a requirement that States operating risk adjustment collect or calculate, at a minimum, individual risk scores. This requirement minimizes the collection of sensitive data while allowing States to calculate rating variation adjustments and payments and charges. We are modifying the privacy and security standards applicable when a State is operating risk adjustment. Protecting the privacy and confidentiality of an individual's personal health information continues to be among HHS' highest priorities. Under a distributed approach, issuers will need to format risk adjustment data, maintain that data in a manner that complies with State or HHS specifications, and in some cases run risk adjustment software. In addition, a State, or HHS on behalf of the State, will not be required to collect claims data; however, the data validation and audit process will be more involved.

Comments: We received a large number of comments on the collection of risk adjustment data, including many comments supporting HHS' proposed collection of risk adjustment data at the State level. A number of other commenters expressed concern for patient privacy under the proposed method of data collection. Some of those concerned about patient privacy did not explicitly oppose the proposed risk adjustment data collection approach, but encouraged HHS to collect de-identified data or carefully consider privacy and security standards, such as techniques to mask or encrypt data. We received many comments in favor of a distributed approach to risk adjustment data collection. These comments focused on the administrative complexity of transmitting claims data

to HHS and the risk of exposing private information and competitively sensitive data, such as unit prices for medical services. Another commenter suggested that States be given flexibility to choose which risk adjustment data collection approach to use when operating risk adjustment.

Response: The transmission by issuers to HHS and the storage by HHS of large amounts of sensitive data pose potential risks to consumer privacy. A distributed approach would leverage the existing data infrastructure of issuers, potentially saving Federal and issuer resources. For these reasons, HHS will utilize a distributed approach to collecting risk adjustment data when operating risk adjustment on behalf of a State.

We considered requiring that all States utilize a distributed approach to risk adjustment data collection, as HHS will do. However, we believe that requiring a particular approach runs counter to the flexibility generally afforded States by the Affordable Care Act and HHS.

We proposed in paragraph (b) that the State, or HHS on behalf of the State, use standard HIPAA transaction standards when collecting data. We proposed in paragraphs (b)(1) and (b)(2) to require States to utilize two specific HIPAA transaction standards for risk adjustment data collection. In paragraph (b)(3), to address consumer privacy concerns, we proposed that States must utilize specific privacy standards in their data collection risk adjustment procedures.

Considering the comments received, we are modifying this paragraph as follows: We are including a requirement that States require issuers to comply with the data privacy and security standards set forth in the State's notice of benefit and payment parameters.

Because we maintain the flexibility for States that operate risk adjustment programs to choose their data collection approaches, we are including a requirement that States limit their collection to the information reasonably necessary to operate the risk adjustment program. For example, a State could not collect an enrollee's name, because that information would not be reasonably necessary to operate the risk adjustment program. We are prohibiting a State from collecting or storing any personally identifiable information for use as a unique identifier for an enrollee's data, unless that information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State. The term "personally identifiable information" is a broadly used term across Federal agencies, and has been defined in the Office of

Management and Budget Memorandum M-07-16. In order to reduce duplicative guidance or potentially conflicting regulatory language, we are not defining personally identifiable information in this final rule, and incorporate the aforementioned definition into this final rule.

The privacy and security standards outlined above reflect the changes in the risk adjustment data collection approach in paragraph (a) of this section. We note that these standards should be read to represent a minimum standard to be used in the risk adjustment program. We expect that States will build on these minimum privacy and security standards when establishing a risk adjustment data collection program.

Comment: We received a number of comments about privacy concerns associated with the proposed collection of risk adjustment data. Some commenters believed that HHS should finalize a requirement that any risk adjustment data collected be de-identified. Others preferred that data not be collected.

Response: We are committed to applying strong privacy and security standards to risk adjustment data collected by States or HHS on behalf of a State. We are amending the proposed privacy and security standards so that States that limit their collection of personally identifiable information to that which is reasonably necessary to carry out their risk adjustment methodology. In paragraph (b)(4), we require States to implement security standards that provide administrative, technical, and physical safeguards consistent with the standards described in the HIPAA Security Rule at 45 CFR 164.308, 164.310, and 164.312. We recognize that the specific requirements for data collection may vary depending on the amount and type of data States choose to collect, and thus we decided to permit States to design security requirements to accommodate these requirements. This final rule does not preclude States from implementing stricter security standards, particularly if they choose to collect additional risk adjustment data. HHS will not be collecting the claims data from issuers needed to run the risk adjustment methodology when HHS runs risk adjustment on behalf of a State. HHS will issue further guidance regarding the privacy and security standards applicable when HHS is operating risk adjustment on behalf of a State.

In paragraph (c), we proposed that States with existing all-payer claims databases may request an exception from the minimum standards for data

collection. In paragraph (d), we proposed that the State must make certain risk adjustment data available to support other activities, including: recalibrating Federally certified risk adjustment models; verifying risk corridor submissions; and verifying and auditing reinsurance claims. We have removed paragraphs (c) and (d) because these requirements are not compatible with flexibility with regard to risk adjustment data collection. In the proposed rule and preamble, we discussed a number of ways risk adjustment data could be used to support other programs such as verifying risk corridor submissions, reinsurance payments, cost-sharing reductions, and quality improvement efforts. We are continuing to explore how to obtain the data needed to support these programs. We anticipate working closely with States and issuers to efficiently gather or access the data needed to support these programs.

Comments: We received a few comments requesting that existing data collection initiatives such as all-payer claims databases be utilized to the fullest extent possible to support risk adjustment.

Response: A State operating a risk adjustment program may choose to utilize all-payer claims databases, provided that the State complies with the requirements set forth in this paragraph.

Comments: We received several comments supporting the use of risk adjustment data for other Affordable Care Act purposes. Two commenters were wary of permitting access to data for uses beyond risk adjustment because they view the data as sensitive and wish to limit Federal access to it.

Response: We believe that HHS' use of a distributed approach for risk adjustment addresses many concerns regarding centralized data collection of risk adjustment data. We are currently exploring options to collect the information needed for other purposes. We believe that States administering a risk adjustment program should, to the extent possible, seek efficiencies in data collection across programs.

6. Risk Adjustment Data Validation Standards (§ 153.350)

In § 153.350, we proposed that States have a reliable data validation process, which is essential to the establishment of a credible risk adjustment program. In paragraph (a), we proposed 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. In paragraph (b), we proposed that the State, or HHS on

behalf of the State, be permitted to adjust the average actuarial risk for each plan based on the error rate found in the validation. In paragraph (c), we proposed that the State, or HHS on behalf of the State, be permitted to adjust payments and charges based on the changes to average actuarial risk. Finally, in paragraph (d), we proposed that the State, or HHS on behalf of the State, be required to provide an appeals process for issuers.

Considering the comments received, we are finalizing this provision, with the following modifications: We are expanding the data validation requirements to include requirements applicable to a distributed risk adjustment data collection approach, and are making a number of clarifying modifications throughout this section.

Comments: We received several comments on data validation. We received a number of comments supporting the proposed data validation requirements. For the most part, commenters supported data validation requirements for every issuer offering risk adjustment covered plans in a State. A few commenters suggested that HHS add requirements on States, establish a national validation methodology, or perform the validation itself.

One commenter suggested that States be allowed to establish minimum values, under which annual data validation would not be required. For example, issuers with fewer than 5,000 members and less than 1 percent of the overall market would not be required to validate data annually; instead, these issuers would be required to validate data every 2 or 3 years.

Response: We believe that the data validation standards we are finalizing represent appropriate minimum standards. We believe that annual data validation for all issuers is necessary to ensure a robust risk adjustment program, and so do not believe that minimum values for annual data validation or data validation that occurs less frequently are appropriate.

Comment: We also received a number of comments about the specific data validation methodology or process. Several commenters suggested that data validation be completed throughout the year and certified at the end of the year. One commenter suggested including a requirement that data validation be maintained for the duration of risk adjustment operation. One commenter suggested that diagnoses identified by health care providers apply even if, upon subsequent audit, HHS determines that the patient's medical records did not support the provider's diagnosis. One commenter urged that States be

required to design risk adjustment data validation standards using a methodology similar to that used under the CMS-Hierarchical Condition Category system.

Response: We believe that a State should have the discretion to design its risk adjustment program, including the method for data validation. Given that risk adjustment occurs at the State level, the possibility of differences from State to State do not present a significant problem. For this reason, we are finalizing the data validation requirements with the modifications described above.

Comment: We received one comment suggesting that we insert the phrase "or HHS on behalf of the State" in paragraph (c).

Response: In the preamble to the proposed rule, we proposed "that the State, or HHS on behalf of the State, adjust payments and charges based on the changes to average actuarial risk." However, the phrase "or HHS on behalf of the State" was omitted from the proposed regulation text in paragraph (c). We are amending the final rule text to be consistent with § 153.350(a) and (b) of, and the preamble to, the proposed rule.

E. Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

In subpart E of the proposed rule, we proposed standards for health insurance issuers that complemented the standards for the transitional reinsurance program more fully described in the preamble to subpart C of the proposed rule. Subpart C discussed standards of the program applicable to States. In subpart E, we discussed the standards applicable to health insurance issuers and self-insured group health plans.

1. Reinsurance Contribution Funds (§ 153.400)

In § 153.400, we proposed to codify in regulation 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 proposed 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. In paragraph (b), we proposed that if the State establishes multiple applicable reinsurance entities, the contributing entity must contribute an appropriate payment to each applicable reinsurance entity. We proposed in paragraph (c) (now paragraph (d)), that contributing entities

be required to provide the data necessary for the applicable reinsurance entity to calculate the amounts due from each contributing entity.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with the following modifications:

We are clarifying in paragraph (a) that a contributing entity must make contributions for all reinsurance contribution enrollees who reside in a State at the national rate and any additional contribution rate if a State elects to collect additional contributions. We are adding paragraph (a)(1), which clarifies that all contributing entities must make reinsurance contributions on behalf of all group health plans and health insurance coverage they represent except those set forth in paragraph (a)(2). For example, contributing entities are required to make reinsurance contributions on behalf of plans in the Federal Employee Health Benefit Program, State and local government employee plans, and grandfathered health plans. The Affordable Care Act requires these issuers and third-party administrators on behalf of self-insured plans to make reinsurance contributions.

In paragraph (a)(2), we are clarifying that contributing entities are not required to make contributions on behalf of plans or health insurance coverage that consists solely of excepted benefits within the meaning of section 2791(c) of the PHS Act. Section 1341(b)(3)(B)(i) of the Affordable Care Act requires the contribution amount for an issuer to be based on the issuer's fully insured commercial book of business for all major medical products. Issuers of certain plans are excluded from making reinsurance contributions because those plans are not "commercial books of business" or "major medical" products. Thus, private Medicare and Medicaid plans and Federal and certain State high-risk pools are exempt from making reinsurance contributions because they are not a "commercial book of business." Further, stand-alone vision and dental plans and other plans defined as excepted benefits within the meaning of section 2791(c) of the PHS Act are exempt because they are not "major medical" products.

In a new paragraph (c), we are requiring that each contributing entity submit contributions due to the Federal applicable reinsurance entity on a quarterly basis beginning January 15, 2014. We believe this timeframe is consistent with industry practice and will allow for timely transfer of

contribution funds to States and the U.S. Treasury. We believe that States should have the flexibility to set the frequency of collections by the applicable reinsurance entity.

In a new paragraph (d), we are clarifying that each contributing entity must submit to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions, data required to substantiate contribution amounts, in the format and with the timing specified by the State or HHS. For example, HHS may request this data in the form of a report that specifies the number of reinsurance contribution enrollees covered by a plan in each State in a month.

Comment: We received a number of comments requesting clarification as to whether certain types of plans, such as multi-State plans and CO-OP plans, are contributing entities.

Response: We believe that section 1341(b)(1)(A) of the Affordable Care Act directs a broad cross-section of issuers and self-insured plans to make reinsurance contributions, given the uncertainty of the size and characteristics of the population that will participate in the Exchanges. We discuss whether certain plans are required to make reinsurance contributions in the preamble above.

Comment: One commenter suggested that HHS clarify whether the Basic Health Plans described in Section 1331 of the Affordable Care Act will be subject to reinsurance contributions or eligible for reinsurance payments.

Response: Since guidance and regulations regarding the Basic Health Plans have not yet been issued by HHS, we are unable to provide direction at present on whether these plans are subject to the reinsurance program.

Comment: We received several comments recommending that reinsurance contributions be collected on a quarterly basis. One commenter recommended an annual collection.

Response: We have included a provision that requires that contributions to HHS be submitted quarterly in paragraph (c). A State that elects to collect contributions may set its own timeframe for collection. However, we encourage States to adopt a timeframe similar to the one adopted by HHS to minimize the burden on issuers in multiple States.

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) of the proposed rule, we

proposed that reinsurance-eligible plan issuers be required to submit a request for reinsurance payment to the applicable reinsurance entity. We proposed in paragraph (b) that this request be made according to the method specified in the annual HHS notice of benefit and payment parameters.

For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions, with certain clarifying changes.

Comment: We received a comment requesting that HHS provide standards for issuers to request payment.

Response: Issuers of reinsurance-eligible plans will make requests for payment in accordance with the procedures set forth in the annual HHS notice of benefit and payment parameters. If a State establishes a reinsurance program, then it will publish guidance regarding data requirements for reinsurance payment in its State notice of benefit and payment parameters.

Comment: We received a few comments regarding the frequency of reinsurance payments. One commenter suggested a monthly reinsurance payment cycle. The commenter suggested that the reinsurance entity pay claims at 75 percent of the eligible amounts, with the remaining 25 percent of eligible claims becoming payable at the end of the year to the extent funds are available. One commenter suggested a payment process at the end of the benefit year. Another commenter suggested that reinsurance payment requests be permitted to be submitted whenever an individual claim causes a beneficiary's accumulated claims costs for the plan year to exceed the attachment point, and that adjustments be permitted to be submitted as the claim fully develops.

Response: Further guidance on the reinsurance claim and payment process will be provided in the HHS notice of benefit and payment parameters.

Comment: We received comments regarding the deadline for reinsurance payment requests and late claims. One commenter suggested that reinsurance-eligible claims be required to be submitted no more than six months after the plan year, and that claims not filed within that timeframe become ineligible for reinsurance payment. Another commenter suggested that the ability to submit late claims be restricted to ensure that late claims do not delay MLR rebates to consumers or risk corridors payments to insurers.

Response: We will provide further guidance on the deadline for requests

and on late claims in the annual HHS notice of benefit and payment parameters.

F. Subpart F—Health Insurance Issuer Standards Related to the Temporary Risk Corridors Program (§ 153.500–§ 153.530)

In this subpart, we proposed requirements on health insurance issuers related to the temporary risk corridors program which section 1342 of the Affordable Care Act established for the first three years of Exchange operation (2014–2016). Risk corridors create a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. QHP issuers with allowable costs that are less than 97 percent of the QHP's target amount will remit charges for a percentage of those savings to HHS, while QHP issuers with allowable costs greater than 103 percent of the QHP's target amount will receive payments from HHS to offset a percentage of those losses.

1. Definitions (§ 153.500)

In § 153.500, we proposed a number of definitions for purposes of administering risk corridors. We proposed to define "allowable administrative costs" as 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). We proposed to 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. "Charge" was defined as the flow of funds from QHP issuers to HHS. "Direct and indirect remuneration" was defined by reference to the definition used for Medicare Part D purposes. "Payment" was defined as the flow of funds from HHS to QHP issuers. "Qualified health plan" was defined by reference to the definition for the term included in the proposed Exchange Establishment rule. "Risk corridors" was defined as any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount. "Target amount" was defined as 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.

Considering the comments received and other considerations discussed below, we are finalizing this section with the following modifications:

We are adding the defined term, “administrative costs,” meaning total non-claims costs for a QHP as defined in § 158.160(b). We are revising the defined term, “allowable administrative costs,” to mean administrative costs, capped at 20 percent of premiums earned. We are revising the definition of “allowable costs” to reference the MLR term “incurred claims” and to include quality improvement and health information technology expenditures, as defined in the MLR rule. We are also referencing the after-the-fact adjustments described in § 153.530(b) for reinsurance and risk adjustment amounts paid or received by a QHP issuer.

We are revising the definition of “direct and indirect remuneration” to mean prescription drug rebates received by the issuer within the meaning of § 158.140(b)(1)(i). This definition matches the concept from the MLR rule, which takes into account rebates, but not other forms of remuneration, such as price concessions and discounts.

We are adding the defined term, “premiums earned,” meaning monies paid by or for enrollees with respect to a QHP as a condition of receiving coverage under that plan, including any fees or other contributions paid by or for enrollees. This defined term references the equivalent definition in the MLR rule, and is intended to clarify that premiums are to be determined in a manner consistent with the MLR rule, a consistency we seek with respect to the risk corridors program when practicable. We are revising the defined term, “target amount,” to reference the new defined term “premiums earned.”

We are moving the definition of “qualified health plan” to subpart A. We are not modifying the definitions of “charge,” “payment,” or “risk corridors.” Finally, we are making a number of clarifying modifications throughout this section. Many of the revisions we are making to defined terms in this subpart are intended to parallel terms used in the MLR rule, to the extent feasible. These revised definitions are used in the risk corridors calculation in a manner that is mathematically identical to the statutory formulation in section 1342 of the Affordable Care Act.

Comment: In the preamble of the proposed rule, we discussed the possibility of imposing a 20 percent limitation on allowable administrative costs. A number of commenters supported this limitation. Some commenters supported the 20 percent limitation because it would prevent an issuer with high administrative costs from receiving risk corridors payments,

and then using those payments to pay the required MLR rebates. Other commenters stated that imposing a limitation would be consistent with the MLR rule—a consistency that could reduce the need for issuers to maintain data for two different formulas.

Response: We are revising the definition of allowable administrative costs accordingly.

Comment: We received a number of comments that supported including quality improvement expenditures in allowable costs. Some commenters also suggested including health information technology expenses, which the MLR rule also takes into account. The commenters stated that including quality improvement expenses and health information technology expenditures in allowable costs would ensure consistency with MLR requirements, and would incentivize issuers to make these investments, which could inure to the benefit of enrollees. Some commenters requested that we adopt certain modifications to those MLR definitions. For example, two commenters suggested that HHS adopt a standard-based “functional approach” for determining whether an activity or function is a quality improvement activity similar to that employed by MLR. Under this approach, the function of the activity would dictate whether it was a quality improvement activity that issuers could include in allowable costs. Another commenter recommended that quality improvement activity expenditures be based on projections.

Response: We viewed the proposed rule as including these costs in allowable costs, because they are not among the administrative costs in § 158.160(b). We are revising the definition of allowable costs to make clear that it includes both expenditures to improve health care quality and expenditures related to health information technology and meaningful use requirements. However, we are not modifying those MLR definitions for purposes of risk corridors, in order to retain consistency with the MLR calculation.

Comment: A few commenters requested that the risk corridors program not utilize the Medicare Part D formulation of direct and indirect remuneration. They stated that the Part D formulation is too broad for the risk corridors program, and that a narrower construct is appropriate here. Commenters contrasted the formulation applicable to Medicare, a governmental program, with the formulation that in their view should be applicable to commercial plans. Commenters

recommended including a number of different definitions of rebates, discounts, and price concessions. One commenter recommended using the formulation used in the retiree drug subsidy program under subpart R of the Medicare Modernization Act regulations at 42 CFR 423.880 *et seq.*

Response: We acknowledge the breadth of the proposed definition of direct and indirect remuneration, and are revising the definition to be consistent with the approach adopted by the MLR rule. The MLR rule requires deduction of prescription drug rebates received by an issuer for both reporting and calculation purposes. We intend that MLR rules for defining and determining when prescription drug rebates are received by an issuer apply for risk corridors purposes.

Comment: One commenter recommended that allowable costs be defined as the sum of claims incurred during the risk corridors reporting year and paid through March 31 of the following year plus unpaid claims liabilities associated with claims incurred during the risk corridors reporting year.

Response: We agree that the calculation of allowable costs should include a run-out period and unpaid claims liabilities, and are clarifying that allowable costs should be calculated in accordance with the MLR rule.

Comment: We received four comments about the definition of “QHP.” Three commenters stated that a plan offered by an issuer outside of the Exchange that is identical to a QHP should be subject to the risk corridors program. Those commenters cited administrative simplicity, and stated that “the pricing of QHPs is supposed to be the same whether offered on or off an Exchange.” A fourth commenter requested guidance on the issue.

Response: The Affordable Care Act provides that the risk corridors program applies to QHPs. For risk corridors purposes, the QHP definition set forth in the Exchange Establishment rule applies. A QHP issuer is not precluded from offering a QHP outside an Exchange. If a QHP issuer does so, the QHP offered outside an Exchange is subject to the risk corridors program. We believe that, in keeping with the discussion of the same premium provision in the preamble of the Exchange Establishment rule, this generally means that health plans that are substantially the same as a QHP will be subject to the risk corridors program. HHS may clarify this standard in future rulemaking or guidance.

Comment: A number of commenters requested that the risk corridors

calculation take into account profits in a manner similar to the MLR rule. Some commenters requested that allowable administrative costs include profits, margin, or underwriting gain. This inclusion would be consistent with the MLR rule, which permits an issuer in certain circumstances to have administrative expenses and profits up to 20 percent of after-tax premium revenues before a rebate is due. Commenters also noted that section 1342(a) of the Affordable Care Act states that risk corridors calculations are to be based on a similar program under Medicare Part D, which includes return on investment, an analog to profits, in the definition of target amount.

Response: The proposed rule did not address profits in the risk corridors calculation. In the HHS notice of benefit and payment parameters, we intend to propose that profits be included within administrative costs for purposes of the risk corridors calculation, consistent with MLR.

Comment: A number of commenters requested that the risk corridors calculation take into account taxes in a manner similar to the MLR rule. The MLR rule requires reporting of a broad range of taxes, and deduction of certain taxes from premiums in the MLR denominator. One commenter noted that taxes may either be subtracted from premiums or added to allowable administrative costs.

Response: The proposed rule did not address taxes in the risk corridors calculation. In the HHS notice of benefit and payment parameters, we intend to propose that taxes and other expenses be included within administrative costs for purposes of the risk corridors calculation, with those Federal and State taxes and licensing and regulatory fees described in § 158.161(a), § 158.162(a)(1), and § 158.162(b)(1) exempt from the 20 percent cap on allowable administrative expenses.

Comments: Several commenters sought clarification as to whether any of the risk corridors elements were projections. Various commenters suggested that premiums or administrative costs should reflect projections. One commenter requested a clarification to confirm the intent to use projected costs as the targeted amount.

Response: Section 1342 of the Affordable Care Act does not allow the use of projections. Furthermore, because the temporary risk corridors program is designed to limit the extent of actual issuer losses (and gains) with respect to QHPs, the program will use actual data, not projected data.

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

In § 153.510 of the proposed rule, we proposed to establish risk corridors by specifying risk percentages above and below the target amount. In § 153.510(a), we proposed to require a QHP issuer to adhere to the requirements set by HHS for the establishment and administration of a risk corridors program for calendar years 2014 through 2016. The preamble to the proposed rule stated that we would issue guidance in the annual HHS notice of benefit and payment parameters for QHPs regarding reporting and the administration of payments and charges. The preamble also stated that risk corridors guidance will be plan-specific, and not issuer-specific, as is the case with respect to the MLR rule, and that we interpreted the risk corridors provisions to apply to all QHPs offered in the Exchange.

In § 153.510, we also established the payment methodology for the risk corridors program, using the thresholds and risk-sharing levels specified in statute. In § 153.510(b), we described the method for determining payment amounts to QHP issuers. 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 a QHP with 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.

In § 153.510(c), we described 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 proposed 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 with 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 a QHP with allowable costs below 92 percent of the target amount, the QHP issuer will remit charges to HHS in 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.

While we did not propose deadlines in the proposed rule, we discussed in the preamble timeframes for QHP

issuers to remit charges to HHS. We suggested, for example, that a QHP issuer required to make a risk corridors payment may be required to remit charges within 30 days of receiving notice from HHS, and that HHS would make payments to QHP issuers that are owed risk corridors amounts within a 30-day period after HHS determines that a payment should be made to the QHP issuer. QHP issuers who are owed these amounts will want prompt payment, and payment deadlines should be the same for HHS and QHP issuers. We sought comment on these proposed payment deadlines in the preamble to the proposed rule.

Considering the comments received, we are finalizing this section as proposed, with a few clarifying modifications.

Comments: We received a number of comments suggesting that the risk corridors calculation should be performed at a less granular level than the plan level. The most common suggestion was aggregation at the issuer level, although other alternatives were suggested. One commenter suggested aggregation at the carrier, State and business line level, while another recommended applying the risk corridors calculation separately to an issuer's aggregate non-group QHP business and aggregate small group QHP business. One reason advanced for these alternatives was consistency with the MLR rules, which apply at the issuer level. Commenters also noted that issuers do not currently accumulate data at the plan level. Some commenters stated that issuer-level data would be more credible and reliable.

Response: We have carefully considered the commenters' suggestions, but are not making the requested change. The statutory language governing risk corridors does not afford the necessary flexibility. The statutory provision that governs risk corridors at section 1342(a) of the Affordable Care Act describes the risk corridors program as one in which "a qualified health plan offered in the individual or small group market shall participate * * *". By contrast, section 2718 of the PHS Act, which governs the MLR program, requires the calculation of a ratio with respect to an issuer.

Comment: One commenter requested that the risk corridors program may be based on targeted medical costs (net premiums) in addition to the premium rates.

Response: We are not making the changes proposed by the commenter because section 1342 of the Affordable Care Act does not provide the flexibility necessary to do so. That section requires

that the risk corridors program be based upon the ratio of a plan's total costs, other than administrative costs, to its total premiums, reduced by the administrative costs. In codifying that section in regulation, we have sought to define the relevant terms in a manner consistent with those used in the MLR calculation.

Comments: A number of commenters addressed the risk corridors payment deadline. Three commenters agreed that 30 days was a reasonable timeframe for both payments and charges, and one commenter recommended that payments and charges be paid once per year. One commenter suggested requiring issuers of QHPs to submit risk corridors data within 30 days after submission of a request for payment to HHS or receipt of demand for payment from HHS.

Response: We plan to address the risk corridors payment deadline in the HHS notice of benefit and payment parameters.

3. Attribution and Allocation of Revenue and Expense Items (§ 153.520)

In § 153.520(a)(3) of the proposed rule (now § 153.530(d)), we proposed rules for accounting for reinsurance claims submitted on a date to be determined by HHS for a given reinsurance benefit year. Specifically, we proposed that a QHP issuer be required to attribute reinsurance payments to risk corridors based on the date on which the valid reinsurance claim was submitted. For example, if the QHP issuer were to submit a reinsurance claim on or before the deadline for a benefit year, that QHP issuer would attribute the claim payment to the risk corridors calculation for the benefit year in which the costs were accrued. Conversely, if the QHP issuer were to submit a claim after the deadline for a benefit year, that QHP issuer would attribute the claim payment to the risk corridors calculation for the following benefit year.

We are finalizing this provision as proposed, with the following modifications:

We are revising § 153.520(d) to clarify that an issuer must attribute not only reinsurance payments, but also reinsurance contributions and risk adjustment payments and charges to the benefit year for which the contributions, charges, or payments apply, not the year in which the claim was submitted.

In addition, we are including the new paragraphs § 153.520(a), § 153.520(b), § 153.520(c), and § 153.520(e) to clarify the attribution of items, such as quality improvement and health information technology expenditures, that are

typically not plan-specific. Paragraph 153.520(a) requires that each item of revenue and expense in allowable costs and target amount for a QHP must be reasonably attributable to that QHP's operations. Paragraph 153.520(b) states that each item must be reasonably allocated across the issuer's plans (that is, QHPs and non-QHPs). Thus, § 153.520(a) and § 153.520(b) require an issuer to allocate shared revenue and expense items between its health plans and its other business lines, and then to attribute its shared items within its health plans to each plan. To the extent that the issuer is utilizing a method for allocating expenses for MLR purposes, the method used for risk corridors purposes under § 153.520 must be consistent. Paragraph 153.520(c) requires an issuer to disclose to HHS a detailed description of the methods and bases for the attribution and allocation. We plan to specify the timing and method of disclosure in future guidance. Finally, § 153.520(e) requires an issuer to maintain the supporting records for the attribution and allocation for 10 years, and to make the records available to HHS upon request.

Comments: We received a few comments to the proposed provision attributing reinsurance payments to the applicable benefit year. One commenter stated that the rule was inconsistent with issuers' pricing practices, the MLR calculation, and financial reporting practices. The commenter stated that issuers could manipulate risk corridors payments by delaying claims submissions, and that claims not submitted in time for the 2016 calculation would not be eligible for risk corridors, since the program would have terminated. Another commenter recommended that reinsurance amounts be on a "basis other than a paid basis" in order to be consistent with the MLR calculation. Another commenter recommended attribution of reinsurance claims to the year of submission, even if the claims were incurred in a prior benefit year.

Response: We are clarifying in the rule that reinsurance and risk adjustment payments, contributions, and charges are attributed to the benefit year with respect to which the reinsurance or risk adjustment amounts apply. For example, reinsurance payments received in 2015 for claims costs incurred in 2014 (even if the reinsurance claim was properly submitted in 2015) would be attributed to 2014 for purposes of risk corridors calculations.

4. Risk Corridors Data Requirements (§ 153.530)

To support the risk corridors program calculations, we proposed in § 153.520 of the proposed rule that all QHP issuers submit data needed to determine actual performance relative to their target amounts, to be collected in standard formats specified by HHS. We proposed in § 153.520(a) to require that QHP issuers submit data related to actual premium amounts collected, 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 proposed that risk adjustment and reinsurance be regarded as after-the-fact adjustments to premiums for purposes of determining risk corridors amounts. Therefore, § 153.520(a)(1) of the proposed rule required that the reported premium amounts be increased by the amounts paid to the QHP issuer for risk adjustment and reinsurance, and § 153.520(a)(2) required that 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 sought comment on this issue in the preamble.

We proposed in § 153.520(b) that QHP issuers be required to submit allowable cost data to calculate the risk corridors in a format to be specified by HHS, and that allowable costs be reduced for any direct and indirect remuneration received. Finally, we proposed that allowable costs be reduced by the amount of any cost-sharing reductions received from HHS.

Considering the comments received, we are finalizing this provision, with the following modifications:

In order to more clearly reflect section 1342(c)(1)(B) of the Affordable Care Act, we are revising this section so that the adjustments for reinsurance and risk adjustment are made to allowable costs. We are also making a number of clarifying modifications throughout this section.

Comments: Commenters generally agreed that reinsurance and risk adjustment payments and charges should be treated as after-the-fact adjustments to risk corridors. One commenter noted the inconsistency between the proposed rule's treatment of reinsurance and risk adjustment payments and charges as adjustments to premium revenue, and section 1342 of the Affordable Care Act, which requires that those adjustments be made to allowable costs. Another commenter

noted that under the MLR rule, these adjustments are made to premium revenue, and urged that the risk corridors program handle these adjustments in the same manner. One commenter requested clarification that the attribution of reinsurance payments “received” be determined on an accrual rather than cash basis. Another commenter, who requested that the risk adjustment program be delayed until at least 2016 because of the complexity of implementing the risk adjustment, reinsurance, and risk corridors programs simultaneously, requested that, for consistency, HHS only take into account reinsurance for purposes of the temporary risk corridors program during those initial years.

Response: In order to more clearly reflect the requirements of the Affordable Care Act, we are revising the section so that those payments and charges are adjustments to allowable costs, rather than premium revenue. We agree with the commenter that reinsurance and risk adjustment payments and charges should be reflected in risk corridors on an accrual basis, and are reflecting that requirement in § 153.520(d) of this final rule. Since all three programs will play important and different roles in stabilizing premiums beginning in 2014, we believe that both the risk adjustment and reinsurance programs should be taken into account as after-the-fact adjustments for purposes of the risk corridors calculation, as required by the statute.

Comments: Commenters expressed concern about the interaction of risk corridors, reinsurance, and risk adjustment with the MLR calculation. Commenters discussed the need for the MLR timeline to take into account those other calculations, payments, and charges. One commenter discussed the challenges faced by publicly held issuers who must also comply with Federal securities laws’ disclosure requirements. Two commenters included detailed timelines encompassing proposed due dates for reinsurance, risk adjustment, risk corridors and MLR.

Commenters also supported our efforts to use, where practicable, MLR definitions and concepts in the risk corridors rules, but noted difficulties in using data collected for MLR purposes for premium stabilization purposes because MLR data is compiled at the issuer level, while risk corridors data will be required to be collected at the plan level.

Response: We will provide additional details on timeline-related issues in future guidance. We anticipate that the

accounting profession will take appropriate measures to guide issuers, as it has in past analogous circumstances, such as with the retiree drug subsidy program under the Medicare Modernization Act, which was first effective in 2006. We will continue efforts to minimize reporting burden by seeking to utilize data already collected for MLR.

Comments: We received a comment on the issue of how to determine the allowable costs for a QHP if the issuer fails to comply with the reporting requirements in § 153.530. The commenter recommended that HHS use quarterly reports to determine a final payment liability using the lowest HHS payment liability minus a certain percentage of withhold (penalty) of either the premium payments or risk corridors payment.

Response: We interpret the comment as suggesting that HHS determine a baseline amount of allowable costs or payment liability reflecting experience of other issuers. The approach is one of several reasonable methods. We will consider it along with other approaches. We are evaluating measures we could take to address non-compliance.

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 markets both inside and outside of the Exchanges. We noted in the introduction to subpart D of this part that the risk adjustment program described in section 1343 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 markets. The foregoing is relevant for this subpart as well, which finalizes the health insurance issuer standards that are necessary to carry out risk adjustment as described in subpart D.

1. Reserved (§ 153.600)

Section 153.600 of the proposed rule defined a number of terms used in this subpart. Those definitions have been moved to subpart A. We are reserving this section for future use.

2. Risk Adjustment Issuer Requirements (§ 153.610)

We proposed in paragraph (a) that all issuers of risk adjustment covered plans be required to submit risk adjustment data according to the timetable and

format prescribed by the State, or HHS on behalf of the State. Considering the comments received, we are finalizing this definition, with the following modifications: We are modifying the requirement that issuers submit risk adjustment data to the State, or HHS on behalf of the State, to align with the changes to § 153.340(a) and (b) discussed above. We are adding a requirement that issuers that offer risk adjustment covered plans store required risk adjustment data in accordance with the risk adjustment data collection approach established by HHS or the State. We note that use of a distributed model may require issuers to format risk adjustment data and maintain that data in a manner that complies with specifications promulgated by the State, or HHS on behalf of the State, and to run risk adjustment software.

Comment: We received many comments supporting the requirement that issuers submit risk adjustment data to the State, or HHS on behalf of the State. A number of commenters requested that HHS expand the definition of risk adjustment data to include rate setting data that may not be available from State Departments of Insurance. Other commenters stated that the amount and type of data envisioned in the proposed rule was appropriate.

Response: We are making only minor changes to this provision, to align with changes made to § 153.340(a).

Comment: One commenter suggested that participation in risk adjustment should be voluntary. Two other commenters urged HHS to delay risk adjustment until sufficient data is available. We received several comments suggesting that the timeframe for data submission be left to States.

Response: The Affordable Care Act requires that issuers of risk adjustment covered plans participate in the risk adjustment program. We believe that there will be sufficient data to administer the risk adjustment program, even in the initial years. Therefore, we are finalizing the policy that all issuers offering risk adjustment covered plans must participate in the program by providing the specified information to the State, or HHS on behalf of the State, on a timeframe determined by that State.

In paragraph (b) of the proposed rule, we proposed to permit contractual arrangements between issuers and providers, suppliers, physicians, and other practitioners to ensure that issuers receive the necessary risk adjustment data. Considering the comments received, we are finalizing this paragraph as paragraph (c).

Comments: We received a number of comments in response to this provision. Two commenters supported a requirement permitting issuers to require providers, suppliers, physicians, and other practitioners to submit risk adjustment data to those issuers. We received two comments expressing reservations about the requirement on the grounds that it would place additional burdens on practitioners.

Response: We believe that the risk adjustment program is highly dependent on high quality risk adjustment data. Issuers depend on providers, suppliers, physicians, and other practitioners to submit this data to them. Because issuers will receive or be required to make risk adjustment payments based in part on the amount and quality of this risk adjustment data, we believe it is fair to permit issuers to require suppliers, physicians, and other practitioners to submit that data to them in their contracts. We are therefore finalizing this paragraph.

In paragraph (c) of the proposed rule, we proposed 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. Additionally, we requested comment as to whether issuers should have a 30-day timeframe in which to pay net charges to the State that assessed those charges, or to HHS on behalf of the State. Considering the comments received, we are finalizing this paragraph, clarifying that charges include any adjustments made pursuant to data validation described in § 153.350.

Comment: We received a few comments supporting the requirement that issuers remit charges to the State, or HHS on behalf of the State.

Response: In response to comments, we are finalizing the requirement that issuers pay risk adjustment charges to the State, or HHS on behalf of the State. We are clarifying that charges include any adjustments made pursuant to data validation described in § 153.350.

Comment: We received one comment supporting a requirement that issuers be required to pay net charges within 30 days of the assessment of those charges by a State, or HHS on behalf of a State.

Response: In response to the comment, we are adding a provision that issuers must pay net charges to the State, or HHS on behalf of the State, within 30 days of the assessment of those charges.

3. Compliance With Risk Adjustment Standards (§ 153.620)

The credibility of risk adjustment is important to stabilizing health insurance premiums in the Exchanges. Consistent with § 153.350 of the proposed rule, we proposed in § 153.620 that risk adjustment covered plan issuers must make available data to HHS or the State to support validation of the risk adjustment data that they have submitted. In paragraph (b), we proposed that risk adjustment covered plan issuers retain the risk adjustment data that they have reported for a period of ten years. For the reasons described in the proposed rule and considering the comments received, we are finalizing these provisions as proposed with a few modifying clarifications.

Comment: We received several comments supporting the requirement that issuers make data required for validation of risk adjustment data available to States or HHS on behalf of the State. Two commenters suggested that HHS establish sanctions for issuers that do not comply with the data validation and records maintenance requirements. One commenter opposed this requirement, suggesting that the requirement would force issuers to disclose sensitive data.

Response: We believe that the data validation and records maintenance standards are necessary to support the credibility of the risk adjustment program. After consideration of the comments received, we are finalizing the proposed provision with a minor drafting change to § 153.610(b) to clarify that the provision applies when the State, or HHS on behalf of the State, requests the data.

Comment: We received several comments suggesting that a ten-year record retention requirement was too long and would impose a significant burden on issuers.

Response: We believe that the record retention requirements should be consistent with other Federal record retention requirements, and are finalizing the proposed provision.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of the final rule that differ from the proposed rule are as follows:

Subpart A—General Provisions (§ 153.10 and § 153.20)

- We have moved a number of reinsurance-related definitions to subpart A. We have made technical changes to the definition of “attachment

point,” “coinsurance rate,” “contribution rate,” and “reinsurance cap” to reflect comments received.

- We have moved a number of risk adjustment-related definitions to subpart A. We have added several new definitions—“individual risk score,” “calculation of plan average actuarial risk,” “calculation of payments and charges,” “risk adjustment data collection approach,” and “risk adjustment data.” We also modified the definition of “risk adjustment methodology” to mean all parts of risk adjustment—the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program. We have modified the definition of “risk adjustment data” to mean all data that are used in a risk adjustment model, or the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data.

Subpart B—State Notice of Benefit and Payment Parameters (§ 153.100 and § 153.110)

- We have clarified that a State that establishes a reinsurance program must publish a notice of benefit and payment parameters if it intends to modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, or modify any reinsurance parameters. We have clarified that States have the flexibility to establish a reinsurance entity regardless of whether or not they establish a State Exchange.

- We have clarified that a State operating a risk adjustment program must publish a notice of benefit and payment parameters setting forth the risk adjustment methodology and data validation that it will use.

- We have specified that State notices of benefit and payment parameters be issued by March 1 of the calendar year prior to the first benefit year for which the notice applies.

- We have clarified that a State that does not publish a notice of benefit and payment parameters forgoes its right to modify the data requirements for reinsurance payments, collect reinsurance contributions, use more than one applicable reinsurance entity, modify any reinsurance parameters, or use any risk adjustment methodology or data validation standards other than those published in the HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of the State.

- We have specified that a State that elects to collect additional reinsurance contributions must describe the purpose of the additional collection and the additional contribution rate.

- We have clarified that a State that modifies the reinsurance parameters from those published in the annual HHS notice of benefit and payment parameters must apply those parameters uniformly throughout the State.

Subpart C—State Standards Related to the Reinsurance Program (§ 153.200–§ 153.250)

- We have clarified that States that establish an Exchange are not required to establish a reinsurance program.

- We have revised the process for collection of contributions so that HHS will collect contributions from self-insured plans, while the State has the option to collect from fully insured plans. We have required States to notify HHS by December 1, 2012, if they elect to collect reinsurance contributions from fully insured plans for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if they elect to collect reinsurance contributions from fully insured plans for any benefit year after 2014.

- We have directed each State to notify HHS of the percentage of reinsurance contributions received by HHS allocated to each applicable reinsurance entity, if applicable.

- We have added provisions specifying that if a State elects to collect additional reinsurance contributions, HHS will only collect additional amounts for administrative expenses, and will not collect additional amounts for reinsurance payments.

- We are no longer requiring that reinsurance payments be linked to essential health benefits.

Subpart D—State Standards Related to the Risk Adjustment Program (§ 153.300–§ 153.350)

- We have added a deadline for States to notify issuers of payments and charges.

- We have added a provision that States must submit annual risk adjustment program summary reports to HHS.

- We have clarified the standards for publication of risk adjustment methodology in HHS and State notices of benefit and payment parameters.

- We have modified the proposed approach to risk adjustment data collection, as follows: When HHS operates a risk adjustment program, it will use a distributed approach so that individual data remains with the issuer.

When a State operates a risk adjustment program, it may choose the approach that best suits its program.

- We have modified the privacy and security standards applicable when a State is operating risk adjustment.

- We have adjusted the data validation standards to account for the new approach to risk adjustment data collection.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program (§ 153.400 and § 153.410)

- We have clarified that contributing entities must make reinsurance contributions to HHS and the applicable reinsurance entity, if the State elects to collect reinsurance contributions.

- We have clarified which contributing entities must make reinsurance contributions.

- We have clarified issuer standards for States that elect to collect additional funds.

- We have specified a collection timeframe for submission of reinsurance contributions to HHS.

- We have clarified that reinsurance contributions data must be submitted to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions.

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program (§ 153.500–§ 153.530)

- We added the defined terms “administrative costs” and “premiums earned” to be consistent with the MLR regulations.

- We revised the defined term “allowable administrative costs” to include a 20 percent cap on such costs.

- We revised the defined term “allowable costs” to include quality improvement and health information technology expenditures under the MLR regulations.

- We revised the defined term “direct and indirect remuneration” to conform with the MLR regulations.

- We revised the provision regarding attribution of reinsurance payments based on the date on which the reinsurance claim was submitted. The final rule specifies that reinsurance payments and contributions and risk adjustment payments and charges be allocated to the benefit year for which they apply.

- We added a number of provisions clarifying how revenue and expense items not typically plan-specific are to be allocated and attributed to plans.

- We revised the provisions concerning after-the-fact adjustments to allowable costs to more clearly reflect the relevant statutory requirements.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program (§ 153.610 and § 153.620)

- We have modified issuers’ data submission standards to reflect the flexibility afforded to States in collecting risk adjustment data.

- We have included a requirement that issuers that offer risk adjustment covered plans store all required risk adjustment data in accordance with the risk adjustment data collection approach established by HHS, or the State.

- We have specified that issuers remit risk adjustment charges within 30 days.

IV. Collection of Information Requirements

This final rule includes requirements that differ from those included in the proposed rule. The following provisions of provisions this final rule involve changes from the information collection requirements set forth in the proposed rule:

- As described in § 153.210(a), we have added a new provision to the final rule under which a State that contracts with more than one applicable reinsurance entity must notify HHS of the percentage of reinsurance contributions received from HHS for the State to be allocated to each applicable reinsurance entity.

- As described in § 153.220(b), we have added a new standard to the final rule under which a State electing to collect reinsurance contributions from issuers in the fully insured market must notify HHS of its intention to do so.

- As described in § 153.310(d), we have added a new standard to the final rule under which a State operating a risk adjustment program must submit annual summary reports of risk adjustment operations to HHS.

- As described in § 153.340(b)(1), we have modified the risk adjustment data collection standards from the proposed rule. A State operating a risk adjustment program must collect or calculate individual risk scores generated by the risk adjustment model in the Federally certified risk adjustment methodology.

- As described in § 153.400(d), we have modified the data standards applicable to contributing entities with respect to contribution amounts so that a contributing entity in the individual and fully insured market is no longer required to submit enrollment and premium data and a contributing entity in the self-insured market is no longer required to submit data on covered lives and total expenses. Instead, a contributing entity is required to submit

data necessary to substantiate the contribution amounts for the contributing entity.

- As described in § 153.520(c), we have added a new standard to the final rule under which a QHP issuer must submit to HHS a report with detailed description of the methods and specific bases used to attribute revenues and expenses in allowable costs and target amount to each QHP and across plans.

- As described in § 153.520(e), we have added a new standard to the final rule under which a QHP issuer must maintain for ten years and make available to HHS upon request the data used to make certain attributions and allocations of items of revenue or expenses, together with all supporting information required to determine that these methods and bases were accurately implemented.

In addition, this final rule describes some information collections for which HHS plans to seek approval at a later date. For these information collections, HHS will issue future **Federal Register** notices to seek comments on those information collections, as required by the Paperwork Reduction Act. Included among such information collections for which HHS plans to seek later approval are the following requirements:

- As described in § 153.310(d), a State operating a risk adjustment program must submit annual summary reports of risk adjustment operations to HHS.

- As described in § 153.400(d), a contributing entity must submit data required to substantiate the contribution amounts for the contributing entity.

- As described in § 153.410(b), issuers of reinsurance-eligible plans, in order to receive reinsurance payments, must make requests for payment in accordance with the standards of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the applicable State notice of benefit and payment parameters.

- As described in § 153.520(c), a QHP issuer must submit to HHS a report with a detailed description of the methods and specific bases used to attribute revenues and expenses in allowable costs and target amount to each QHP and across plans.

- As described in § 153.530, a QHP issuer must submit to HHS data on premiums earned, allowable costs, and allowable administrative costs with respect to each QHP that the QHP issuer offers.

- As described in § 153.610(a)–(b) and § 153.620(b), an issuer that offers risk adjustment covered plans must submit or make accessible, and must

store, all risk adjustment data for those risk adjustment covered plans.

- As described in § 153.620, an issuer that offers risk adjustment covered plans must comply with data validation requests by the State or HHS on behalf of the State.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a control number assigned by OMB.

V. Summary of Regulatory Impact Analysis

The following section focuses on the benefits and costs of the requirements included in this final rule, summarizing analysis from the detailed Regulatory Impact Analysis, available at <http://cciio.cms.gov> under “Regulations and Guidance.” That Regulatory Impact Analysis evaluates the impacts of this final rule and a second final rule, titled “Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers.” The second final rule was made available for public inspection at the Office of the Federal Register on March 12, 2012.

A. Introduction

HHS has examined the impacts of the final 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 12866 and 13563 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 insurance issuers offering comprehensive health insurance policies fall below the size thresholds for “small” business established by the SBA. HHS concludes that this rule will not have a significant impact on a substantial number of small entities.

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 establish a reinsurance program or operate a risk adjustment program, the final rule does not impose a mandate to incur costs above the \$136 million threshold on State, local, or tribal governments. Because operational details on how health insurance issuers and entities that must participate in the reinsurance program have not been finalized, we are not able to estimate whether the final rule imposes a mandate to incur costs above the \$136 million threshold on the private sector.

B. Need for This Regulation

This rule implements standards for States related to reinsurance and risk adjustment, and for health insurance issuers related to reinsurance, risk corridors, and risk adjustment consistent with 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 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 enrollees. The temporary federally administered risk corridors program serves to protect against rate-setting uncertainty for QHPs 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 higher-risk populations (such as individuals with chronic conditions).

C. Summary of Costs and Benefits

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

Methods of Analysis

This regulatory impact analysis references Congressional Budget Office (CBO) estimates relating to the Affordable Care Act and CMS estimates published in the FY 2013 President's Budget relating to the Affordable Care Act and the proposed form of this rule. The CBO estimates remain the most comprehensive accounting of all the interacting provisions pertaining to the Affordable Care Act, and contain cost estimates of certain provisions that have not been independently estimated by

CMS. We expect that the requirements in this final rule will significantly alter neither CBO's estimates nor CMS's estimates. Our review and analysis of the requirements of the final rule indicate that the impacts are within the margin of error of CBO's and CMS's models.

Summary of Costs and Benefits

CBO estimated program payments and receipts for reinsurance and risk adjustment. As those programs 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 the risk corridors program, but assumed collections would equal payments to plans in the aggregate. The payments and receipts in risk adjustment and reinsurance are financial transfers between issuers and the entities running those programs.

TABLE 1—ESTIMATED OUTLAYS AND RECEIPTS FOR REINSURANCE AND RISK ADJUSTMENT PROGRAMS FY2012–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. Note that although the estimates above are based upon CBO analyses, CBO did not account for reinsurance collections payable to the U.S. Treasury. Consequently, the receipts in the President's Fiscal Year 2013 Budget are higher than those estimated by CBO, though not appreciably different.

Source: CBO. 2011. *Letter to Hon. Nancy Pelosi*. March 20, 2010.

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. 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, reducing the risk premium.

Costs. There are administrative costs to States and Exchanges to set up and administer these premium stabilization programs. However, States may use Exchange Planning and Establishment Grant funding awarded pursuant to section 1311 of the Affordable Care Act to develop these programs. There are also reporting costs for issuers to submit data and financial information.

Regulatory Options Considered

Options considered for the 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-based programs with Federal guidelines on methodology, while it establishes risk corridors as a federally run program.

HHS identified two regulatory options to the approach set forth in this final rule, as required by Executive Order 12866.

Uniform Standards for Reinsurance and Risk Adjustment: Under this option, HHS would have set a single standard for State operation of reinsurance and risk adjustment. This option would have restricted State flexibility.

State Flexibility for Reinsurance and Risk Adjustment: Under this option, States would have had a great deal of flexibility around whether and how to implement reinsurance and risk adjustment programs. This option would have allowed States to develop these programs to fit their State-specific characteristics. The programs would

have been subject to few Federal standards.

Summary of Estimate Costs for Each Option

A single standard for State operations of reinsurance and risk adjustment could have resulted in reduced Federal oversight cost. However, this option could also have reduced innovation and limited the diffusion of successful policies. On the other hand, while State flexibility could have allowed for State innovation, it would have increased the administrative burden on the Federal government and multi-State issuers, as policies and procedures could have varied significantly between States. HHS has adopted a middle course that aims to limit administrative costs, especially for the transitional reinsurance program, while also ensuring that the policy aims of the premium stabilization programs are met. These costs and benefits are discussed more fully in the detailed Regulatory Impact Analysis.

D. Accounting Statement

Category	Primary estimate	Year dollar	Unit discount rate (percent)	Period covered
Benefits:				
Annualized Monetized (\$millions/year)	Not estimated	2011	7	2012–2016
	Not estimated	2011	3	2012–2016
Costs:				
Annualized Monetized (\$millions/year)	Not estimated	2011	7	2012–2016
	Not estimated	2011	3	2012–2016
Transfers:				

Category	Primary estimate	Year dollar	Unit discount rate (percent)	Period covered
Federal Annualized Monetized (\$millions/year).	9925	2011	7	2012–2016
	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 Regulatory Impact Analysis, available at <http://ccio.cms.gov> under “Regulations and Guidance.”

VI. 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 RFA 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 final 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 the Affordable Care Act. For purpose of the regulatory flexibility analysis, we expect entities offering health insurance plans, including fully insured health plan issuers and self-insured health plan issuers, 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 this NAICS code. Health issuers could also be classified in NAICS code 621491 (HMO Medical Centers), in which case the SBA size standard for small entities would be annual receipts of \$10 million or less.

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 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” entities established by the SBA.

Additionally, as discussed in the Medical Loss Ratio interim final rule (75 FR 74918), HHS used 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, HHS used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. HHS 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.

This final rule contains standards for premium stabilization programs required of health plan issuers including the risk adjustment program as well as the transitional reinsurance program and temporary risk corridors programs. Because we believe that few insurance firms offering comprehensive health insurance policies fall below the size thresholds for “small” entities established by the SBA, we conclude that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 45 CFR Part 153

Administrative practice and procedure, Adverse selection, Health care, Health insurance, Health records, Organization and functions (Government agencies), Premium Stabilization, 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 amends 45 CFR subtitle A, subchapter B, by adding part 153 to read as set forth below:

Subtitle A—Department of Health and Human Services

Subchapter B—Requirements Relating To Health Care Access

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

Subpart A—General Provisions

Sec.

153.10 Basis and scope.

153.20 Definitions.

Subpart B—State Notice of Benefit and Payment Parameters

153.100 State notice of benefit and payment parameters.

153.110 Standards for the State notice of benefit and payment parameters.

Subpart C—State Standards Related to the Reinsurance Program

153.200 [Reserved]

153.210 State establishment of a reinsurance program.

153.220 Collection of reinsurance contribution funds.

153.230 Calculation of reinsurance payments.

153.240 Disbursement of reinsurance payments.

153.250 Coordination with high-risk pools.

Subpart D—State Standards Related to the Risk Adjustment Program

153.300 [Reserved]

153.310 Risk adjustment administration.

153.320 Federally certified risk adjustment methodology.

153.330 State alternate risk adjustment methodology.

153.340 Data collection under risk adjustment.

153.350 Risk adjustment data validation standards.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

- 153.400 Reinsurance contribution funds.
153.410 Requests for reinsurance payment.

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

- 153.500 Definitions.
153.510 Risk corridors establishment and payment methodology.
153.520 Attribution and allocation of revenue and expense items.
153.530 Risk corridors data requirements.

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

- 153.600 [Reserved]
153.610 Risk adjustment issuer requirements.
153.620 Compliance with risk adjustment standards.

Authority: Secs. 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

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 (Pub. L. 111–148, 24 Stat. 119):

(1) Section 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(2) Section 1341. Transitional reinsurance program for individual market in each State.

(3) Section 1342. Establishment of risk corridors for plans in individual and small group markets.

(4) Section 1343. Risk adjustment.

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

§ 153.20 Definitions.

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

Alternate risk adjustment methodology means a risk adjustment methodology proposed by a State for use instead of a Federally certified risk adjustment methodology that has not yet been certified by HHS.

Applicable reinsurance entity means a not-for-profit organization that is exempt from taxation under Chapter 1 of the Internal Revenue Code of 1986 that carries out reinsurance functions under this part on behalf of the State. An entity is not an applicable reinsurance entity to the extent it is carrying out reinsurance functions under subpart C of this part on behalf of HHS.

Attachment point means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits in a benefit year, after which threshold the claims costs for such benefits are eligible for reinsurance payments.

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

Calculation of payments and charges means the methodology applied to plan average actuarial risk to determine risk adjustment payments and charges for a risk adjustment covered plan.

Calculation of plan average actuarial risk means the specific procedures used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including adjustments for variable rating and the specification of the risk pool from which average actuarial risk is to be calculated.

Coinsurance rate means the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for claims costs incurred for an enrolled individual's covered benefits in a benefit year after the attachment point and before the reinsurance cap.

Contributing entity means a health insurance issuer or a third party administrator on behalf a self-insured group health plan.

Contribution rate means, with respect to a benefit year, the per capita amount each contributing entity must pay for a reinsurance program established under this part with respect to each reinsurance contribution enrollee who resides in that State.

Exchange has the meaning given to the term in § 155.20 of this subchapter.

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

Grandfathered health plan has the meaning given to the term in § 147.140(a) of this subchapter.

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

Health insurance coverage has the meaning given to the term in § 144.103 of this subchapter.

Health insurance issuer or issuer has the meaning given to the term in § 144.103 of this subchapter.

Health plan has the meaning given to the term in section 1301(b)(1) of the Affordable Care Act.

Individual market has the meaning given to the term in § 144.103 of this subchapter.

Individual risk score means a relative measure of predicted health care costs

for a particular enrollee that is the result of a risk adjustment model.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan or QHP has the meaning given to the term in § 155.20 of this subchapter.

Qualified individual has the meaning given to the term in § 155.20 of this subchapter.

Reinsurance cap means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits, after which threshold, the claims costs for such benefits are no longer eligible for reinsurance payments.

Reinsurance contribution enrollee means an individual covered by a plan for which reinsurance contributions must be made pursuant to § 153.400.

Reinsurance-eligible plan means, for the purpose of the reinsurance program, any health insurance coverage offered in the individual market, except for grandfathered plans and health insurance coverage not required to submit reinsurance contributions under § 153.400(a).

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(c) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any other plan determined not to be a risk adjustment covered plan in the annual HHS notice of benefit and payment parameters.

Risk adjustment data means all data that are used in a risk adjustment model, the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data.

Risk adjustment data collection approach means the specific procedures by which risk adjustment data is to be stored, collected, accessed, transmitted, validated and audited and the applicable timeframes, data formats, and privacy and security standards.

Risk adjustment methodology means the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program.

Risk adjustment model means an actuarial tool used to predict health care

costs based on the relative actuarial risk of enrollees in risk adjustment covered plans.

Risk pool means the State-wide population across which risk is distributed.

Small group market has the meaning given to the term in section 1304(a)(3) of the Affordable Care Act.

State has the meaning given to the term in § 155.20 of this subchapter.

Subpart B—State Notice of Benefit and Payment Parameters

§ 153.100 State notice of benefit and payment parameters.

(a) *General requirement for reinsurance.* A State establishing a reinsurance program must issue an annual notice of benefit and payment parameters specific to that State if that State elects to:

(1) Modify the data requirements or data collection frequency for health insurance issuers to receive reinsurance payment from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Collect reinsurance contributions pursuant to § 153.220(a)(1);

(3) Collect additional reinsurance contributions pursuant to § 153.220(g);

(4) Use more than one applicable reinsurance entity; or

(5) Modify any reinsurance payment parameters from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

(b) *Risk adjustment requirements.* A State operating a risk adjustment program must issue an annual notice of benefit and payment parameters specific to that State setting forth the risk adjustment methodology and data validation standards it will use.

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters, it must do so by March 1 of the calendar year prior to the benefit year for which the notice applies.

(d) *State failure to publish notice.* Any State establishing a reinsurance program or operating a risk adjustment program that fails to publish a State notice of benefit and payment parameters within the period specified in paragraph (c) of this section must—

(1) Adhere to the data requirements and data collection frequency for health insurance issuers to receive reinsurance payments that are specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Forgo the collection of reinsurance contributions pursuant to § 153.220(a);

(3) Forgo the collection of additional reinsurance contributions pursuant to § 153.220(g);

(4) Forgo the use of more than one applicable reinsurance entity;

(5) Adhere to the reinsurance parameters specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year; and

(6) Adhere to the risk adjustment methodology and data validation standards published in the annual HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of a State.

§ 153.110 Standards for the State notice of benefit and payment parameters.

(a) *Data requirements.* If a State that establishes a reinsurance program elects to modify the data requirements or data collection frequency for health insurance issuers to receive reinsurance payment from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State notice of benefit and payment parameters must specify those modifications.

(b) *Reinsurance collection.* If a State that establishes a reinsurance program elects to collect reinsurance contributions pursuant to § 153.220(a), then the State must announce its intention to do so in the State notice of benefit and payment parameters.

(c) *Additional collections.* If a State that establishes a reinsurance program elects to collect additional funds pursuant to § 153.220(g), the State must publish the following:

(1) A description of the purpose of the additional collection, including whether it will be used to cover reinsurance payments, administrative costs, or both; and

(2) The additional contribution rate at which the funds will be collected.

(d) *Multiple reinsurance entities.* If a State plans to use more than one applicable reinsurance entity, the State must publish in the State notice of benefit and payment parameters, for each applicable reinsurance entity—

(1) The geographic boundaries for that entity;

(2) An estimate of the number of enrollees in fully insured plans within those boundaries;

(3) An estimate of the number of enrollees in the individual market within those boundaries;

(4) An estimate of the reinsurance contributions that will be collected by the applicable reinsurance entity;

(5) The percentage of reinsurance contributions received from HHS for the

State to be allocated to the applicable reinsurance entity; and

(6) An estimate of the amount of reinsurance payments that will be made to issuers with respect to enrollees within those boundaries.

(e) *Reinsurance payment.* If a State that establishes a reinsurance program intends to modify the attachment point, reinsurance cap, or coinsurance rate from the corresponding parameters specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State must—

(1) Describe those modified parameters in the State notice of benefit and payment parameters; and

(2) Apply the modified parameters uniformly throughout the State.

(f) *Risk adjustment content.* A State operating a risk adjustment program must provide the information set forth in § 153.330(a) and the data validation standards set forth pursuant to § 153.350 in the State notice of benefit and payment parameters.

Subpart C—State Standards Related to the Reinsurance Program

§ 153.200 [Reserved]

§ 153.210 State establishment of a reinsurance program.

(a) *General requirement.* Each State is eligible to establish a reinsurance program for the years 2014 through 2016.

(1) If a State establishes a reinsurance program, the State must enter into a contract with one or more applicable reinsurance entities to carry out the provisions of this subpart.

(2) If a State 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;

(ii) Use the same payment parameters with respect to each applicable reinsurance entity; and

(iii) Notify HHS in the manner and timeframe specified by HHS of the percentage of reinsurance contributions received from HHS for the State to be allocated to each applicable reinsurance entity.

(3) A State may permit an applicable reinsurance entity to subcontract specific administrative functions required under this subpart and subpart E of this part.

(4) A State must review and approve subcontracting arrangements to ensure efficient and appropriate expenditures

of administrative funds collected under this subpart.

(5) A State must ensure that the applicable reinsurance entity completes all reinsurance-related activities for benefit years 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 entity to serve as an applicable reinsurance entity for each State. In such a case, the reinsurance programs for those States must be operated as separate programs.

(c) *Non-electing States.* HHS will establish a reinsurance program for each State that does not elect to establish its own reinsurance program.

(d) *Oversight.* Each State that establishes a reinsurance program must ensure that the applicable reinsurance entity complies with all provisions of this subpart and subpart E of this part throughout the duration of its contract.

§ 153.220 Collection of reinsurance contribution funds.

(a) *Collections.* If a State establishes a reinsurance program, then—

(1) The State may elect to—

(i) Have the applicable reinsurance entity collect contributions for reinsurance contribution enrollees who reside in that State directly from issuers of health plans; or

(ii) Ensure that the applicable reinsurance entity accepts contributions for reinsurance contribution enrollees who reside in that State with respect to issuers of health plans from HHS.

(2) The State must ensure that the applicable reinsurance entity accepts contributions for reinsurance contribution enrollees who reside in that State with respect to all contributing entities other than issuers of health plans from HHS.

(b) *Notification of election to collect.* If a State establishes a reinsurance program, then that State must notify HHS by December 1, 2012, if the State elects to collect reinsurance contributions from fully insured plans for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if the State elects to collect reinsurance contributions from fully insured plans for any benefit year after 2014, in each case pursuant to paragraph (a)(1)(i) of this section. The State's notification will be effective for the applicable benefit year and each subsequent benefit year during which activities related to the transitional reinsurance program continue.

(c) *Contribution funding.* Reinsurance contributions collected must fund the following:

(1) Reinsurance payments 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; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(d) *Distribution of reinsurance contributions.* If a State establishes a reinsurance program, HHS will distribute funds collected for reinsurance contribution enrollees who reside in a State to the applicable reinsurance entity for that State (or the applicable reinsurance entities, if more than one, in accordance with the allocation specified by the State pursuant to § 153.210(a)(2)(ii)), less:

(1) The State's pro rata share of the U.S. Treasury contribution described in paragraph (c)(2) of this section; and

(2) The State's pro rata share of administrative expenses incurred by HHS when performing reinsurance functions under this subpart.

(e) *National contribution rate.* HHS will set in the annual HHS notice of benefit and payment parameters for the applicable benefit year the national contribution rate and the proportion of contributions collected under the national contribution rate to be allocated to:

(1) Reinsurance payments;

(2) Payments to the U.S. Treasury as described in paragraph (c)(2) of this section; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(f) *State collections.* If a State elects to have the applicable reinsurance entity collect contributions pursuant to paragraph (a)(1)(i) of this section, the State must ensure that:

(1) The applicable reinsurance entity for the State collects contributions for reinsurance contribution enrollees who reside in that State directly from issuers of health plans in the amounts required under the national contribution rate.

(2) Reinsurance contributions are allocated as required in the annual HHS notice of benefit and payment parameters for the applicable benefit year, such that:

(i) Contributions allocated for reinsurance payments are only used for reinsurance payments; and

(ii) Contributions allocated for payments to the U.S. Treasury are paid to the U.S. Treasury in a timeframe to be established by HHS.

(g) *Additional State collections.* If a State establishes a reinsurance program, it may elect to collect more than the amounts that would be collected based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year to provide:

(1) Funding for administrative expenses of the applicable reinsurance entity; or

(2) Additional funding for reinsurance payments.

(h) *Administration of additional State collections.* If a State elects to collect additional amounts pursuant to paragraph (g) of this section for administrative expenses or reinsurance payments, then:

(1) The State must notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment parameters for the applicable benefit year of the additional contribution rate that it elects to collect for additional administrative expenses. The State must ensure that the State's applicable reinsurance entity—

(i) Collects these additional amounts for additional administrative expenses from issuers of health plans when the State elects to collect contributions from such issuers under paragraph (a)(1) of this section; and

(ii) Accepts additional amounts for additional administrative expenses from HHS from all contributing entities from which HHS collects in accordance with the State's election under paragraph (a)(1) of this section.

(2) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the State must ensure that the applicable reinsurance entity collects all additional reinsurance contributions for the purpose of reinsurance payments from all contributing entities.

§ 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 claims costs for an individual enrollee's covered benefits in a benefit year exceed the attachment point.

(b) *Reinsurance payment parameters.* If a State establishes a reinsurance program, the State must use, subject to any modifications made pursuant to paragraph (d) of this section, 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 annual HHS notice of benefit and payment parameters for the applicable benefit year.

(c) *Reinsurance payments.* If a State establishes a reinsurance program, the State must ensure, subject to § 153.240(b)(1), that the reinsurance payment represents the product of the coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs between the attachment point and the reinsurance cap.

(d) *State modification of reinsurance payment formula.* If a State establishes a reinsurance program, the State may modify the reinsurance payment formula in accordance with the following:

(1) The State may only use one or more of the following methods to modify the reinsurance payment formula:

- (i) Increasing or decreasing the attachment point;
- (ii) Increasing, decreasing, or eliminating the reinsurance cap; or
- (iii) Increasing or decreasing the coinsurance rate.

(2) The State must publish any such modification to the reinsurance payment formula and parameters in a State notice of benefit and payment parameters as described in subpart B of this part.

(3) Any State modification to the reinsurance payment formula pursuant to paragraph (d)(1) of this section must be reasonably calculated to ensure that reinsurance contributions received toward reinsurance are sufficient to cover payments that the applicable reinsurance entity is obligated to make under that State formula for the given benefit year for the reinsurance program.

(4) The State must use a uniform attachment point, coinsurance rate, and reinsurance cap throughout the State.

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* If a State establishes a reinsurance program, 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 of benefit and payment parameters described in subpart B of this part.

(b) *Reinsurance entity payments.* If a State establishes a reinsurance program,

the State must ensure that each applicable reinsurance entity does not make payments to health insurance issuers that exceed contributions received to date by the applicable reinsurance entity.

(1) If a State, or HHS on behalf of the State, determines that reinsurance payments requested for a benefit year will likely exceed the reinsurance contributions that will be received for the year, the State may require that the applicable reinsurance entity reduce (or HHS on behalf of the State may reduce) reinsurance payments, so long as the manner in which payments are reduced is fair and equitable for all health insurance issuers in the individual market.

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

(c) *Maintenance of records.* If a State establishes a reinsurance program, 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 must 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 that the State high-risk pool conforms to the provisions of this subpart.

Subpart D—State Standards Related to the Risk Adjustment Program

§ 153.300 [Reserved]

§ 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 to operate 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 operate 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.* If a State is operating a risk adjustment program, the State may elect to have an entity other than the Exchange perform the State functions of this subpart, provided that the entity meets the standards promulgated by HHS to be an entity eligible to carry out Exchange functions.

(c) *Timeframes.* A State, or HHS on behalf of the State, must implement risk adjustment for the 2014 benefit year and every benefit year thereafter. For each benefit year, a State, or HHS on behalf of the State, must notify issuers of risk adjustment payments due or charges owed annually by June 30 of the year following the benefit year.

(d) *State summary reports.* Each State operating a risk adjustment program must submit to HHS an annual summary of risk adjustment program operations in the manner and timeframe specified by HHS.

§ 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 a Federally certified risk adjustment methodology. A risk adjustment methodology may become Federally certified by one of the following processes:

(1) The risk adjustment methodology is developed by HHS and published in an annual HHS notice of benefit and payment parameters; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in an annual HHS notice of benefit and payment parameters.

(b) *Publication of methodology in notices.* The publication of a risk adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters or by a State in an annual State notice of benefit and payment parameters described in subpart B of this part must 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 the calculation of individual risk scores.

(2) A complete description of the calculation of plan average actuarial risk.

(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk adjustment data collection approach.

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in the annual HHS notice of benefit and payment parameters for the applicable year the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.* (1) A State request to HHS for the certification of an alternate risk adjustment methodology must include:

(i) The elements specified in § 153.320(b);

(ii) The calibration methodology and frequency of calibration; and

(iii) The statistical performance metrics specified by HHS.

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

(i) Accurately explains the variation in health care costs of a given population;

(ii) Links risk factors to daily clinical practice and is 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.* If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment 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) of this section;

(2) A State request to implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology must include any changes to the parameters described in paragraph (a)(1) of this section.

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* If a State is operating a risk adjustment program, the State must collect risk adjustment data.

(b) *Minimum standards.* (1) If a State is operating a risk adjustment program, the State may vary the amount and type of data collected, but the State must collect or calculate individual risk scores generated by the risk adjustment model in the applicable Federally certified risk adjustment methodology;

(2) If a State is operating a risk adjustment program, the State must require that issuers offering risk adjustment covered plans in the State comply with data privacy and security standards set forth in the applicable risk adjustment data collection approach; and

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State.

(4) If a State is operating a risk adjustment program, 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.

§ 153.350 Risk adjustment data validation standards.

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

(b) *Adjustment to plan average actuarial risk.* The State, or HHS on behalf of the State, may adjust the plan average actuarial risk for a risk adjustment covered plan based on errors discovered with respect to implementation of risk adjustment software or as a result of data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments.* The State, or HHS on behalf of 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, or HHS on behalf of the State, must provide an administrative process to appeal findings with respect to the implementation of risk adjustment software or data validation.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make reinsurance contributions at the national contribution rate (and any additional contribution rate if the State has elected to collect additional contributions pursuant to § 153.220(g)) for the reinsurance program for all reinsurance contribution enrollees who reside in a State, in a frequency and manner determined by HHS or the State, to HHS or the applicable reinsurance entity, as applicable.

(1) A contributing entity must make reinsurance contributions on behalf of its group health plans and health insurance coverage, except as set forth in paragraph (a)(2) of this section.

(2) A contributing entity is not required to make contributions on behalf of plans or health insurance coverage that consist solely of excepted benefits as defined by section 2791(c) of the PHS Act.

(b) *Multiple reinsurance entities.* If the State establishes or contracts with more than one applicable reinsurance entity, the contributing entity must make reinsurance contributions to each applicable reinsurance entity for the reinsurance contribution enrollees who reside in the applicable geographic area.

(c) *Timeframe for Federal collections.* Each contributing entity must submit contributions to HHS on a quarterly basis beginning January 15, 2014.

(d) *Data requirements.* Each contributing entity must submit to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions, data required to substantiate the contribution amounts for the contributing entity, in the manner and timeframe specified by the State or HHS.

§ 153.410 Requests for reinsurance payment.

(a) *General requirement.* An issuer of a reinsurance-eligible plan may make a

request for payment when an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment set forth in the annual HHS notice of benefit and payment parameters for the applicable year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

(b) *Manner of request.* An issuer of a reinsurance-eligible plan must make requests for payment in accordance with the requirements of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

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

§ 153.500 Definitions.

The following definitions apply to this subpart:

Administrative costs mean, with respect to a QHP, total non-claims costs incurred by the QHP issuer for the QHP, as described in § 158.160(b) of this subchapter.

Allowable administrative costs mean, with respect to a QHP, administrative costs of the QHP, up to 20 percent of the premiums earned with respect to the QHP (including any premium tax credit under any governmental program).

Allowable costs mean, with respect to a QHP, an amount equal to the sum of incurred claims of the QHP issuer for the QHP, within the meaning of § 158.140 of this subchapter (including adjustments for any direct and indirect remuneration); expenditures by the QHP issuer for the QHP for activities that improve health care quality as set forth in § 158.150 of this subchapter; expenditures by the QHP issuer for the QHP related to health information technology and meaningful use requirements as set forth in § 158.151 of this subchapter; and the adjustments set forth in § 153.530(b).

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

Direct and indirect remuneration means prescription drug rebates received by a QHP issuer within the meaning of § 158.140(b)(1)(i) of this subchapter.

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

Premiums earned mean, with respect to a QHP, all monies paid by or for enrollees with respect to that plan as a condition of receiving coverage, including any fees or other contributions paid by or for enrollees,

within the meaning of § 158.130 of this subchapter.

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

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

§ 153.510 Risk corridors establishment and payment methodology.

(a) *General requirement.* A QHP issuer must adhere to the requirements set by HHS in this subpart and in the annual HHS notice of benefit 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 will pay the QHP issuer an amount equal to 50 percent of the allowable costs 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 will pay 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 in 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 in 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 Attribution and allocation of revenue and expense items.

(a) *Attribution to QHP.* Each item of revenue or expense in allowable costs or

the target amount with respect to a QHP must be reasonably attributable to the operation of the QHP, with the attribution based on a generally accepted accounting method, consistently applied. To the extent that an issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(b) *Allocation across plans.* Each item of revenue or expense in allowable costs or the target amount must be reasonably allocated across a QHP issuer's plans, with the allocation based on a generally accepted accounting method, consistently applied. To the extent that an issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(c) *Disclosure of attribution and allocation methods.* A QHP issuer must submit to HHS a report, in the manner and timeframe specified in the annual HHS notice of benefit and payment parameters, with a detailed description of the methods and specific bases used to perform the attributions and allocations set forth in paragraphs (a) and (b) of this section.

(d) *Attribution of reinsurance and risk adjustment to benefit year.* A QHP issuer must attribute reinsurance payments and contributions and risk adjustment payments and charges to allowable costs for the benefit year with respect to which the reinsurance payments or contributions or risk adjustment calculations apply.

(e) *Maintenance of records.* A QHP issuer must maintain for 10 years and make available to HHS upon request the data used to make the attributions and allocations set forth in paragraphs (a) and (b) of this section, together with all supporting information required to determine that these methods and bases were accurately implemented.

§ 153.530 Risk corridors data requirements.

(a) *Premium data.* A QHP issuer must submit to HHS data on the premiums earned with respect to each QHP that the issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters.

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to each QHP that the QHP issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters. For purposes of this subpart, allowable costs must be—

(1) Increased by—

(i) Any risk adjustment charges paid by the issuer for the QHP under the risk adjustment program established pursuant to subpart D of this part; and

(ii) Any reinsurance contributions made by the issuer for the QHP under the transitional reinsurance program established pursuant to subpart C of this part.

(2) Reduced by—

(i) Any risk adjustment payments received by the issuer for the QHP under the risk adjustment program established pursuant to subpart D of this part;

(ii) Any reinsurance payments received by the issuer for the QHP under the transitional reinsurance program established pursuant to subpart C of this part; and

(iii) Any cost-sharing reduction payments received by the issuer for the QHP.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to each QHP that the QHP issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters.

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

§ 153.600 [Reserved]

§ 153.610 Risk adjustment issuer requirements.

(a) *Data requirements.* An issuer that offers risk adjustment covered plans must submit or make accessible all required risk adjustment data for those risk adjustment covered plans in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(b) *Risk adjustment data storage.* An issuer that offers risk adjustment covered plans must store all required risk adjustment data in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(c) *Issuer contracts.* An issuer that offers risk adjustment covered plans may include in its contract with a provider, supplier, physician, or other practitioner, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframe 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.

(d) *Assessment of charges.* An issuer that offers risk adjustment covered plans

that has a net balance of risk adjustment charges payable, including adjustments made pursuant to § 153.350(c), will be notified by the State, or by HHS on behalf of the State, of those net charges, and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, as applicable.

(e) *Charge submission deadline.* An issuer must remit net charges to the State, or HHS on behalf of the State, within 30 days of notification of net charges payable by the State, or HHS on behalf of the State.

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* An issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State.

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must retain any information requested to support risk adjustment data validation for a period of at least ten years after the date of the report.

Dated: March 14, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 14, 2012.

Kathleen Sebelius,
Secretary.

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