Patient Protection and Affordable Care Act: Standards Related to Reinsurance, Risk Corridors and Risk Adjustment
Summary of Proposed Rule
July 15, 2011

On July 15, 2011, the Department of Health and Human Services (HHS) published in the Federal Register a notice of proposed rulemaking implementing the reinsurance, risk corridors and risk adjustment provisions of the Patient Protection and Affordable Care Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152). Together, these laws are referred to as the Affordable Care Act (ACA).[1]

The ACA included the reinsurance, risk corridor and risk adjustment provisions to mitigate the impact of potential adverse selection and stabilize insurance premiums in the individual and small group markets as insurance reforms and Exchanges are implemented, beginning in 2014. Consistent with the provisions of the ACA, this proposed rule implements standards for States related to reinsurance and risk adjustment. In addition, it implements standards for health insurance issuers related to reinsurance, risk corridors and risk adjustment. The reinsurance and risk corridor programs are temporary; the risk adjustment program will be on-going.

The following provides a detailed summary of the proposed rule. **Bold font is used to indicate where the Departments have explicitly asked for public comment although all aspects of the proposal are open for comment.** HHS encourages comment letters to be organized by the proposed rule's section to which the comment applies by referencing the file code (CMS-9975-p) and the specific "issue identifier" that precedes the section which the comment addresses. **The 75-day comment period closes on September 28, 2011.**

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[1] Also on July 15, 2011, the Department of Health and Human Services published the Notice of Proposed Rulemaking implementing the Exchange provisions, summarized in a separate HPA document.

I. Background

A. Legislative Overview

The Notice of Proposed Rulemaking (NPRM) reviews the regulatory history relating to implementation of the Exchanges, which were designed in the ACA to offer competition, choice and purchasing clout for individual consumers and small businesses. On August 3, 2010, HHS issued a *Request for Comment* (RFC) relating to Exchanges. This was followed on November 18, 2010 with the *Initial Guidance to the States on Exchanges*. On March 14, 2011, HHS issued a proposed rule for the *Application, Review and Reporting Process for Waivers for State Innovation.* In addition to the proposed rule summarized below, HHS also made public on July 11, 2011 a proposed rule relating to the components of the Exchange.

Three provisions of the ACA seek to mitigate the potential effects of risk selection and stabilize premiums in the individual and small groups markets as insurance reforms and the Exchanges are implemented, starting in 2014. Section 1341 provides that each State must establish a transitional reinsurance program to help stabilize premiums for coverage in the individual insurance market during the first three years of Exchange operation (2014-2016). Section 1342 provides that the Secretary of HHS establish a transitional risk corridor program that will apply to qualified health plans (QHPs) in the individual and small group markets for the same three years. Section 1343 provides that each State may establish a program of risk adjustment for all non-grandfathered plans in the individual and small group markets inside and outside of the Exchange. An additional section (1321(a)) gives the Secretary broad authority, in consultation with stakeholders (ensuring balanced representation among them), to establish standards and regulations to implement the statutory requirements related to Exchanges, reinsurance, risk adjustment and other components of title I of the ACA. Finally, section 1321(c) authorizes the Secretary to establish Exchanges and implement reinsurance, risk adjustment and other components of title I in States that have not done so.

B. Introduction

The risk mitigation provisions of the ACA are designed to minimize the possible negative effects of adverse selection. As discussed in the Preamble, the primary strategy for reducing adverse selection is by broadening the risk pool. This entails making coverage affordable through lower premiums, targeted financial assistance, and requiring individuals to obtain coverage so that they pay premiums in sickness and health.

To further minimize the negative effects of adverse selection and foster a stable marketplace from one year to the next, however, the ACA anticipates the need for additional measures. To this end, it calls for the establishment by the States of transitional reinsurance for issuers participating in the individual market by making payments for the first three years (2014-2016) for high-cost cases. The intent is for the reinsurance to attenuate rate increases that might otherwise occur because of the immediate enrollment of individuals with unknown health status, potentially including, at the State's discretion, those currently in State high risk pools.

In addition, the ACA provides for a temporary Federally-administered risk-corridor program, designed to protect against uncertainty in setting rates in the Exchange by limiting the extent of issuer losses (and gains). Under this program, for 2014-2016, an issuer of a QHP whose gains are greater than 3% of the issuer's projections will have to remit charges to HHS, while HHS must make payments to an issuer of a QHP plan that experiences losses greater than 3% of the issuer's projections.

The third measure, the permanent risk adjustment program, is intended to provide adequate payments to issuers that attract high-risk populations (such as those with chronic conditions). Under this program, generally, funds are transferred from issuers with lower risk enrollees to issuers with higher risk enrollees. Section 1343 of the ACA indicates that the Secretary may utilize criteria and methods similar to the criteria and methods utilized under Parts C or D of Medicare.

Proposed standards for the three programs are addressed in this proposed rule. A chart in the Preamble summarizes major distinguishing different characteristics of the three risk mitigation programs (see page 41932 of the July 15, 2011 *Federal Register*).

In the August 3, 2010 RFC, HHS invited public input regarding the rules for the Exchanges and related functions such as reinsurance and risk adjustment.[2] HHS notes that it is not directly responding to these comments in this NPRM (although the comments are addressed in general as appropriate for each section) but intends to respond to comments from the RFC as well as comments on this NPRM as part of the final rule. HHS also plans to disseminate parameters that will rely on factors that may change each year, such as the national reinsurance contribution rate and the Federally certified risk adjustment model, in an annually updated Federal notice of benefit and payment parameters. In terms of consultation with stakeholders, HHS notes that it has had "weekly meetings with the National Association of Insurance Commissioners, regular contact with States that received Exchange planning grants, and meetings with tribal representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties."

II. Provisions of the Proposed Regulation

A. Subpart A- General Provisions

1. Basis and Scope (§153.10)

In this section, the proposed rules are based on sections 1321 and 1341-1343 of title I of the ACA.

2. Definitions (§153.20)

Many of the terms used in this section are defined explicitly in the ACA, in previous rules or in the NPRM for Exchanges published concurrently with this NPRM. New definitions were created to carry out regulations proposed in part 153. HHS notes that when a term is defined in part 153

[2] The comment period for the Request for Comment closed October 4, 2010.

other than in subpart A, the definition of the term is applicable only to the relevant subpart or section.

The proposed rule includes definitions for the following: applicable reinsurance entity, benefit year, contributing entity, enrollee, Exchange, grandfathered health plan, group health plan, health insurance issuer or issuer, health plan, individual market, reinsurance-eligible plan, risk adjustment covered plan, small group market and State.

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

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

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

A State operating an Exchange, as well as a State establishing a reinsurance program, would be required to issue an annual notice to describe the specific parameters that the State will employ if it intends to utilize any reinsurance or risk adjustment parameters that differ from those specified in the forthcoming annual Federal notice of benefit and payment parameters (which will have a public comment period). The following chart details the schedules for the forthcoming annual Federal notice of benefit and payment parameters[3] for 2014 and subsequent years, with the first two dates occurring in the calendar year two years before the effective date.

Annual Federal Notice of Benefit and Payment Parameters	
HHS publishes advance notice	Mid-October
Comment period ends	Mid-November
HHS published final notice	Mid-January

States that plan to modify parameters would issue their notice by no later than early March in the calendar year before the effective date. **Comment is requested on whether the proposed timing allows issuers sufficient time to reflect these State requirements in setting rates and in particular, whether the schedule should be adjusted in the initial year to provide additional time for setting rates for 2014.**

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 prescribed above, the parameters set forth in the forthcoming annual Federal notice would serve as the State parameters.

[3] From this point forward, the forthcoming annual Federal notice of benefit and payment parameters is referred to as the "forthcoming annual Federal notice."

2. Standards for the State Notices (§153.110)

Reinsurance. If a State operating an Exchange or establishing a reinsurance program intends to modify a Federal reinsurance payment parameter, the State notice must specify at least: (1) the data requirements and data collection frequency for issuers to receive reinsurance payment; (2) the reinsurance attachment point, reinsurance cap, and coinsurance rate (see §153.230 below), if different from the corresponding parameters specified in the forthcoming annual Federal notice of benefit and payment parameters; and (3) if a State plans to use more than one applicable reinsurance entity, for each applicable entity, its geographic boundaries and estimates of the: (i) number of enrollees in group health plans, including the fully insured and self insured market; (ii) number of enrollees in the individual market; (iii) amount of reinsurance payments that will be made to issuers; and (iv) amount of all premiums in the geographic region that will be available for contributions for each reinsurance entity. HHS will provide States with estimates for these values at the State level in the forthcoming annual Federal notice.

Risk adjustment content. If a State operating an Exchange intends to modify a Federal risk adjustment parameter, the State notice must provide a detailed description of and rationale for any modifications, including: (1) the methodology for determining average actuarial risk, (including the establishment of risk pools and the Federally-certified risk adjustment model as specified in §153.320) and (2) the risk adjustment data validation methodology set forth in §153.35.

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

Overview. Under section 1341 of the ACA, all health insurance issuers, and third party administrators on behalf of self-insured group health plans, must make contributions to a not-for-profit reinsurance entity to support reinsurance payments to individual market issuers that cover high-cost individuals, except for high-cost individuals in grandfathered individual market health plans. As a basis for reinsurance payments, the Secretary is directed to develop a list of 50 to 100 medical conditions to identify high-cost individuals or to identify alternative methods for payment in consultation with the American Academy of Actuaries (AAA). This subpart codifies the reinsurance provisions of section 1341. Related standards on health insurance issuers with respect to reinsurance are proposed in subpart E.

HHS posits three "critical policy goals" of the transitional reinsurance program: (1) offer protection to issuers against medical cost overruns for high-cost enrollees in the individual market, particularly those enrollees who are newly insured or those with previously excluded conditions, thereby allowing issuers to set lower premiums; (2) permit early and prompt payment of reinsurance funds during the benefit year to help offset the potential high costs of issuers early in the benefit year (particularly important since risk adjustment and risk corridors are likely to be calculated after the end of the benefit year); and (3) require minimal administrative burden since reinsurance is temporary and thus, the costs of setting up and administering the program must be commensurate with its benefits over its three-year window.

In response to the RFC, HHS received a number of comments on the transitional reinsurance program. Multiple respondents emphasized that, although underlying enrollee conditions are referenced in the ACA, reinsurance programs typically do not consider the health status of the individual and are not tied to underlying conditions that lead to high enrollee medical costs. Instead, reinsurance is tied to high claims costs beyond a specific dollar threshold within a coverage period. Some commenters noted that coverage of specific conditions under a reinsurance program could lead to discriminatory practices toward certain individuals. Concerns were also expressed that traditional reinsurance which makes payments based solely on incurred costs does not encourage efficient and effective care. Finally, commenters suggested entities that could serve as the applicable reinsurance entity for a State.

The Preamble notes that all of these comments were considered in the development of this subpart. The Department "believes that States should have discretion to make a number of decisions within the proposed standards, including the appropriateness of any specific entity as an administrator of the reinsurance program."

1. Definitions (§153.200)

This section proposes definitions "critical to the establishment of a properly functioning transitional reinsurance program." They include:

Attachment point. The threshold dollar amount of costs incurred by a health insurance issuer for payment of essential health benefits provided for an enrolled individual, after which threshold, the costs for covered essential health benefits are eligible for reinsurance payments.

Essential health benefits. To be proposed in future rulemaking (see below).

Coinsurance rate. The rate at which the applicable reinsurance entity will reimburse the issuer for costs incurred to cover essential health benefits after the attachment point and before the reinsurance cap.

Reinsurance cap. The threshold dollar amount for costs incurred by an issuer for payment of essential health benefits provided for an enrolled individual, after which threshold, the costs for covered essential health benefits are no longer eligible for reinsurance payments.

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

Percent of premium. The percent of total revenue, based on earned premiums as described in §158.130(a) (relating to Medical Loss Ratios), in all fully-insured markets (inside and outside of the Exchange) or the percent of total medical expenses in a self-insured market.

Third party administrator. The claims processing entity for a self-insured group health plan. (The Preamble states that if a self-insured group health plan processes its own claims, the self-

insured plan will be considered a third-party administrator for the purpose of the reinsurance program.)

In order to ensure reinsurance payments are made on a comparable set of benefits, HHS proposes that payments be calculated for costs to cover the essential health benefits package. **Comments are requested on alternatives to the use of the essential health benefits package.**

2. State establishment of a reinsurance program (§153.210)

In general. The ACA requires that each State that elects to operate an Exchange must also establish a reinsurance program. Such a State must either enter into a contract with an existing applicable reinsurance entity or establish an applicable reinsurance entity to carry out the reinsurance program as set forth in this subpart.

Because HHS believes the statute allows State flexibility in selecting an applicable reinsurance entity, more specific guidelines are not proposed. A State may set up more than one reinsurance entity (potentially increasing administrative costs). Any State that chooses to have more than one reinsurance entity must publish in a State Notice (see §153.110 above), information regarding the geographic divisions between the applicable entities. These must be distinct and, together, cover the State's entire individual market and not just certain areas or populations. A State may permit a reinsurance entity to subcontract administrative functions, provided that the State reviews and approves these arrangements.

The establishment of, or contract with, the applicable reinsurance entity must extend for a sufficient period to ensure that the entity can fulfill all reinsurance requirements 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 a reinsurance entity is available for required payment activities for that period. When establishing or contracting with a reinsurance entity, States must establish sufficient time to pay reinsurance claims after 2016. This time cannot extend past December 31, 2018.

Multi-State reinsurance arrangements. Several States may contract with one reinsurance entity but that entity must maintain separate risk pools for each State's reinsurance programs. In such cases, each contract would be considered to be an individual reinsurance arrangement between a specific State and the applicable reinsurance entity.

Special State circumstances; non-electing States. A State that does not elect to establish an Exchange may nevertheless operate its own reinsurance program and if it does, it must carry out the provisions of this subpart. If a State does not elect to establish an Exchange and does not determine to operate its own reinsurance program, HHS will establish the reinsurance program to perform all of that State's reinsurance functions (including the collection of contributions from issuers and third party administrators on behalf of self-insured plans).

Oversight. Each State that establishes an Exchange or operates a reinsurance program must ensure that each applicable reinsurance entity complies with requirements throughout the duration of its contract or establishment.

3. Collection of reinsurance contribution funds (§153.220)

In general. Section 1341 of the ACA provides for the collection of contribution funds to cover all reinsurance payments and also permits the collection of funds to cover administrative costs incurred by the reinsurance entity. These funds must be collected by the reinsurance entity from all health insurance issuers and third party administrators on behalf of self-insured plans.

The aggregate contribution funds (to be used exclusively for paying reinsurance or administering the reinsurance programs) are specified by the ACA as $10 billion in 2014, $6 billion in 2015, and $4 billion in 2016. These funds would be returned to issuers that qualify for the transitional reinsurance program. Additional funds ($2 billion in calendar years 2014 and 2015, and $1 billion in 2016) are authorized by the ACA to be collected by the reinsurance entity for deposit into the general fund of the U.S. Treasury. HHS observes that although the Congressional Budget Office scored the additional contributions as an offset for the costs of administering the ACA's Early Retiree Reinsurance Program within the 10 year budget window, these funds will not be used for that purpose but will instead go to the Treasury.

Contribution rate. Although the transitional reinsurance program is State-based, the ACA sets the contribution levels for the program on a national basis. HHS considered two approaches to collecting contribution funds: (1) use of a national uniform contribution rate, and (2) use of a State-level allocation. Both would be set by HHS to ensure that the sum of all contribution funds equals the national amounts (as specified above).

HHS concludes that the first approach is simpler. Also, since significant uncertainty exists about Exchange enrollment (numbers of people and their health status) and about the costs of care for new enrollees, a national contribution rate is the "less ambiguous approach of the two." All contribution funds collected by a State establishing a reinsurance program, using 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. HHS asserts that the alternative of a State-level allocation would be more complex to administer. **HHS asks for comments regarding whether to use a State level allocation or a national rate.**

For determining contributions using a national rate, HHS considered two methods: (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. It finds the first approach to be the fairest method since it allows States that tend to have higher premium and health care costs, and thus reinsurance claims, to collect additional funds towards reinsurance. In contrast, "a flat, per capita amount could represent an excessively high percent of premium for products that are designed and intended to have low premiums targeted toward a population such as young adults and children."

HHS proposes to establish the percentage of premium amount through a forthcoming annual Federal notice, based on its estimate of total premiums in the fully insured market and medical expenses in the self-insured market. **HHS invites comments regarding the preferred method for calculating health insurance issuer contribution funds using a national rate.**

HHS further proposes that a State may collect more than its amount collected in the national rate, if it believes these amounts to be insufficient to cover the payments it will make under the payment formula and notes that nothing in the ACA precludes a State from supplementing this program. HHS also proposes that a State may collect more than its amount collected at the national rate to cover the administrative costs of the applicable reinsurance entity.

Regarding the frequency of collections, HHS **invites comment on the most appropriate method and frequency to collect the reinsurance contribution funds.** For example, funds could be collected from contributing entities on a monthly basis beginning in January 2014 so that reinsurance payments could begin in February 2014.

4. Calculation of reinsurance payments (§153.230)

In general. As required under the ACA, HHS has consulted with the American Academy of Actuaries (AAA) in setting the proposed payment policy for the reinsurance program. This policy addresses: (1) how to determine the individuals who are covered by reinsurance, and (2) how to determine payment amounts. Given the short-term nature of the program, HHS's primary objective is to select an approach that is administratively and operationally simple, but satisfies the goals of the program. It proposes that coverage upon which the payment policy is determined be based on items and services within the essential health benefits for an individual enrollee that exceeds an attachment point. **Comments are requested regarding this proposed provision or if HHS should allow reinsurance payment for more generous coverage beyond that provided by essential health benefits.**

Reinsurance payment. The reinsurance payment formula and State specific values for the attachment point, reinsurance cap, and coinsurance rate would be announced in the forthcoming annual Federal notice (which would facilitate possible changes in values in 2015 and 2016). The Preamble notes that the ACA does not suggest that the transitional reinsurance program replace commercial reinsurance or internal risk mitigation strategies and that a continued need will exist for ongoing commercial reinsurance. Therefore, **HHS proposes establishing a reinsurance cap set at the attachment point of traditional reinsurance and seeks comment on this approach.**

States must ensure that the reinsurance payment represents the product of the coinsurance rate times all health insurance issuer costs for an individual's essential health benefits which the issuer incurs between the attachment point and the reinsurance cap. However, since States may have unique situations, a State could establish its own payment formula by varying the attachment point, coinsurance rate, and reinsurance cap.

Rationale. The Preamble presents HHS' reasoning for this proposed policy along with a discussion of some operational issues related to the timing of reinsurance payments. Four different approaches were identified by the AAA to implement reinsurance payment provisions:[4] (1) Identification of individuals with specific conditions based on claims data; (2) identification of individuals with specific conditions based on survey data; (3) identification of high-risk

[4] Available at: www.actuary.org/pdf/health/Reinsurance%20Options%209%2022%202010.pdf.

individuals using risk adjustment data and a condition-based risk adjustment model; and (4) identification of reinsurance-eligible individuals based on medical cost to the issuer for covered benefits. The last option, which HHS would adopt, focuses on all high-cost enrollees without respect to the conditions that caused the increased cost. It is the most familiar to issuers and administratively less burdensome than the first and second options. The third option might mitigate some of the burden and cost concerns but it would not eliminate the timing issues that are critical to effective reinsurance implementation. HHS concludes that all of the condition-based approaches to eligibility identification would be more burdensome in comparison to the medical cost approach without significant improvement in outcomes from a determination standpoint. **Comments are requested "for a suitable method for ensuring that issuer costs are appropriate and accurate."**

The AAA discussed two principal approaches to calculating the reinsurance payments: (1) payments for costs incurred above an attachment point and (2) a fixed payment schedule for specific conditions. HHS proposes the first approach because it:

- Aligns compensation with costs by reimbursing issuers that have enrollees in the individual market who actually experience higher health costs;
- Represents a more traditional view of reinsurance.
- Is consistent with the Early Retiree Reinsurance Program;
- Is simpler operationally (the only data needed are cost and claims data for individuals); and
- Works in tandem with the medical-cost method of determining eligibility.

The fixed payment schedule option, rejected by HHS, would have the effect of paying the same amount for all individuals who present with a specific condition regardless of actual enrollee cost, would penalize issuers that attract more individuals with higher disease burden within disease categories, and could thus be less effective in mitigating the actual financial impact of adverse selection.

HHS notes that using the attachment point to determine reinsurance payments can reduce incentives for issuers to control costs. But combining a reinsurance cap – and the requirement for an issuer coinsurance rate above the attachment point and below the cap – may provide incentives for issuers to control costs. **HHS invites comment "regarding the best method of determining payments for the reinsurance program, which can relate to either our criteria for selecting eligible enrollees for payment or the method for calculating the payment amounts."**

Payments to the U.S. Treasury. All payments to the general fund of the Treasury would be made in a manner specified in the forthcoming annual Federal notice. Payments could be made, for example, on a monthly or quarterly basis commencing February 28, 2014, continuing through January 31, 2017 or until States have remitted the full amount of all payments. **Comment is requested "as to the most appropriate frequency and method for applicable reinsurance entities to remit payment to the U.S. Treasury."**

State modification of reinsurance payment formula. Some degree of State variation from the reinsurance parameters described above would be permitted (based on the ACA's reference to "model regulation" as opposed to strict Federal regulation). A State would be permitted to alter the attachment point, reinsurance cap, including elimination of the cap, and coinsurance rate. Any modification to the payment formula and parameters would have to be included in a State notice (see §153.110 above). In addition, the State would have to ensure that all proposed alterations to the HHS reinsurance formulas, including payments and contributions, result in the applicable reinsurance entity having sufficient contributions to meet of all of its obligations for payments. Such State alterations would not require HHS approval. Differing reasons why a State may want to make adjustments to the HHS formula are suggested in the Preamble (e.g., it may want to increase the reinsurance benefit above the level established by HHS).

5. Disbursement of reinsurance payments (§153.240)

Data collection. States would be required to ensure that the applicable reinsurance entity collects from issuers of reinsurance-eligible plans data required to calculate payments according to the data requirements and data collection frequency specified by the State notice (§153.110) or in the forthcoming annual Federal notice. Since reinsurance eligibility and payments would be based on the issuer's medical costs, HHS believes that a standard method of collecting the required information is a reasonable goal, easily achievable, and will enable multi-State health insurance issuers to submit data promptly without causing disruption for any single-State issuer.

Reinsurance entity payments. A State would be required to ensure that each applicable reinsurance entity makes payments that do not exceed contributions and makes payments to issuers of reinsurance-eligible plans according to §153.230 (see above). A State could reduce payments on a pro rata basis to match the amount of contributions it received in a given reinsurance year. Any pro rata reductions would have to be made in a fair and equitable manner for all individual market issuers. A State would have to ensure that a reinsurance entity makes payments to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment. **HHS invites comments on appropriate timeframes for payments for reinsurance claims submitted, "particularly since reinsurance claims may exceed contributions for a given month, but not total projected contributions for the entire year."**

HHS also seeks comment on the deadlines by which an issuer could submit a claim for a given reinsurance benefit year (e.g., under Medicare Part D, it is within 6 months after the end of the coverage year, a standard HHS sees as appropriate). Also being considered is whether this deadline should be standardized. A standard deadline allows for an orderly completion of the payment processes that depend upon reinsurance, specifically the risk corridors program and the medical loss ratio (MLR) reporting to support the rebate calculations. The absence of a standard deadline could result in excessive delays in the completion of the rebate calculations which would, in turn, delay receipt of rebate payments by the affected enrollees.

HHS also proposes that for each benefit year, a State maintain all records related to the reinsurance program for 10 years, consistent with requirements for record retention under the False Claims Act. **Comments are solicited on this requirement.**

5. Coordination with high-risk pools (§153.250)

HHS would codify the requirement under section 1341(d) of the ACA that States must eliminate or modify high risk pools to the extent necessary to carry out the reinsurance program. A State that continues its high risk pool would be allowed to coordinate its high risk pool with its reinsurance program to the extent it conforms to the provisions of this subpart. **HHS seeks comment regarding whether a high risk pool that continues operation after January 1, 2014 should be considered an individual market plan eligible for reinsurance under this provision.**

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

Overview. In this subpart, standards are proposed for States with respect to risk adjustment; parallel provisions for health insurance issuers are proposed in subpart G, summarized below. HHS asserts that the proposed Federal standards provide States with discretion to make a number of decisions within those standards.

Section 1343 of the ACA provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group markets both in and outside of the Exchange. The Secretary, in consultation with the States, is required to establish criteria and methods to be used by the States in determining the actuarial risk of plans within a State. States electing to operate an Exchange, or HHS on behalf of States not electing to operate an Exchange, will assess charges to plans that experience lower than average actuarial risk and use them to make payments to plans that have higher than average actuarial risk.

Comments received in response to the RFC addressed Federal and State roles in administering risk adjustment, the model(s) used to do risk adjustment, and other issues. Many noted difficulties in obtaining certain types of data accurately and expressed concerns about audit requirements. Upcoding concerns as well as issues of credibility of the underlying systems to support risk adjustment were also voiced. In addition, transition issues were identified such as the timing of claims data availability in the early years of the program. It was pointed out that even States developing "all payer claims databases," will not contain any data from the currently uninsured individuals, who are expected to comprise a segment of new individual market enrollees.

1. Definitions (§153.300)

Definitions that are specifically applicable to this subpart are provided. HHS emphasizes the distinction made between risk adjustment models and risk adjustment methodologies.

Risk adjustment model. An actuarial tool used to predict health plan costs based on the relative actuarial risk of enrollees in risk adjustment covered plans (i.e., non-grandfathered plans in the individual and small group market).

Risk adjustment methodology. The specific set of procedures used to determine average actuarial risk.

Federally-certified risk adjustment methodology. A risk adjustment methodology that has been developed and promulgated by HHS or has been certified by HHS. (As discussed below, States may use a modified methodology if it has been certified by HHS and deemed a Federally-certified risk adjustment methodology.)

Alternate risk adjustment methodology. A risk adjustment methodology proposed by one or more States for use in place of the Federally-certified risk adjustment methodology, not yet certified by HHS.

Risk pool. The population across which risk is distributed in risk adjustment.

2. Risk adjustment administration (§153.310)

Under Section 1343(a) of the ACA, States must assess risk adjustment charges and provide risk adjustment payments based on plan actuarial risk as compared to a State average. HHS interprets this provision to mean that risk pools must be aggregated at the State level, even if a State decides to utilize regional Exchanges. 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, HHS provides that if multiple States contract with a single entity to administer risk adjustment, risk may not be combined across State lines, but must be pooled at the individual State-level.

State eligibility to establish a risk adjustment mechanism. Any State electing to establish an Exchange would be eligible to establish a risk adjustment program. For States that do not operate an Exchange, HHS would establish a risk adjustment program. Also, HHS would administer all of the risk adjustment functions for any State that elects to establish an Exchange but does not elect to administer risk adjustment.

Entities eligible to carry out risk adjustment activities. A State may elect to have an entity other than the Exchange perform the risk adjustment functions provided that the selected entity meets the requirements for eligibility to serve as the Exchange proposed in §155.110 of the notice of proposed rulemaking entitled, "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans."

Timeframes. All payment calculations would have to commence with the 2014 benefit year. Although the ACA does not explicitly set forth a timeframe by which risk adjustment programs must start, HHS believes risk adjustment should be coordinated with reinsurance and risk corridors to help stabilize the individual and small group markets and ensure the viability of the Exchanges. Moreover, timely completion of the risk adjustment process is important because risk adjustments affect calculations of both risk corridors and the premium rebates for issuers not meeting minimum Medical Loss Ratio (MLR) standards.

HHS seeks comment on the appropriate deadline by which risk adjustment must be completed (e.g., by June 30 of the year following the benefit year). An example timeline, similar to the approach under Medicare Advantage risk adjustment, is described in the Preamble.

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

HHS is also proposing in the Preamble (but not in the draft regulation) that in order to ensure that each State's risk adjustment program is functioning properly, States 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. This report would include the average actuarial risk score for each plan, corresponding charges or payments, and any additional information HHS deems necessary to support risk adjustment methodology determinations. C**omment is sought on the requirements for such reports, including data elements and timing.**

3. Federally-certified risk adjustment methodology (§153.320)

Overview. As noted above, section 1343(b) of the ACA requires HHS to establish criteria and methods for risk adjustment in coordination with the States. Based on this authority, HHS would establish a baseline methodology to be used by a State, or HHS on behalf of the State, in determining average actuarial risk. HHS will develop a Federally-certified risk adjustment methodology that may utilize criteria and methods similar to the criteria and methods utilized under Part C or D of Medicare. In doing this, HHS seeks "to minimize issuer burden and will leverage existing processes" related to Medicare Parts C or D risk adjustment wherever appropriate while recognizing the differences in market demographics in determining methodologies.

HHS considered proposing a requirement that all States utilize a Federally-certified risk adjustment methodology developed and promulgated by HHS but rejected this approach because States may have alternative methods that can achieve similar results. In addition, some States have already implemented risk adjustment models for programs such as Medicaid. HHS believes that "methods and criteria" in the ACA "can be interpreted to allow certain levels of State variation provided that States meet basic Federal standards."

General requirement. A State-submitted alternative risk adjustment methodology may become a Federally-certified risk adjustment methodology through HHS certification. A State's alternate methodology should offer similar or better performance in that State than the Federally-certified risk adjustment methodology as determined based on the criteria in §153.330 (see below). After HHS approved a State alternative methodology, that methodology would be considered a Federally-certified risk adjustment methodology.

Publication of methodology in notices. A State that is operating a risk adjustment program would have to use one of the Federally-certified risk adjustment methodologies that HHS would publish in a forthcoming annual Federal notice or that had been published by the State in that State's annual notice. These notices would include a full description of the risk adjustment model, including but not limited to: demographic factors, diagnostic factors, and utilization factors if any; the qualifying criteria for establishing that an individual is eligible for a specific factor; the

weights assigned to each factor; the data required to support the model; and information on deadlines for data submission and the schedule for risk adjustment factor determination. **Comments are invited on other information that should be included in this notice.**

The risk adjustment methodology would also describe any adjustments made to the risk adjustment model weights when calculating average actuarial risk. The Preamble clarifies that adjustments include any premium rating variation.[5] Allowed variation in rating needs to be accounted for so that risk adjustment does not adjust for the actuarial risk that issuers have already incorporated into their premium rates.

HHS requests comments on the implications of risk adjustment approaches for market efficiency, potential incentives created in how issuers set rates, and how approaches address rating variation allowed for age, family size, and tobacco use. Comments are invited on other approaches to determining average actuarial risk and whether links exist between potential actuarial risk methodology and potential payments and charges methodology. HHS also seeks comments on the extent of State flexibility that should be allowed in adopting an approach to determining average actuarial risk.

Use of methodology for States that do not elect an Exchange. HHS would specify in a forthcoming annual Federal notice the Federally-certified risk adjustment methodology that would apply when the Federal government operates the risk adjustment program in States that do not elect to operate an Exchange, or that elect to operate an Exchange but not a risk adjustment program.

Assessing alternate risk adjustment methodologies. To assist States in assessing a potential alternate methodology, HHS would publish in the forthcoming annual Federal notice the basic standards any alternate methodology would have to meet. This would contain details of one or more Federally-certified risk adjustment methodologies (i.e. the requisite number or types of factors and the statistical metrics the models would be expected to achieve). Prior to that formal publication, and as part of the development of the Federally-certified methodologies and associated standards for alternate risk adjustment methodologies, HHS would consult with States regarding their development and the minimum standards for alternate risk adjustment methodologies. States could use information from the consultation process to either develop their own methodologies or decide to utilize the Federally-certified risk adjustment methodology.

The ACA does not specify the method by which States are expected to determine the precise value of payments and charges. HHS identifies two methods that may achieve the goals of mitigating financial impact of adverse selection on risk adjustment covered plans while also limiting overall issuer uncertainty:

A plan's average actuarial risk would be multiplied by the *State's average normalized premium.* (To get the normalized premium, a plan's actuarial value would be divided by its premium, a necessary step because plan premiums reflect differences in benefits and administration,

[5] As noted in the Preamble, section 2701 of the PHS Act as amended by the ACA permits issuers to vary rates within defined maximum ranges based on age and tobacco use. Plans may also vary rates by geographic rating area and family size.

including actuarial value.) States then would use these normalized average premiums as the basis for the State normalized average premiums, weighted by enrollee months, for all plans in a specific risk pool. The State normalized average premium represents the premium that would be used in the risk adjustment charges and payments calculation. The next step would be to calculate the amount by which a plan's average actuarial risk deviates from the State average actuarial risk. This deviation in actuarial risk would be multiplied by the State normalized average premium, the plan's enrollee months, and the plan's actuarial value.

Under an alternative methodology, the plan's average actuarial risk would be multiplied by the *plan-specific premium* which then would be used as the basis for calculating the gross plan charges and gross plan payments.[6] To determine the gross plan charges and total plan payments that would be collected from or disbursed to health plans through risk adjustment, the deviation in actuarial risk would be multiplied by the aggregated plan premiums.

Comment is requested on the validity of the assumptions made in this section, including the two methods described, and any alternative methods that could be used to calculate payments and charges that would reduce uncertainty for plans. HHS also seeks comment on any intentional and unintentional consequences from the use of either methodology.

HHS observes that because of premium variance, inequalities between payments and charges can be expected. If a simple collection of gross plan charges and disbursement of gross plan payments is implemented, aggregate surpluses or deficits may result. To adjust gross calculations when gross plan payments are greater than gross plan charges, HHS identifies three options: (1) decrease plan payments on a prorated basis to equal plan charges; (2) increase plan charges on a prorated basis to equal plan payments; or (3) split the shortfall between high-risk and low-risk plans and pro-rating in both directions. If instead gross plan charges are greater than the sum of gross plan payments: (1) gross plan charges could be reduced on a prorated basis such that the net plan charges are sufficient to cover total plan payments; and (2) excess plan charges could be placed in a reserve account that would provide a margin of error to ensure that all necessary payments can be covered by charges.

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

4. State alternate risk adjustment methodologies (§153.330)

HHS interprets the statutory provision regarding the Secretary's establishment of criteria and methods for risk adjustment under section 1343(b) to require substantive Federal oversight of the risk adjustment process. Thus, while HHS proposes to allow States to utilize alternate risk adjustment methodologies, States taking advantage of this flexibility would also be required to submit their proposed alternate methodologies for HHS review and certification.

[6] HHS explains that this assumes that plan premiums reflect State average actuarial risk and the expectation that risk adjustment accounts for favorable or adverse selection.

Certain information about the proposed methodology would have to be included in the State's request: (i) the risk pools to which the methodology would apply; and (ii) a full description of the risk adjustment model, consisting of: factors employed in the model; weights associated with each factor; the data collection method; the schedule for data collection and risk adjustment factor calculation; the calibration methodology and frequency of calibration and statistical performance metrics of the model, as specified by HHS (e.g., R-squared or predictive ratios).

If the State wanted to use a Federally-certified risk adjustment model but with State-specific weights, retaining all other characteristics of that model, it would only need to provide the State-specific weights and a description of the calibration methodology, as well as an attestation that all other model attributes would be implemented consistently with the Federally-certified methodology.

All State requests to use an alternate methodology would be evaluated based on the extent to which the methodology: (i) accurately explains cost variation within a given population; (ii) chooses risk factors that are clinically meaningful to providers; (iii) encourages favorable behavior and discourages unfavorable behavior; (iv) uses data that are complete, high in quality and available in a timely fashion; (v) provides stable risk scores over time and across plans; and (vi) minimizes administrative burden.[7]

Timing and application of State requests to use an alternate methodology. HHS considered proposing to require State requests to be submitted to HHS no later than early November in the calendar year two years before the effective date. This would give issuers detailed information about risk adjustment prior to setting rates for any benefit year (the risk adjustment methodology would affect both the total value of premiums received after accounting for payments and charges, as well as health plan administrative costs). HHS proposes a scenario where it would evaluate proposed alternate methodologies submitted within required timeframes and notify States within 60 days, at the time of the publication of the forthcoming annual Federal notice, whether such methodologies had been certified. If HHS approved a State' alternate methodology, this methodology would be considered a Federally-certified risk adjustment methodology and could be implemented in the State that proposed it as well as any other State that elected to implement an Exchange. States would have to submit requests for alternate methodology certification only 30 days after the *advance* annual Federal notice and prior to publication of the *final* annual Federal notice. "[Any] advantage in allowing States additional time would be offset by a lesser ability to leverage State alternative models and inadequate time for issuers to reflect methodology decisions in setting rates." **HHS seeks comments regarding this timeline and potential alternatives for States to request submissions for an alternate risk adjustment methodology.**

[7] HHS explains in the Preamble that these criteria are based on the principles that guided the creation of the hierarchical condition categories (HCC) model used in Medicare's risk adjustment program (for Medicare Advantage), as well as criteria described by AcademyHealth in its 2004 risk assessment paper (see www.hcfo.org/pdf/riskadjustment.pdf) and criteria described by the American Academy of Actuaries in its 2010 risk adjustment paper (www.actuary.org/pdf/health/Risk_Adjustment_Issue_Brief_Final_5-26-10.pdf).

State renewal of alternate methodology. States that operate a risk adjustment program would be required to renew HHS certification of alternate methodologies whenever changes occur, including at the time of recalibration, which the State must identify when initially requesting certification for the alternate model. The proposed requirements for describing an update to a certified risk adjustment model are the same as those for the initial model. Any change to the model between the last certified version and the recalibrated version would have to be described. Also, the State would be required to send a notification if it intended to use the certified alternate model with no changes to any of the basic parameters.

5. Data collection under risk adjustment (§153.340)

Data collection requirements. A State, or HHS on behalf of the State, would be responsible for collecting the data for use in determining individual risk scores needed for the risk adjustment process. HHS is considering the following possibilities for data collection:

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

HHS observes that the third approach would leverage existing infrastructures established to support Exchanges and would keep individual-level data with the issuers, eliminating privacy risks related to transmission. But concerns may arise about errors that some issuers might make in calculating individual risk scores and plan averages. Also, the complicated nature of a distributed model could prove challenging for some issuers, especially smaller ones, and would thus require significant involvement by the State, or HHS on behalf of the State. Moreover, issuers would need to have the capabilities to respond to multiple queries to support other functions, such as data to recalibrate the Federally-certified risk adjustment model, reconciling cost-sharing reductions payments, verifying risk corridor submissions, or auditing cost-sharing reductions or reinsurance payments.

HHS seeks comments on the use of these data for auditing purposes.

HHS concludes in favor of the intermediate approach (#2) as the most complete, actuarially sound methodology and a methodology that also supports other functions requiring encounter level data, while maintaining State flexibility. To address concerns that might arise related to consumer privacy and standard submission formats, HHS proposes national standards (discussed below). **HHS seeks comments on the proposed approach as potential advantages and disadvantages of the alternate approaches.**

Minimum standards. States, or HHS on behalf of the State, would be required to use standard HIPAA transaction standards for data collection. Although the transaction standards promulgated

under the HIPAA administrative simplification provisions do not specifically apply to data collections under section 1343 of the ACA, HHS would require States to utilize two specific HIPAA transaction standards for risk adjustment data collection: the ASC X12N 837 Health Care Claim transaction standard for any claims-related data including encounters and the ASC X12N 834 Enrollment and Maintenance transaction standard for any enrollment or demographic data. HHS would also permit the use of the NCPDP claims transaction standard for prescription drug, claims and encounter data. **Comment is requested on whether HHS should rely on the existing HIPAA and NCPDP standards or engage stakeholders to develop a new set of national standards for use in risk adjustment (e.g., leveraging the claims standards developed with stakeholder input by the Agency for Healthcare Research and Quality).** HHS notes that standardizing data collection would allow State flexibility in modeling without unreasonably increasing issuer burden for multi-State issuers. States could limit the minimum information required to specific data elements if the information submitted represented standard code sets and the values on the HIPAA transactions. Under the proposal, States would not be permitted to reject a HIPAA compliant transaction strictly on the basis that it contained more data than the State required.

To address consumer privacy concerns, HHS proposes that States be required to utilize specific privacy standards in its data collection risk adjustment procedures. Specifically, under paragraph (b)(3) of the proposed rule, "the State, or any official, employee, agent or representative of the State must use individually identifiable information only as specifically required or permitted by this part and must not disclose individually identifiable information except" as needed to make relevant claims and encounter data collected under risk adjustment available to support specified claims related activities. In addition, the State would be required to 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. Finally, the State would be required to establish privacy standards that set forth approved uses and disclosures of individually identifiable information.

HHS also seeks comments on whether submissions of issuers' rate setting rules should be required.

Exception for States with all payer claims databases. States with existing all payer claims databases would be able to request an exception from the minimum standards for data collection. The timing of the request submission would likely be synced with requirements for alternate risk adjustment models. HHS would notify States as to exception status concurrently with the publication of the forthcoming annual Federal notice. **Comment is requested on the timeline.** Requests for an exception from minimum data collection standards would have to include technical specifications, as well as proposed modifications to support risk adjustment and other claims related activities.

Uses of risk adjustment data. The State would be required to make certain claims and encounter data collected under risk adjustment available to support other activities including: recalibrating Federally-certified risk adjustment models; verifying of risk corridor submissions; and verifying and auditing reinsurance claims. Encounter and claims data collected for risk adjustment may be

required to support other Exchange-related functions such as cost-sharing requirements and quality reporting. **HHS seeks comment on these alternative uses of risk adjustment data.**

6. Risk adjustment data validation standards (§153.350)

HHS asserts that a reliable data validation process is essential to the establishment of a credible risk adjustment program and having a positive impact on premium reduction because issuers will then be confident that the effects of adverse selection will be mitigated. HHS asserts that issuers would want data validation to be performed "since the effect of risk adjustment will be a transfer of premiums between issuers."

General requirement. States, and HHS, when HHS performs the risk adjustment function on behalf of States, would perform validation regarding the data submitted. The ACA's risk adjustment process represents a relative actuarial risk calculation. Therefore, for any data validation to have the capacity to extrapolate to adjust specific charges and payments, the validation must cover a sufficient number of plans to allow an equitable adjustment to all health plan risk adjustment factors. The State, or HHS on behalf of the State, would validate a statistically valid sample of all issuers that submit data for risk adjustment every year.

Use of data validation to adjust risk. The State, or HHS on behalf of the State, would be permitted to adjust the average actuarial risk calculated in §153.310 (see above) for all risk adjustment covered plans offered by an issuer based on the risk score determined in the data validation.

Adjustment to charges and payments. The State would be permitted to adjust charges and payments to all risk adjustment covered plan issuers based on the above calculated adjustments.

Appeals. The State would be required to provide an administrative process to appeal data validation findings.[8]

Comments are requested on appropriate timeframes for the data validation process (e.g. three years for completing the data validation "so as to ensure some finality" in the adjustment process). **They are also requested on the data validation provision more generally and any alternatives that may be able to satisfy the need to provide assurance that the charges and payments truly represent relative plan risk.**

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

In this subpart, HHS proposes requirements for health insurance issuers that complement the requirements for the transitional reinsurance program described in the Preamble for States (subpart C). he requirements also apply to third party administrators on behalf of self-insured group health plans.

[8] Although the language in the proposed rule refers to the State with respect to adjustment to charges and payments and appeals, the Preamble includes the clause "or *HHS on behalf of the State. . . .*" after "The State".

1. Reinsurance contribution funds (§153.400)

This section codifies section 1341 of the ACA, which requires that the reinsurance program be funded by contribution funds from contributing entities.

General requirement. Each contributing entity would be required to make contributions, in a frequency and manner to be determined by the State or HHS, to the applicable reinsurance entity in the State. HHS gives the example of requiring entities to submit contributions on a monthly or quarterly basis starting in January 2014 and i**nvites comments on the appropriate frequency and manner in which payments should be made by contributing entities.**

Multiple reinsurance entities. If the State establishes or contracts with more than one reinsurance entity, the contributing entity would be required to contribute an appropriate payment to each applicable reinsurance entity according to the formula established by the State.

Data requirements. Each contributing entity would be required to provide the data necessary for the applicable reinsurance entity to calculate the amounts due from each contributing entity. The types of data required would depend on the contributing entity. For contributing entities in the individual and fully-insured group markets, enrollment and premium data would be required. For those in the self-insured market, data on covered lives and total medical expenses would be required. Data could be collected on a monthly or quarterly basis beginning January 2014. **HHS invites comments on the appropriate timing to collect data submissions from contributing entities and on whether there are existing sources of data that can be drawn upon.**

2. Requests for reinsurance payment (§153.410)

General requirement. A reinsurance-eligible plan issuer would be required to submit a request for reinsurance payment to the applicable reinsurance entity.

Manner of request. The requests for payment would be made according to the method that will be specified by the State as described in 153.110 or in the forthcoming annual Federal notice.

HHS invites comments regarding methods for requesting payments and the frequency and deadline for such requests.

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

Overview. In this subpart, HHS propose requirements on health insurance issuers related to the temporary (three-year) risk corridor program. Risk corridors create a mechanism for sharing risk for allowable costs between the Federal government and QHP issuers. The ACA directs HHS to administer the risk corridors program. Qualified Health Plan issuers of QHPs with costs that are less than 97% of the QHP's costs projections would remit charges for a percentage of those savings to HHS, while QHP issuers of QHP's with costs greater than 103% of cost projections would receive payments from HHS to offset a percentage of those losses.

1. Definitions (§153.500)

Allowable costs. 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.

Allowable administrative costs. The total non-medical costs defined in §158.160(b) (non-claims costs other than taxes and regulatory fees), including costs for the administration and operation of the health insurance issuer. **Comment is invited on whether HHS should consider costs for activities that improve health care quality as described in §158.150 and §158.151 (relating t MLRs) for allowable costs to be consistent with the ACA's MLR policy and on whether to limit administrative costs to 20% consistent with the MLR standard.** HHS suggests that if the allowable administrative costs differ from calculations for the MLR rebate, issuers may be incentivized to use risk corridors payments to pay for their MLR rebates.

Charge. The flow of funds from QHP issuers to HHS.

Direct and indirect remuneration. This means prescription drug price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by a QHP issuer or an intermediary contracting organization with which a QHP issuer has contracted. Such concessions include but are not limited to: discounts, charge backs, rebates, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, and grants. The term applies regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the QHP issuer and regardless of the terms of the contract between the issuer and the intermediary contracting organization.[9]

Payment. The flow of funds from HHS to QHP issuers.

Qualified health plan. Has the meaning given to the term proposed in the general definitions section of the proposed rule for Establishment of Exchanges and Qualified Health Plans.

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

Target amount. The amount equal to the total premiums incurred by the QHP, including any premium tax credits or financial assistance from any governmental program, reduced by the allowable administrative costs of the plan.[10]

2. Risk corridor establishment and payment methodology (§153.510)

[9] HHS notes that this is same way the term was defined in the risk corridor provision implemented as a result of the Medicare Modernization Act of 2003 for the Part D program.
[10] In the preamble, the term "issuer" is used instead of "plan".

General requirement. HHS would establish risk corridors by specifying risk percentages above and below the target amount. A QHP issuer would be required to adhere to the requirements set by HHS for the establishment and administration of a risk corridor program for calendar years 2014 through 2016. Guidance would be provided in the forthcoming annual Federal notice regarding reporting and the administration of payments and charges similar to part 158 (Issuer Use of Premium Revenue: Reporting and Rebating Requirements). Risk corridors guidance would be plan specific and not issuer specific. The risk corridor provision would apply to all QHPs offered in the Exchange.

HHS payments to health insurance issuers. The proposed payment methodology adopts the thresholds and risks-sharing levels specified in section 1342 of the ACA. The risk corridor thresholds would be applied when a QHP's allowable costs reached plus or minus three percent of the target amount. Accordingly, HHS would pay a QHP issuer whose QHP incurred allowable costs for a benefit year that are greater than 103% of its target amount. Conversely, a QHP issuer would have to pay HHS if its QHP's allowable costs for a benefit year were less than 97% of its target amount. A QHP issuer whose QHP's allowable costs for a benefit year were greater than 97% but less than 103% of the target amount would neither make nor receive payments for risk corridors. (Additional information on the calculation of the payments to the QHPs or the issuers' remittance of charges to HHS is provided in the following table. In addition, specific examples are provided in the Preamble to demonstrate how the corridors would be applied.

QHP's Allowable Costs of Target Amount	Risk Corridor Payment
>108%	HHS pays amount = 2.5% of target amount + 80% of allowable costs in excess of 108% of target amount
>103% -- ≦108%	HHS pays amount = 50% of target amount in excess of 103% of target amount
97% -- 103%	No risk corridor payment
≥92% -- <97%	QHP issuer pays HHS amount = 50% of difference between 97% of target amount and allowable costs
< 92%	QHP issuer pays HHS amount = 2.5% of target amount + 80% of difference between 92% of target amount and allowable costs
Source: Health Policy Alternatives based on §1342(b) of the ACA and §153.510 of the July 15, 2011 Notice of Proposed Rulemaking	

HHS notes that while it is not proposing deadlines at this time, it has considered timeframes for QHP issuers to remit charges to HHS. For example, a QHP issuer required to make a risk corridor payment could be required to remit charges within 30 days of receiving notice from HHS; the same 30-day timeframe could apply to HHS if required to make payments to the QHP issuer. **Comments are invited as to "the appropriate frequency QHP issues should remit charges to HHS."**

3. Risk corridor standards for QHP issuers (§153.520)

To support the risk corridor program calculations, all QHP issuers would be required to submit data needed to determine actual performance relative to their target amounts. Data would be collected in standard formats specified by HHS.

Adjusted premium data. QHP issuers would be required to submit data related to actual premium amounts that they collected, including premium amounts paid by parties other than the QHP enrollee and, specifically, advance premium tax credits paid by the government.[11] Risk adjustment and reinsurance would be regarded as an after-the-fact adjustment to premiums for purposes of determining risk corridor amounts (and this is reflected in the language of the proposed rule).[12] In short the reported premium amounts would be increased by the amounts paid to the QHP issuer for risk adjustment and reinsurance. And reported premium amounts would 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. **Comment is invited on the treatment of reinsurance and risk adjustment as after-the-fact adjustments to premium for purposes of determining risk corridor amounts.**

Accounting for reinsurance payments. QHP issuers would attribute reinsurance payments to risk corridors based on the date on which the valid reinsurance claim was submitted. The Preamble includes the following example: If the QHP issuer submits a claim on or before the deadline for a benefit year, that issuer would attribute the claim payment to risk corridor calculation for the benefit year in which the costs were accrued. Conversely, if the issuer submits a claim after the deadline for a benefit year, then it would attribute the claim payment to risk corridor calculation for the following benefit year.

Allowable costs. QHP issuers would have to submit allowable cost data to calculate the risk corridors in a format specified by HHS. Allowable costs would be net of direct and indirect remuneration and (as noted above) reduced for any cost-sharing reductions payments received from HHS. **HHS invites comment on an appropriate deadline for QHP issuers to complete submission of all risk corridor data "especially since this would interact with the MLR process." Comment is also sought on "how HHS could determine allowable costs for QHP issuers in calculating risk corridors, if a QHP issuer fails to comply with the reporting provisions [described above].** In this context, HHS "seeks to limit the reporting requirements on issuers in submitting this information and would like to prevent duplicative data collection requirements on issuers for the temporary risk corridors program." **HHS seeks comment on how it can utilize data from section 2718 of the PHS Act (added by the ACA and the relating to the data for MLR calculations and premium rebates) to meet the data submission requirements for risk corridors.**

[11] Section 1342(c)(2) defines the target amount of a plan as an amount equal to the total premiums (including any premium subsidies under any governmental program), reduced by the administrative costs of the plan..

[12] HHS notes in the Preamble that "Medicare Advantage, Medicare Prescription Drug Benefit Program and Medicaid managed care risk adjustment programs similarly result in adjustments to total payments to plans. However, in these programs, the adjustment occurs concurrently with payments because they are made by the government (excluding monthly premium payments made by beneficiaries)."

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

Whereas subpart D of the NPRM proposes a process, methodology, and model for implementing the risk adjustment program for the States, this subpart describes some of the comments to the RFC related to risk adjustment and HHS's approach to the issuer standards needed to carry out risk adjustment as described in subpart D.

1. Definitions (§153.600)

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

2. Risk adjustment issuer requirements (§153.610)

Data submission. All issuers of risk adjustment covered plans would be required to submit risk adjustment data according to the timetable and format prescribed by the State, or HHS on behalf of the State. Data may include but is not limited to: claims and encounter data for items and services rendered, enrollment and demographic information; and prescription drug utilization data. **HHS seeks comment on whether other categories of data such as methods for setting rates should be required in support of risk adjustment.**

HHS outlines the following timeline for risk adjustment data submission but does not include a specific requirement in the proposed rule. Claims and encounter data would have to be submitted every 30 days and no later than the end of 180 days following the date of service; enrollment and demographic information would have to be submitted by the end of the month following enrollment; issuer rate-setting rules by the end of the month in which they become effective; and prescription drug utilization data every 30 days, and no later than the end of 90 days following date of service. HHS recognizes potential limitations of such a timeframe and **solicits comments on these and alternative timeframes.**

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

Assessment of charges. After charges and payments for all risk adjustment covered plans have been calculated (by the State, or by HHS on behalf of the State), issuers that offer risk adjustment covered plans with a net balance of risk adjustment charges payable would be notified of those net charges and would have to remit those charges to the State, or to HHS on behalf of the State. **HHS is considering proposing that issuers be given a 30-day timeframe in which to pay all these net charges and seeks comment on this and alternative timeframes.**

In the Preamble, HHS observes that since risk adjustment pools individual and small group market risk on a State level, payments and charges will be netted out at the State level. Issuers in multiple States would have to settle with each State individually.

3. Compliance with risk adjustment standards (§153.620)

Issuer support of data validation. Consistent with proposed §153.350 (see above), issuers would have to provide the required documentation in response to any HHS or State validation to substantiate the risk adjustment data that they have submitted.

Issuer records maintenance requirements. Issuers would be required to retain the required documentation to substantiate the risk adjustment data that they have submitted for a period of at least ten years after the date of the report.

III. Collection of Information Requirements

In this section, HHS discusses implications of the proposed rule for information collection as required under the Paperwork Reduction Act and notes that it is required to provide a 60-day notice in the *Federal Register* and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget for review and approval. To this end, HHS requires comment on:

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

To assess paperwork burden, HHS has to make assumptions regarding the wages of personnel needed to accomplish the proposed collection of information. Wage rates are based on the Employer Costs for Employee Compensation report by the U.S. Bureau of the Labor statistics and represent a national average. Wage rates estimates include a 35% fringe benefit estimate for State employees and a 30% fringe benefit estimate for private sector employees. The paperwork burden estimates assume full participation of all States and the District of Columbia in operating an Exchange and that all States operate the reinsurance and risk adjustment programs. Because HHS recognizes that not all States will elect to operate their own Exchanges, the estimates should be considered an upper bound of burden.

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

States would issue an annual notice of benefits and payment parameters specific to that State. HHS estimates a minimum burden for the development of the State notice since States have the option to adopt the parameters in the forthcoming annual Federal notice and would only have to indicate their intention of using these parameters in their annual notice. Factoring in labor costs

for time spent, HHS estimates a cost to each State of $10,520 and a total estimated cost burden of $536,520 for all States.

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

Subpart C includes reporting requirements and maintenance of records for States for reinsurance. The data types required are not described in this proposed rule to allow for State flexibility but the types of data that might be used to make reinsurance payments may include claims data or encounter data. HHS estimates that it will take about 12 hours on an annual basis for the applicable reinsurance entity to collect this information in an electronic format from issuers. It will take approximately 52 hours annually for States to maintain records (not only maintenance of data for the reinsurance program, but all books, records, documents, and other evidence of accounting procedures and practices related to the reinsurance program). Each State would take approximately 64 hours to meet the provisions of this subpart at a cost per State of $3,740 and a total burden cost of $190,740.

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

Part 153, subpart D describes reporting requirements for States related to the risk adjustment program. HHS notes that it provides minimum burden estimates in this section for the collection and submission of risk-related data, particularly encounter data, since States would be required to collect this information for Medicaid beginning in 2012. States would be required to implement privacy standards for all data to be collected for the risk adjustment program at an estimated cost per State of $2,310 to create and implement privacy standards. The total burden is estimated at $117,810. States would be able to file for an exception from minimum data collection standards, as described in §153.430(c). Assuming 5 States elect to file for exception, the total burden of a minimum data reporting exception per State is $979 for a total cost of $4,895.

States would also collect risk-related data from health insurance issuers. These risk-related data include claims, encounter, demographic, and enrollment data as described in §153.340. While HHS does not specify the data collection timeframe for risk adjustment data, assumptions are included on the timing of data submission. States would have to submit to HHS de-identified claims and encounter data for use in recalibrating Federally-certified risk adjustment models. States would submit summarized and individual-level claims and encounter data from reinsurance-eligible plans for audit purposes. And States would provide claims and encounter data for Exchange-related activities such as cost-sharing requirements and quality reporting. HHS estimates that it will take each State approximately 30 hours to meet these reporting requirements with a cost for each State of $1,826 and a total cost burden of $93,126.

As discussed in §153.330, States must submit a request to HHS for review and approval of an alternate risk adjustment methodology. HHS estimates that 5 States will request an approval for an alternate risk adjustment methodology and that all States requesting approval of an alternative risk adjustment methodology will update their methodology once. In total, HHS estimates that it will take approximately 38 hours for a State electing to establish an alternate risk adjustment

methodology to meet the reporting requirements with a total estimated burden of 190 hours and a per State cost of $2,266. The total estimated cost burden for five States is $11,330. In addition, States choosing to run a risk adjustment program would have to validate their risk adjustment data annually. The cost estimate for validating the risk adjustment data annually is $1,760 per State, for a total burden of $89,760.

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

Part 153, subpart E includes proposed reporting requirements for health insurance issuers related to the transitional reinsurance program. All health insurance issuers both inside and outside of the Exchanges would be required to provide enrollment and premium data (covered lives and total expenses for the self-insured market) to the applicable reinsurance entity for the estimation and collection of contributions. Issuers of reinsurance-eligible plans would have to submit data necessary in order to receive reinsurance payment. For the purpose of this estimate, HHS utilizes estimates of the number of issuers provided by the Healthcare.gov website (1,827 in the individual and small group markets). Although not all will offer QHPs, the estimate of 1827 is used to obtain the upper bound of participation and burden. The estimate for meeting these requirements for each issuer $1,488; for all issuers, the total is $2,718,576.

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

Under Part 153, subpart F, issuers of QHPs would be required to report data on premiums collected and allowable costs related to the risk corridors program. Again, not all issuers would offer QHPs, but to provide an upper bound of participation and burden, HHS assumed that all would do so. The cost burden for each issuer is an estimated $744. The total burden cost estimate for all issuers is $1,359,288.

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

Part 153, subpart G includes reporting requirements for health insurance issuers related to the risk adjustment program. Health insurance issuers would be required to submit data such as claims and encounter data for items and services rendered; enrollment and demographic information; issuer rate-setting rules; and prescription drug utilization data. Health insurance issuers would also submit data for validation and verification activities to HHS and States. Finally, health insurance issuers would maintain risk adjustment data for a period of ten years. To meet these requirements, HHS estimates an annual cost for each issuer to be $2,002 and $3,657,654 for all issuers.

Comments on these information collection and recordkeeping requirements should be submitted electronically as specified in the ADDRESSES section of the proposed rule; or to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-9975-P Fax: (202) 395-5806; or Email: OIRA_submission@omb.eop.gov.

IV. Regulatory Impact Analysis and Other Requirements

Summary of Preliminary Regulatory Impact Analysis. The summary analysis of benefits and costs included in the proposed rule is drawn from the detailed Preliminary Regulatory Impact Analysis which appears in the *Federal Register* and incorporates both this proposed rule and the one related to Exchanges. A summary of the full Regulatory Impact Statement appears as an attachment to this document.

Regulatory Flexibility Act. HHS has determined that are few, if any, insurance firms underwriting comprehensive health insurance policies that fall below the size thresholds for "small" business established by the Small Business Administration (currently $7 million in annual receipts for health insurers; $10 million or less for HMO medical centers). However, the Department has previously estimated for the MLR interim final rule that there are potentially 28 small entities with less than $7 million in accident and health earned premiums offering individual or group comprehensive major medical coverage, although many of these may be subsidiaries of larger carriers. **HHS requests comment on whether the small entities affected by this rule have been fully identified. HHS also requests comment and information on potential costs for these entities and on any alternatives that HHS should consider.**

Unfunded Mandates. Because States are not required to set up an Exchange or operate reinsurance and risk adjustment, the Secretary has determined that the proposed rule is not subject to the Unfunded Mandates Reform Act of 1995 (UMRA).

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

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, HHS observes that it has engaged in consultation with and has worked cooperatively with affected States and notes a range of consultations. "Throughout the process of developing this NPRM, HHS has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide access to Affordable Insurance Exchanges for consumers in every State. By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132."

ATTACHMENT:
PRELIMINARY REGULATORY IMPACT ANALYSIS

The Centers for Medicare and Medicaid Services (CMS) prepared a "Preliminary Regulatory Impact Analysis" of the two proposed rules, on the Establishment of Exchanges and Qualified Health Plans, and on Standards Related to Reinsurance, Risk Corridors and Risk Adjustment. That combined analysis is available at http://cciio.cms.gov/resources/files/cms-9989-p2.pdf, and each of the proposed rules includes a brief summary of the impact analysis.

I. Executive Orders

OMB has determined that the proposed rules are "economically significant" under the executive orders that govern regulatory review, because it is likely to have an annual effect of more than $100 million in any one year. As a result, CMS prepared the Regulatory Impact Analysis (RIA) to present the costs and benefits. CMS reviews briefly the provisions in the two notices of proposed rulemaking and their statutory basis.

II. Estimates of the Impact of Exchanges

CMS notes that the RIA references estimates of the CMS Office of the Actuary (April 22, 2010), but primarily uses the underlying assumptions and analysis conducted by the Congressional Budget Office (CBO) and the staff of the Joint Committee on Taxation (JCT), because that modeling accounted for all of the interactions among the interlocking pieces of the ACA.

CMS presents in Tables 1 and 2 estimates of outlays and receipts for the insurance Exchanges, based on the CBO data, and those tables are summarized below.

Estimated Outlays and Receipts for the Insurance Exchanges, FY 2012-2016, in billions of dollars					
	2012	**2013**	**2014**	**2015**	**2016**
Outlays					
Grant authority for Exchange Start-up	$0.6	$0.8	$0.4	$0.2	$0.0
Reinsurance and risk adjustment program payments	--	--	$11	$18	$18
Receipts					
Reinsurance and risk adjustment program receipts	--	--	$12	$16	$18
Source: Tables 1, 2 in CMS RIA Note: Risk adjustment payments lag receipts by one fiscal quarter					

CMS notes that the start-up funding for Exchanges is funded through a separate grant program.

CMS also presents in Table 3 the estimated number of people enrolled in Exchanges, based on the CBO data.

Estimated Number of People Enrolled in Exchanges, CY 2012-2016, in millions					
	2012	**2013**	**2014**	**2015**	**2016**
Total Exchange Enrollment	--	--	9	14	22
Exchange Enrollees Receiving Tax Credits	--	--	8	12	18
Employment-Based Coverage Purchased Through Exchanges	--	--	3	2	3
Change to Uninsured Coverage	-3	-3	-21	-26	-32
Source: Table 3 in CMS RIA					

III. Benefits

CMS notes that it is difficult to assess benefits of the various provisions of the ACA in isolation, as different elements work together to achieve the goal of making affordable health insurance available to individuals without access to affordable employer-sponsored coverage. CMS describes benefits in four areas.

- Utilization and outcomes: CMS cites studies that show that health insurance coverage improves utilization and health outcomes.
- Financial security: CMS cites studies showing the insecurity associated with a lack of insurance, and the mitigation of financial risk provided by health insurance.
- Uncompensated care: CMS cites studies showing that insurance coverage reduces uncompensated care.
- Premiums: CMS cites CBO's estimates that the Exchange policies would reduce premiums for the same benefits compared with prior law, in particular in the individual market Those savings come from a healthier risk pool resulting from the coverage expansion, as well as lower administrative costs

IV. Costs

CMS presents a review of the impact of Exchanges and on Qualified Health Plans.

Exchanges: CMS notes that the start-up of the Exchanges will be funded through the State Planning and Establishment Grants, with total grant outlays estimated at $2 billion through 2014. Starting in 2015, Exchanges must be self-sustaining and require another source of funding.

CMS reviews a number of functional areas of potential costs: developing and maintaining the Exchange plan; information technology and IT infrastructure, implementation of the Navigators provisions, notifications to applicants, enrollees, and employers, enrollment standards, the applications process, certification of QHPs, and implementation of the SHOP provisions. CMS does not provide cost estimates (apart from those noted in the summary for the information

collection requirements) because States have a great deal of flexibility in how they will set up their Exchanges, and must finance these costs on a self-sustaining basis through user fees or other such mechanisms.

Requirements on QHP Issuers: CMS notes that the cost of participating in the Exchange is an investment for QHP issuers, with substantial benefits expected for the issuer. The Exchange is a centralized outlet to attract and enroll consumers, coupled with market reforms and administrative efficiencies, which can lower sales, marketing and administrative costs, reduce premiums and help attract consumers.

CMS reviews a number of functional areas of potential costs for QHP issuers: securing accreditation, meeting network adequacy standards, and complying with premium rating rules. CMS does not provide cost estimates.

V. Impacts of the Proposed Rule on Standards Related to Reinsurance, Risk Corridors and Risk Adjustment

CMS reviews the impact of the proposed rules for the three risk sharing programs: transitional reinsurance, transitional risk corridors, and the permanent risk adjustment program. CMS notes that insurers charge premiums for expected costs plus a "risk premium. These programs reduce the risk of financial loss that issuers might otherwise expect in 2014, and the issuer can pass on a reduced risk premium to enrollees.

Reinsurance: The reinsurance pool is, by statute, $10 billion in 2014, declining to $6 billion in 2015 and $4 billion in 2016, plus an additional contribution of $2 billion in 2014 and $2015 and $1 billion in 2016. CMS notes that the funds are collected from all issuers, including insured and self-insured markets, but only issuers in the individual market are eligible for payments, so it is redistributive from the non-individual market to the individual market in order to stabilize and limit premium increases in that market in the initial years. CMS estimates that the cost of contributions to the pool will be passed on to enrollees through premium increases of about one percent in the total market, and the benefits of reinsurance will result in premium decreases in the individual market of 10-15 percent. As the reinsurance contributions decrease, their impact on the market will decline, which CMS notes tracks with decreased uncertainty in the market as experience is gained.

Risk corridors: CMS describes the risk corridor program as one that protects against rate setting uncertainty by limiting the amount of insurer losses and gains in the initial three years. It is an "after the fact adjustment to premiums" based on experience. Risk corridors are designed to shift cost from plans that overestimate their risk to plans that underestimate their risk. CMS provides no estimate of the impact.

Risk adjustment: CMS describes the permanent risk adjustment program as one that transfers dollars from health plans with the lowest risk to health plans with the highest risk. CMS estimates, based on CBO analyses, that $22 billion will be transferred among issuers. CMS states that this protects against overall adverse selection by allowing insurers to set premiums according to average actuarial risk. CMS notes that this should lower the risk premium and

allow insurers to price their products conservatively, and mitigate the incentive for health plans to avoid unhealthy members.

VI. Alternatives Considered

CMS notes the significant State flexibility provided under the proposed rules. That flexibility includes the governance structure of the Exchanges, the number of Exchanges in a State, whether to establish combined or separate individual and small business (SHOP) Exchanges, determination of the number and type and standardization of QHPs serving the exchange, and how to implement the requirement that the Exchanges be self-sustaining starting in 2015.

CMS reviews two alternatives it considered calling for less State flexibility: a uniform standard for operations of Exchanges, and a uniform standard for certifying QHPs. CMS sets out the advantages and disadvantages of those alternatives, and its rationale for rejecting them in favor of the proposed rule.

VII. Limitations of Analysis

CMS notes that the estimates are based on the CBO microsimulation model, and are both fair and realistic, but that there is fundamental uncertainty to the modeling: " ... there is greater uncertainty in estimating the impacts of implementing the Affordable Car Act and the Exchanges than in estimating implications of modifying a previously existing program." CMS notes uncertainty in any predictive model for a new program, along with uncertainty about external changes to the economy.