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(i) 100 percent of Medicare payment rates; or

(ii) Where Medicare payment rates cannot be implemented by the federally-administered PCIP, 50 percent of billed charges or a rate using a relative value scale pricing methodology.

[75 FR 45029, July 30, 2010, as amended at 78 FR 30226, May 22, 2013]

Subpart G—Relationship to Existing Laws and Programs

§ 152.39 Maintenance of effort.

(a) *General.* A State that enters into a contract with HHS under this part must demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pool in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered.

(b) *Failure to maintain efforts.* In situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools as required, and approved by HHS, under paragraph (a) of this section.

§ 152.40 Relation to State laws.

The standards established under this section shall supersede any State law or regulation, other than State licensing laws or State laws relating to plan solvency, with respect to PCIPs which are established in accordance with this section.

Subpart H—Transition to Exchanges

§ 152.44 End of PCIP program coverage.

Effective January 1, 2014, coverage under the PCIP program (45 CFR part 152) will end.

§ 152.45 Transition to the exchanges.

Prior to termination of the PCIP program, HHS will develop procedures to transition PCIP enrollees to the Exchanges, established under sections 1311 or 1321 of the Affordable Care Act, to ensure that there are no lapses in health coverage for those individuals.

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

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153.720 Establishment and usage of masked enrollee identification numbers.
153.730 Deadline for submission of data.
153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

AUTHORITY: 42 U.S.C. 18031, 18041, and 18061 through 18063.

SOURCE: 77 FR 17245, Mar. 23, 2012, unless otherwise noted.

Subpart A—General Provisions

§ 153.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act (Pub. L. 111–148, 24 Stat. 119):

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

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

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

(4) Section 1343. Risk adjustment.

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

§ 153.20 Definitions.

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

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

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

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

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

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

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

which average actuarial risk is to be calculated.

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

Contributing entity means—

(1) A health insurance issuer; or

(2) For the 2014 benefit year, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), whether or not it uses a third party administrator; and for the 2015 and 2016 benefit years, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a third party administrator in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Notwithstanding the foregoing, a self-insured group health plan that uses an unrelated third party to obtain provider network and related claim repricing services, or uses an unrelated third party for up to 5 percent of claims processing or adjudication or plan enrollment, will not be deemed to use a third party administrator, based on either the number of transactions processed by the third party, or the value of the claims processing and adjudication and plan enrollment services provided by the third party. A self-insured group health plan that is a contributing entity is responsible for the reinsurance contributions, although it may elect to use a third party administrator or administrative services-only contractor for transfer of the reinsurance contributions.

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

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

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

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

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

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

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

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

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

Individual risk score means a relative measure of predicted health care costs for a particular enrollee that is the result of a risk adjustment model.

Major medical coverage means, for purposes only of the requirements related to reinsurance contributions under section 1341 of the Affordable Care Act, a catastrophic plan, an individual or a small group market plan subject to the actuarial value requirements under §156.140 of this subchapter, or health coverage for a broad range of services and treatments provided in various settings that provides minimum value as defined in §156.145 of this subchapter.

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

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

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

Reinsurance contribution enrollee means an individual covered by a plan

for which reinsurance contributions must be made pursuant to §153.400.

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

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in §146.145(b) of this subchapter, individual health insurance coverage described in §148.220 of this subchapter, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

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

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

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

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

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

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

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

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013; 78 FR 54133, Aug. 30, 2013; 78 FR 65093, Oct. 30, 2013; 79 FR 13834, Mar. 11, 2014; 79 FR 36432, June 27, 2014; 81 FR 94174, Dec. 22, 2016; 84 FR 17561, Apr. 25, 2019]

Subpart B—State Notice of Benefit and Payment Parameters

§153.100 State notice of benefit and payment parameters.

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

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

(2) Collect additional reinsurance contributions under §153.220(d)(1) or use additional funds for reinsurance payments under §153.220(d)(2); or

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

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

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters for a particular benefit year, it must do so by the later of March 1 of the calendar year prior to the applicable benefit year, or by the 30th day following the publication of the final HHS notice of benefit and payment parameters for that benefit year.

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

(1) Adhere to the data requirements for health insurance issuers to receive

reinsurance payments that are specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Forgo the collection of additional reinsurance contributions under §153.220(d)(1) and the use of additional funds for reinsurance payments under §153.220(d)(2);

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

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

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013; 80 FR 10862, Feb. 27, 2015]

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

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

(b) *Additional collections.* If a State that establishes a reinsurance program elects to collect additional funds under §153.220(d)(1) or use additional funds for reinsurance payments under §153.220(d)(2), the State must publish in the State notice of benefit and payment parameters the following:

(1) A description of the purpose of the additional collection, including whether it will be used to cover reinsurance payments made under §153.232, administrative costs, or both;

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

(3) If the purpose of the additional collection includes reinsurance payments (or if the State is using additional funds for reinsurance payments under §153.220(d)(2)), the State supplemental reinsurance payment parameters required under §153.232.

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

(1) The geographic boundaries for that entity;

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

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

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

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013]

Subpart C—State Standards Related to the Reinsurance Program

§153.200 [Reserved]

§153.210 State establishment of a reinsurance program.

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

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

(2) If a State contracts with or establishes more than one applicable reinsurance entity, the State must ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity.

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

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

(5) A State must ensure that the applicable reinsurance entity completes

all reinsurance-related activities for benefit years 2014 through 2016 and any activities required to be undertaken in subsequent periods.

(b) *Multi-State reinsurance arrangements.* Multiple States may contract with a single entity to serve as an applicable reinsurance entity for each State. In such a case, the reinsurance programs for those States must be operated as separate programs.

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

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

(e) *Reporting to HHS.* Each State that establishes a reinsurance program must ensure that each applicable reinsurance entity provides information regarding requests for reinsurance payments under the national contribution rate made under §153.410 for all reinsurance-eligible plans for each quarter during the applicable benefit year in a manner and timeframe established by HHS.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013]

§ 153.220 Collection of reinsurance contribution funds.

(a) *Collections.* If a State establishes a reinsurance program, HHS will collect all reinsurance contributions from all contributing entities for that State under the national contribution rate.

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

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

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

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

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

(1) Reinsurance payments;

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

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

(d) *Additional State collections.* If a State establishes a reinsurance program:

(1) The State may elect to collect more than the amounts that would be collected based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year to provide:

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

(ii) Additional funds for reinsurance payments.

(2) A State may use additional funds which were not collected as additional reinsurance contributions under this part for reinsurance payments under the State supplemental payment parameters under §153.232.

[77 FR 17245, Mar. 23, 2012, as amended at 77 FR 29236, May 17, 2012, 78 FR 15525, Mar. 11, 2013; 78 FR 66655, Nov. 6, 2013]

§ 153.230 Calculation of reinsurance payments made under the national contribution rate.

(a) *Eligibility for reinsurance payments under the national reinsurance parameters.* A health insurance issuer of a reinsurance-eligible plan becomes eligible for reinsurance payments from contributions collected under the national contribution rate when its claims costs for an individual enrollee's covered benefits in a benefit year exceed the national attachment point.

(b) *National reinsurance payment parameters.* The national reinsurance payment parameters for each benefit year commencing in 2014 and ending in 2016 set forth in the annual HHS notice of

benefit and payment parameters for each applicable benefit year will apply with respect to reinsurance payments made from contributions received under the national contribution rate.

(c) *National reinsurance payments.* Each reinsurance payment made from contributions received under the national contribution rate will be calculated as the product of the national coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs in the applicable benefit year between the national attachment point and the national reinsurance cap.

(d) *Uniform adjustment to national reinsurance payments.* If HHS determines that all reinsurance payments requested under the national payment parameters from all reinsurance-eligible plans in all States for a benefit year will not be equal to the amount of all reinsurance contributions collected for reinsurance payments under the national contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments for all States. Each applicable reinsurance entity, or HHS on behalf of a State, must reduce or increase the reinsurance payment amounts for the applicable benefit year by any adjustment required under this paragraph (d).

[78 FR 15526, Mar. 11, 2013, as amended at 78 FR 66655, Nov. 6, 2013; 79 FR 13835, Mar. 11, 2014]

§ 153.232 Calculation of reinsurance payments made under a State additional contribution rate.

(a) *State supplemental reinsurance payment parameters.* (1) If a State establishes a reinsurance program and elects to collect additional contributions under § 153.220(d)(1)(ii) or use additional funds for reinsurance payments under § 153.220(d)(2), the State must set supplemental reinsurance payment parameters using one or more of the following methods:

(i) Decreasing the national attachment point;

(ii) Increasing the national reinsurance cap; or

(iii) Increasing the national coinsurance rate.

(2) The State must ensure that additional reinsurance contributions and funds projected to be received under § 153.220(d)(1)(ii) and § 153.220(d)(2), as applicable, for any applicable benefit year are reasonably calculated to cover additional reinsurance payments that are projected to be made only under the State supplemental reinsurance payment parameters (that will not be paid under the national payment parameters) for the given benefit year.

(3) All applicable reinsurance entities in a State collecting additional reinsurance contributions must apply the State supplemental reinsurance payment parameters established under paragraph (a)(1) of this section when calculating reinsurance payments.

(b) *General requirement for payments under State supplemental reinsurance parameters.* Contributions collected under § 153.220(d)(1)(ii) or funds under § 153.220(d)(2), as applicable, must be applied towards requests for reinsurance payments made under the State supplemental reinsurance payments parameters for each benefit year commencing in 2014 and ending in 2016.

(c) *Eligibility for reinsurance payments under State supplemental reinsurance parameters.* If a State establishes State supplemental reinsurance payment parameters under § 153.232(a)(1), a reinsurance-eligible plan becomes eligible for reinsurance payments from contributions under § 153.220(d)(1)(ii) or funds under § 153.220(d)(2), as applicable, if its incurred claims costs for an individual enrollee's covered benefits in the applicable benefit year:

(1) Exceed the State supplemental attachment point set forth in the State notice of benefit and payment parameters for the applicable benefit year if a State has established such a supplemental attachment point under § 153.232(a)(1)(i);

(2) Exceed the national reinsurance cap set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year if a State has established a State supplemental reinsurance cap under § 153.232(a)(1)(ii); or

(3) Exceed the national attachment point set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year if a State has established a supplemental coinsurance rate under §153.232(a)(1)(iii).

(d) *Payments under State supplemental reinsurance parameters.* Each reinsurance payment made from contributions received under §153.220(d)(1)(ii) or funds under §153.220(d)(2), as applicable, will be calculated with respect to an issuer's incurred claims costs for an individual enrollee's covered benefits in the applicable benefit year as the sum of the following:

(1) If the State has established a State supplemental attachment point, to the extent the issuer's incurred claims costs for such benefits in the applicable benefit year exceed the State supplemental attachment point but do not exceed the national attachment point, the product of such claims costs between the State supplemental attachment point and the national attachment point multiplied by the national coinsurance rate (or, if the State has established a State supplemental coinsurance rate, the State supplemental coinsurance rate);

(2) If the State has established a State supplemental reinsurance cap, to the extent the issuer's incurred claims costs for such benefits in the applicable benefit year exceed the national reinsurance cap but do not exceed the State supplemental reinsurance cap, the product of such claims costs between the national reinsurance cap and the State supplemental reinsurance cap multiplied by the national coinsurance rate (or, if the State has established a State supplemental coinsurance rate, the State supplemental coinsurance rate); and

(3) If the State has established a State supplemental coinsurance rate, the product of the issuer's incurred claims costs for such benefits in the applicable benefit year between the national attachment point and the national reinsurance cap multiplied by the difference between the State supplemental coinsurance rate and the national coinsurance rate.

(e) *Uniform adjustment to payments under State supplemental reinsurance payment parameters.* If all requested reinsurance payments under the State supplemental reinsurance parameters calculated in accordance with paragraph (a)(1) of this section from all reinsurance-eligible plans in a State for a benefit year will exceed all reinsurance contributions collected under §153.220(d)(1)(ii) or funds under §153.220(d)(2) for the applicable benefit year, the State must determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments. Each applicable reinsurance entity in the State must reduce all such requests for reinsurance payments for the applicable benefit year by that adjustment.

(f) *Limitations on payments under State supplemental reinsurance parameters.* A State must ensure that:

(1) The payments made to issuers must not exceed the issuer's total paid amount for the reinsurance-eligible claim(s); and

(2) Any remaining additional funds for reinsurance payments collected under §153.220(d)(1)(ii) must be used for reinsurance payments under the State supplemental reinsurance payment parameters in subsequent benefit years.

[78 FR 15526, Mar. 11, 2013]

§153.234 Eligibility under health insurance market rules.

A reinsurance-eligible plan's covered claims costs for an enrollee incurred prior to the application of the following provisions do not count towards either the national reinsurance payment parameters or the State supplemental reinsurance payment parameters: 45 CFR 147.102, 147.104 (subject to 147.145), 147.106 (subject to 147.145), 156.80, and subpart B of part 156.

[78 FR 15527, Mar. 11, 2013]

§153.235 Allocation and distribution of reinsurance contributions

(a) *Allocation of reinsurance contributions.* HHS will allocate and disburse to each State operating reinsurance (and will distribute directly to issuers if HHS is operating reinsurance on behalf of a State), reinsurance contributions collected from contributing entities under the national contribution rate

for reinsurance payments. The disbursed funds would be based on the total requests for reinsurance payments made under the national reinsurance payment parameters in all States and submitted under §153.410, net of any adjustment under §153.230(d).

(b) *Excess reinsurance contributions.* Any reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments for any benefit year but unused for the applicable benefit year will be used for reinsurance payments under the national reinsurance payment parameters for subsequent benefit years.

[78 FR 15527, Mar. 11, 2013]

§153.240 Disbursement of reinsurance payments.

(a) *Data collection.* If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity:

(1) Collects data required to determine reinsurance payments as described in §§153.230 and 153.232, as applicable, from an issuer of reinsurance-eligible plans or is provided access to such data, according to the data requirements specified by the State in the State notice of benefit and payment parameters described in subpart B of this part.

(2) Makes reinsurance payments to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment from that health insurance issuer in accordance with the requirements of §153.410.

(3) Provides a process through which an issuer of a reinsurance-eligible plan that does not generate individual enrollee claims in the normal course of business may use estimated claims costs to make a request for payment (or to submit data to be considered for reinsurance payments) in accordance with the requirements of §153.410. The State must ensure that such requests for reinsurance payment (or a subset of such requests) are subject to validation.

(b) *Notification of reinsurance payments.* For each applicable benefit year,

(1) A State, or HHS on behalf of the State, must notify issuers annually of:

(i) Reinsurance payments under the national payment parameters, and

(ii) Reinsurance payments under the State supplemental payment parameters if applicable, to be made for the applicable benefit year no later than June 30 of the year following the applicable benefit year.

(2) A State must provide to each issuer of a reinsurance-eligible plan the calculation of total reinsurance payment requests, on a quarterly basis during the applicable benefit year in a timeframe and manner specified by HHS, made under:

(i) The national reinsurance payment parameters, and

(ii) State supplemental reinsurance payments parameters if applicable.

(c) *Maintenance of records.* If a State establishes a reinsurance program, the State must maintain documents and records relating to the reinsurance program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated reinsurance program's compliance with Federal standards. The State must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) *Privacy and security.* (1) If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity's collection of personally identifiable information is limited to information reasonably necessary for use in the calculation of reinsurance payments, and that use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).

(2) If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity implements security standards that provide administrative, physical, and technical safeguards for the personally

identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15527, Mar. 11, 2013; 78 FR 65093, Oct. 30, 2013]

§ 153.250 Coordination with high-risk pools.

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

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

§ 153.260 General oversight requirements for State-operated reinsurance programs.

(a) *Accounting requirements.* A State that establishes a reinsurance program must ensure that its applicable reinsurance entity keeps an accounting for each benefit year of:

(1) All reinsurance contributions received from HHS for reinsurance payments and for administrative expenses;

(2) All claims for reinsurance payments received from issuers of reinsurance-eligible plans;

(3) All reinsurance payments made to issuers of reinsurance-eligible plans; and

(4) All administrative expenses incurred for the reinsurance program.

(b) *State summary report.* A State that establishes a reinsurance program must submit to HHS and make public a report on its reinsurance program operations for each benefit year in the manner and timeframe specified by HHS. The report must summarize the accounting for the benefit year kept pursuant to paragraph (a) of this section.

(c) *Independent external audit.* A State that establishes a reinsurance program must engage an independent qualified auditing entity to perform a financial and programmatic audit for each benefit year of its State-operated reinsurance program in accordance with generally accepted auditing standards (GAAS). The State must:

(1) Provide to HHS the results of the audit, in the manner and timeframe to be specified by HHS;

(2) Ensure that the audit addresses the prohibitions set forth in § 153.265;

(3) Identify to HHS any material weakness or significant deficiency identified in the audit, and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency; and

(4) Make public a summary of the results of the audit, including any material weakness or significant deficiency and how the State intends to correct the material weakness or significant deficiency, in the manner and timeframe to be specified by HHS.

[78 FR 65093, Oct. 30, 2013]

§ 153.265 Restrictions on use of reinsurance funds for administrative expenses.

A State that establishes a reinsurance program must ensure that its applicable reinsurance entity does not use any funds for the support of reinsurance operations, including any reinsurance contributions provided under the national contribution rate for administrative expenses, for any of the following purposes:

(a) Staff retreats;

(b) Promotional giveaways;

(c) Excessive executive compensation; or

(d) Promotion of Federal or State legislative or regulatory modifications.

[78 FR 65093, Oct. 30, 2013]

§ 153.270 HHS audits of State-operated reinsurance programs.

(a) *Audits.* HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of this subpart or subpart B of this part. A State that establishes a reinsurance program must ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with any audit under this section.

(b) *Action on audit findings.* If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart B,

the State must ensure that the applicable reinsurance entity:

(1) Within 60 calendar days of the issuance of the final audit report, provides a written corrective action plan to HHS for approval;

(2) Implements that plan; and

(3) Provides to HHS written documentation of the corrective actions once taken.

[79 FR 13835, Mar. 11, 2014]

Subpart D—State Standards Related to the Risk Adjustment Program

§ 153.300 [Reserved]

§ 153.310 Risk adjustment administration.

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

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

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

(4) Beginning in 2015, any State that is approved to operate an Exchange and elects to operate risk adjustment but has not been approved by HHS to operate risk adjustment prior to publication of its State notice of benefit and payment parameters for the applicable benefit year, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

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

(c) *State responsibility for risk adjustment.* (1) A State operating a risk adjustment program for a benefit year must administer the applicable Federally certified risk adjustment methodology through an entity that—

(i) Is operationally ready to implement the applicable Federally certified risk adjustment methodology and process the resulting payments and charges; and

(ii) Has experience relevant to operating the risk adjustment program.

(2) The State must ensure that the risk adjustment entity complies with all applicable provisions of subpart D of this part in the administration of the applicable Federally certified risk adjustment methodology.

(3) The State must conduct oversight and monitoring of its risk adjustment program.

(4) *Maintenance of records.* A State operating a risk adjustment program must maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated risk adjustment program's compliance with Federal standards. A State operating a risk adjustment program must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) *Approval for a State to operate risk adjustment.* (1) To be approved by HHS to operate risk adjustment under a particular Federally certified risk adjustment methodology for a benefit year, a State must establish that it and its risk adjustment entity meet the standards set forth in paragraph (c) of this section.

(2) To obtain such approval, the State must submit to HHS, in a form and manner specified by HHS, evidence

that its risk adjustment entity meets these standards.

(3) In addition to requirements set forth in paragraphs (d)(1) and (2) of this section, to obtain re-approval from HHS to operate risk adjustment for a third benefit year, the State must, in the first benefit year for which it operates risk adjustment, provide to HHS an interim report, in a manner specified by HHS, including a detailed summary of its risk adjustment activities in the first 10 months of the benefit year, no later than December 31 of the applicable benefit year.

(4) To obtain re-approval from HHS to operate risk adjustment for each benefit year after the third benefit year, each State operating a risk adjustment program must submit to HHS and make public a detailed summary of its risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS.

(i) The summary must include the results of a programmatic and financial audit for each benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with generally accepted auditing standards (GAAS).

(ii) The summary must identify any material weakness or significant deficiency identified in the audit and address how the State intends to correct any such material weakness or significant deficiency.

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

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15527, Mar. 11, 2013; 78 FR 65093, Oct. 30, 2013]

§ 153.320 Federally certified risk adjustment methodology.

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

(1) The risk adjustment methodology is developed by HHS and published in advance of the benefit year in rulemaking; or

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

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

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

(i) Draft factors to be employed in the model, including but not limited to, demographic factors, diagnostic factors, and utilization factors, if any, the dataset(s) to be used to calculate final coefficients, and the date by which final coefficients will be released in guidance;

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

(iii) Weights assigned to each factor; and

(iv) The schedule for the calculation of individual risk scores.

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

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

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

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in notice-and-comment rulemaking by HHS in advance of the applicable benefit year, the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

(d) *State flexibility to request reductions to transfers.* For the 2020 through 2023 benefit years, States can request to reduce risk adjustment transfers in the

State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by up to 50 percent in States where HHS operates the risk adjustment program. For the 2024 benefit year only, only prior participants, as defined in paragraph (d)(5) of this section, may request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by up to 50 percent in States where HHS operates the risk adjustment program.

(1) *State requests.* State requests for a reduction to transfers must include:

(i) Supporting evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State market risk pool;

(ii) The adjustment percentage of up to 50 percent requested for the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool; and

(iii) For the 2020 through 2023 benefit years, a justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments; or

(iv) For the 2024 benefit year only, a justification for the requested reduction demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(2) *Timeframe to submit reduction requests.* States must submit requests for a reduction to transfers in the individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by August 1 of the benefit year that is 2 calendar years prior to the applicable benefit year, in the form and manner specified by HHS.

(3) *Publication of reduction requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters rule and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS' Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule.

(4) *HHS approval.* (i) Subject to paragraph (d)(4)(ii) of this section, HHS will approve State reduction requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market risk pool, and relevant public comments:

(A) For the 2020 through 2023 benefit years, that State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and support the percentage reduction to risk adjustment transfers requested; or State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(B) For the 2024 benefit year only, that the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(ii) HHS may approve a reduction amount that is lower than the amount requested by the State if the supporting evidence and analysis do not fully support the requested reduction

amount. HHS will assess other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool.

(5) *Exception for prior participants.* As used in paragraph (d) of this section, prior participants mean States that submitted a State reduction request in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool in the 2020, 2021, 2022, or 2023 benefit year.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013; 81 FR 94174, Dec. 22, 2016; 83 FR 17059, Apr. 17, 2018; 84 FR 17561, Apr. 25, 2019; 86 FR 24286, May 5, 2021; 87 FR 27387, May 6, 2022; 88 FR 25916, Apr. 27, 2023]

§ 153.330 State alternate risk adjustment methodology.

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

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

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

(iii) The statistical performance metrics specified by HHS.

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

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

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

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

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

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

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

(vii) Minimizes administrative costs.

(b) *Evaluation criteria for alternate risk adjustment methodology.* An alternate risk adjustment methodology will be certified by HHS as a Federally certified risk adjustment methodology based on the following criteria:

(1) The criteria listed in paragraph (a)(2) of this section;

(2) Whether the methodology complies with the requirements of this subpart D;

(3) Whether the methodology accounts for risk selection across metal levels; and

(4) Whether each of the elements of the methodology are aligned.

(c) *State renewal of alternate methodology.* If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology without first obtaining HHS certification.

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

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

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.340 Data collection under risk adjustment.

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

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

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

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment

model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State. Use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).

(4) If a State is operating a risk adjustment program, the State must implement security standards that provide administrative, physical, and technical safeguards for the individually identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.350 Risk adjustment data validation standards.

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

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

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

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

§ 153.360 Application of risk adjustment to the small group market.

Enrollees in a risk adjustment covered plan must be assigned to the applicable risk pool in the State in which the employer's policy was filed and approved.

[78 FR 15528, Mar. 11, 2013]

§ 153.365 General oversight requirements for State-operated risk adjustment programs.

If a State is operating a risk adjustment program, it must keep an accounting of all receipts and expenditures related to risk adjustment payments and charges and the administration of risk adjustment-related functions and activities for each benefit year.

[78 FR 65094, Oct. 30, 2013]

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

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make reinsurance contributions annually: at the national contribution rate for all reinsurance contribution enrollees, in a manner specified by HHS; and at the additional State supplemental contribution rate if the State has elected to collect additional contributions under § 153.220(d)(1), in a manner specified by the State.

(1) In general, reinsurance contributions are required for major medical coverage that is considered to be part of a commercial book of business, but are not required to be paid more than once with respect to the same covered life. In order to effectuate that principle, a contributing entity must make reinsurance contributions for lives covered by its self-insured group health plans and health insurance coverage except to the extent that:

(i) Such plan or coverage is not major medical coverage, subject to paragraph (a)(3) of this section.

(ii) In the case of health insurance coverage, such coverage is not considered to be part of an issuer's commercial book of business;

(iii) Such plan or coverage is expatriate health coverage, as defined by the Secretary, or for the 2015 and 2016 benefit years only, is a self-insured group health plan with respect to which enrollment is limited to participants who reside outside of their home country for at least 6 months of the plan year, and any covered dependents; or

(iv) In the case of employer-provided health coverage, such coverage applies to individuals with respect to which benefits under Title XVIII of the Act (Medicare) are primary under the Medicare Secondary Payor rules under section 1862(b) of the Act and the regulations issued thereunder.

(v) Such plan or coverage applies to individuals with primary residence in a territory that does not operate a reinsurance program.

(vi) In the case of employer-provided group health coverage:

(A) Such coverage applies to individuals with individual market health insurance coverage for which reinsurance contributions are required; or

(B) Such coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives.

(2) Accordingly, as specified in paragraph (a)(1) of this section, a contributing entity is not required to make contributions on behalf of the following:

(i) A self-insured group health plan or health insurance coverage that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act;

(ii) Coverage offered by an issuer under contract to provide benefits under any of the following titles of the Act:

(A) Title XVIII (Medicare);

(B) Title XIX (Medicaid); or

(C) Title XXI (Children's Health Insurance Program);

(iii) A Federal or State high-risk pool, including the Pre-Existing Condition Insurance Plan Program;

(iv) Basic health plan coverage offered by issuers under contract with a State as described in section 1331 of the Affordable Care Act;

(v) A health reimbursement arrangement within the meaning of IRS Notice 2002–45 (2002–2 CB 93) or any subsequent applicable guidance, that is integrated with a self-insured group health plan or health insurance coverage;

(vi) A health savings account within the meaning of section 223(d) of the Code;

(vii) A health flexible spending arrangement within the meaning of section 125 of the Code;

(viii) An employee assistance plan, disease management program, or wellness program that does not provide major medical coverage;

(ix) A stop-loss policy or an indemnity reinsurance policy;

(x) TRICARE and other military health benefits for active and retired uniformed services personnel and their dependents;

(xi) A plan or coverage provided by an Indian Tribe to Tribal members and their spouses and dependents (and other persons of Indian descent closely affiliated with the Tribe), in the capacity of the Tribal members as Tribal members (and not in their capacity as current or former employees of the Tribe or their dependents);

(xii) Health programs operated under the authority of the Indian Health Service; or

(xiii) A self-insured group health plan or health insurance coverage that consists solely of benefits for prescription drugs.

(3) Notwithstanding paragraph (a)(1)(i) of this section, a health insurance issuer must make reinsurance contributions for lives covered by its group health insurance coverage whether or not the insurance coverage constitutes major medical coverage, if—

(i) The group health plan provides health insurance coverage for those covered lives through more than one insurance policy that in combination constitute major medical coverage;

(ii) The lives are not covered by self-insured coverage of the group health plan (except for self-insured coverage limited to excepted benefits); and

(iii) The health insurance coverage under the policy offered by the health

insurance issuer constitutes the greatest portion of inpatient hospitalization benefits under the group health plan.

(b) *Data requirements.* Each contributing entity must submit to HHS data required to substantiate the contribution amounts for the contributing entity, in the manner and timeframe specified by HHS.

(c) *Determination of a debt.* Any amount owed to the Federal government by a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) and its affiliates for reinsurance is a determination of a debt.

[78 FR 15528, Mar. 11, 2013, as amended at 78 FR 65094, Oct. 30, 2013; 79 FR 13835, Mar. 11, 2014; 80 FR 10862, Feb. 27, 2015]

§ 153.405 Calculation of reinsurance contributions.

(a) *In general.* The reinsurance contribution required from a contributing entity for its reinsurance contribution enrollees during a benefit year is calculated by multiplying:

(1) The number of covered lives of reinsurance contribution enrollees during the applicable benefit year for all plans and coverage described in §153.400(a)(1) of the contributing entity; by

(2) The contribution rate for the applicable benefit year.

(b) *Annual enrollment count.* No later than November 15 of benefit year 2014, 2015, or 2016, as applicable, or, if such date is not a business day, the next business day, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS. The count must be determined as specified in paragraphs (d) through (g) of this section, as applicable.

(c) *Notification and payment.* (1) Following submission of the annual enrollment count described in paragraph (b) of this section, HHS will notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments, administrative expenses, and the U.S. Treasury to be paid for the applicable benefit year.

(2) A contributing entity must remit reinsurance contributions to HHS no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making a combined contribution or the first payment of the bifurcated contribution, and no later than November 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making the second payment of the bifurcated contribution.

(d) *Procedures for counting covered lives for health insurance issuers.* A health insurance issuer must use the same method in a benefit year for all of its health insurance plans in the State (including both the individual and group markets) for which reinsurance contributions are required. To determine the number of covered lives of reinsurance contribution enrollees under all health insurance plans in a State for a benefit year, a health insurance issuer must use one of the following methods:

(1) Adding the total number of lives covered for each day of the first nine months of the benefit year and dividing that total by the number of days in the first nine months;

(2) Adding the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year, and dividing that total by the number of dates on which a count was made. For this purpose, the same months must be used for each quarter (for example January, April and July) and the date used for the second and third quarter must fall within the same week of the quarter as the corresponding date used for the first quarter; or

(3) Multiplying the average number of policies in effect for the first nine months of the benefit year by the ratio of covered lives per policy in effect, calculated using the prior National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit (or a form filed with the issuer's State of domicile for the most recent time period).

(e) *Procedures for counting covered lives for self-insured group health plans.*

To determine the number of covered lives of reinsurance contribution enrollees under a self-insured group health plan for a benefit year, a plan must use one of the following methods:

(1) One of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section;

(2) Adding the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year (provided that the date used for the second and third quarters must fall within the same week of the quarter as the corresponding date used for the first quarter), and dividing that total by the number of dates on which a count was made, except that the number of lives covered on a date is calculated by adding the number of participants with self-only coverage on the date to the product of the number of participants with coverage other than self-only coverage on the date and a factor of 2.35. For this purpose, the same months must be used for each quarter (for example, January, April, and July); or

(3) Using the number of lives covered for the most current plan year calculated based upon the ''Annual Return/Report of Employee Benefit Plan'' filed with the Department of Labor (Form 5500) for the last applicable time period. For purposes of this paragraph (e)(3), the number of lives covered for the plan year for a plan offering only self-only coverage equals the sum of the total participants covered at the beginning and end of the plan year, as reported on the Form 5500, divided by 2, and the number of lives covered for the plan year for a plan offering self-only coverage and coverage other than self-only coverage equals the sum of the total participants covered at the beginning and the end of the plan year, as reported on the Form 5500.

(f) *Procedures for counting covered lives for group health plans with a self-insured coverage option and an insured coverage option.* (1) To determine the number of covered lives of reinsurance contribution enrollees under a group health plan with a self-insured coverage option and an insured coverage option for a benefit year, a plan must use one of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section.

(2) Notwithstanding paragraph (f)(1), a plan with multiple coverage options may use any of the counting methods specified for self-insured coverage or insured coverage, as applicable to each option, if it determines the number of covered lives under each option separately as if each coverage option provided major medical coverage (not including any coverage option that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, that only provides benefits related to prescription drugs, or that is a health reimbursement arrangement, health savings account, or health flexible spending arrangement).

(g) *Multiple group health plans maintained by the same plan sponsor*—(1) *General rule.* If a plan sponsor maintains two or more group health plans (including one or more group health plans that provide health insurance coverage) that collectively provide major medical coverage for the same covered lives simultaneously, then those multiple plans must be treated as a single group health plan for purposes of calculating any reinsurance contribution amount due under this section. However, a plan sponsor may treat the multiple plans as separate group health plans for purposes of calculating any reinsurance contribution due under this section if it determines the number of covered lives under each separate group health plan as if the separate group health plan provided major medical coverage.

(2) *Plan sponsor.* For purposes of this paragraph (g), the term ''plan sponsor'' means:

(i) The employer, in the case of a plan established or maintained by a single employer;

(ii) The employee organization, in the case of a plan established or maintained by an employee organization;

(iii) The joint board of trustees, in the case of a multiemployer plan (as defined in section 414(f) of the Code);

(iv) The committee, in the case of a multiple employer welfare arrangement;

(v) The cooperative or association that establishes or maintains a plan established or maintained by a rural electric cooperative or rural cooperative association (as such terms are defined in section 3(40)(B) of ERISA);

(vi) The trustee, in the case of a plan established or maintained by a voluntary employees' beneficiary association (meaning that the association is not merely serving as a funding vehicle for a plan that is established or maintained by an employer or other person);

(vii) In the case of a plan, the sponsor of which is not described in paragraph (g)(2)(i) through (g)(2)(vi) of this section, the person identified by the terms of the document under which the plan is operated as the plan sponsor, or the person designated by the terms of the document under which the plan is operated as the plan sponsor, provided that designation is made, and that person has consented to the designation, by no later than the date by which the count of covered lives for that benefit year is required to be provided, after which date that designation for that benefit year may not be changed or revoked, and provided further that a person may be designated as the plan sponsor only if the person is one of the persons maintaining the plan (for example, one of the employers that is maintaining the plan with one or more other employers or employee organizations); or

(viii) In the case of a plan, the sponsor of which is not described in paragraph (g)(2)(i) through (g)(2)(vi) of this section, and for which no identification or designation of a plan sponsor has been made under paragraph (g)(2)(i)(vii) of this section, each employer that maintains the plan (with respect to employees of that employer), each employee organization that maintains the plan (with respect to members of that employee organization), and each board of trustees, cooperative or association that maintains the plan.

(3) *Exception.* A plan sponsor is not required to include as part of a single group health plan as determined under paragraph (g)(1) of this section any group health plan that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, that only provides benefits related to prescription drugs, or that is a health reimbursement arrangement, health savings account, or health flexible spending arrangement.

(4) *Procedures for counting covered lives for multiple group health plans treated as a single group health plan.* The rules in this paragraph (g)(4) govern the determination of the average number of covered lives in a benefit year for any set of multiple self-insured group health plans or health insurance plans (or a combination of one or more self-insured group health plans and one or more health insurance plans) that are treated as a single group health plan under paragraph (g)(1) of this section.

(i) *Multiple group health plans including an insured plan.* If at least one of the multiple plans is an insured plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified in either paragraph (d)(1) or (2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

(A) The average number of covered lives calculated;

(B) The counting method used; and

(C) The names of the multiple plans being treated as a single group health plan as determined by the plan sponsor and reported to HHS.

(ii) *Multiple group health plans not including an insured plan.* If each of the multiple plans is a self-insured group health plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified either in paragraph (e)(1) or (2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

(A) The average number of covered lives calculated;

(B) The counting method used; and

(C) The names of the multiple plans being treated as a single group health plan as determined by the plan sponsor.

(h) *Maintenance of records.* A contributing entity must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the enrollment count submitted pursuant to this section for a period of at least 10 years, and must

make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance contribution amounts.

(i) *Audits.* HHS or its designee may audit a contributing entity to assess its compliance with the requirements of this subpart. A contributing entity that uses a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under this subpart must ensure that the third party administrator, administrative services-only contractor, or other third party cooperates with any audit under this section.

[78 FR 15528, Mar. 11, 2013, as amended at 78 FR 66655, Nov. 6, 2013; 78 FR 65094, Oct. 30, 2013; 78 FR 66655, Nov. 6, 2014; 79 FR 13835, Mar. 11, 2014; 80 FR 10862, Feb. 27, 2015; 81 FR 12334, Mar. 8, 2016]

§ 153.410 Requests for reinsurance payment.

(a) *General requirement.* An issuer of a reinsurance-eligible plan may make a request for payment when that issuer's claims costs for an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment set forth in subpart B of this part and the HHS notice of benefit and payment parameters and State notice of benefit and payment parameters for the applicable benefit year, if applicable.

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

(c) *Maintenance of records.* An issuer of a reinsurance-eligible plan must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to this section for a period of at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, or, in a State where the State is operating reinsurance, the State or its designee, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance payment requests.

(d) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in §156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension

request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013; 79 FR 13835, Mar. 11, 2014; 86 FR 24286, May 5, 2021]

§ 153.420 Data collection.

(a) *Data requirement.* To be eligible for reinsurance payments, an issuer of a reinsurance-eligible plan must submit or make accessible all required reinsurance data in accordance with the reinsurance data collection approach established by the State, or by HHS on behalf of the State.

(b) *Deadline for submission of data.* An issuer of a reinsurance-eligible plan must submit or make accessible data to be considered for reinsurance payments for the applicable benefit year by April 30 of the year following the end of the applicable benefit year.

[78 FR 15530, Mar. 11, 2013]

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

§ 153.500 Definitions.

The following definitions apply to this subpart:

Adjustment percentage means, with respect to a QHP:

(1) For benefit year 2014—

(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise

(ii) Zero percent.

(2) For benefit year 2015, for a QHP offered by a health insurance issuer in any State, 2 percent.

(3) For benefit year 2016—

(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium, the percentage specified by HHS; and otherwise

(ii) Zero percent.

Administrative costs mean, with respect to a QHP, total non-claims costs incurred by the QHP issuer for the QHP, including taxes and regulatory fees.

After-tax premiums earned mean, with respect to a QHP, premiums earned with respect to the QHP minus taxes and regulatory fees.

Allowable administrative costs mean, with respect to a QHP, the sum of administrative costs of the QHP, other

than taxes and regulatory fees, plus profits earned by the QHP, which sum is limited to the sum of 20 percent and the adjustment percentage of after-tax premiums earned with respect to the QHP (including any premium tax credit under any governmental program), plus taxes and regulatory fees.

Allowable costs means, with respect to a QHP, an amount equal to the pro rata portion of the sum of incurred claims within the meaning of §158.140 of this subchapter (including adjustments for any direct and indirect remuneration), expenditures by the QHP issuer for the QHP for activities that improve health care quality as set forth in §158.150 of this subchapter, expenditures by the QHP issuer for the QHP related to health information technology and meaningful use requirements as set forth in §158.151 of this subchapter, and the adjustments set forth in §153.530(b); in each case for all of the QHP issuer's non-grandfathered health plans in a market within a State, allocated to the QHP based on premiums earned.

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

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

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

Premiums earned mean, with respect to a QHP, all monies paid by or for enrollees with respect to that plan as a condition of receiving coverage, including any fees or other contributions paid by or for enrollees, within the meaning of §158.130 of this subchapter.

Profits mean, with respect to a QHP, the greater of:

(1) The sum of three percent and the adjustment percentage of after-tax premiums earned; and

(2) Premiums earned of the QHP minus the sum of allowable costs and administrative costs of the QHP.

Qualified health plan or *QHP* means, with respect to the risk corridors program only —

(1) A qualified health plan, as defined at §155.20 of this subchapter;

(2) A health plan offered outside the Exchange by an issuer that is the same plan as a qualified health plan, as defined at §155.20 of this subchapter, offered through the Exchange by the issuer. To be the same plan as a qualified health plan (as defined at §155.20 of this subchapter) means that the health plan offered outside the Exchange has identical benefits, premium, cost-sharing structure, provider network, and service area as the qualified health plan (as defined at §155.20 of this subchapter); or

(3) A health plan offered outside the Exchange that is substantially the same as a qualified health plan, as defined at §155.20 of this subchapter, offered through the Exchange by the issuer. To be substantially the same as a qualified health plan (as defined at §155.20 of this subchapter) means that the health plan meets the criteria set forth in paragraph (2) of this definition with respect to the qualified health plan, except that its benefits, premium, cost-sharing structure, and provider network may differ from those of the qualified health plan (as defined at §155.20 of this subchapter) provided that such differences are tied directly and exclusively to Federal or State requirements or prohibitions on the coverage of benefits that apply differently to plans depending on whether they are offered through or outside an Exchange.

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

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

Taxes and regulatory fees mean, with respect to a QHP, Federal and State licensing and regulatory fees paid with respect to the QHP as described in §158.161(a) of this subchapter, and Federal and State taxes and assessments paid with respect to the QHP as described in §158.162(a)(1) and (b)(1) of this subchapter.

Transitional State means a State that does not enforce compliance with §147.102, §147.104, §147.106, §147.150, §156.80, or subpart B of part 156 of this subchapter for individual market and

small group health plans that renew for a policy year starting between January 1, 2014, and October 1, 2014, in accordance with the transitional policy outlined in the CMS letter dated November 14, 2013.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, 15550, Mar. 11, 2013; 78 FR 54133, Aug. 30, 2013; 79 FR 13835, Mar. 11, 2014; 79 FR 30341, May 27, 2014; 80 FR 10863, Feb. 27, 2015]

§ 153.510 Risk corridors establishment and payment methodology.

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

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

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

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

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

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

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

(d) *Charge submission deadline.* A QHP issuer must remit charges to HHS within 30 days after notification of such charges.

(e) A QHP issuer is not subject to the provisions of this subpart with respect to a stand-alone dental plan.

(f) *Eligibility under health insurance market rules.* The provisions of this subpart apply only for plans offered by a QHP issuer in the SHOP or the individual or small group market, as determined according to the employee counting method applicable under State law, that are subject to the following provisions: §§ 147.102, 147.104, 147.106, 147.150, 156.80, and subpart B of part 156 of this subchapter.

(g) *Adjustment to risk corridors payments and charges.* If an issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual value of cost-sharing reductions calculated under § 156.430(c) of this subchapter for the 2014 benefit year, HHS will make an adjustment to the amount of the issuer's 2015 benefit year risk corridors payment or charge measured by the full difference between the certified estimate of 2014 cost-sharing reductions reported and the actual value of cost-sharing reductions provided as calculated under § 156.430(c) for the 2014 benefit year.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 81 FR 12334, Mar. 8, 2016]

§ 153.520 Attribution and allocation of revenue and expense items.

(a) *Attribution to plans.* Each item of expense in the target amount with respect to a QHP must be reasonably attributable to the operation of the QHP issuer's non-grandfathered health plans in a market within a State, with the attribution based on a generally accepted accounting method, consistently applied. To the extent that a QHP issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method

used for purposes of this paragraph must be consistent.

(b) *Allocation across plans.* Each item of expense in the target amount must reflect an amount equal to the pro rata portion of the aggregate amount of such expense across all of the QHP issuer's non-grandfathered health plans in a market within a State, allocated to the QHP based on premiums earned.

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

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

(e) *Maintenance of records.* A QHP issuer must maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk corridors standards, for each benefit year for at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit or other review.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, 15550, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013]

§ 153.530 Risk corridors data requirements.

(a) *Premium data.* A QHP issuer must submit to HHS data on the premiums earned with respect to each QHP that the issuer offers in a manner specified by HHS.

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to the QHP issuer's non-grandfathered health plans in a market within a State in a manner specified by HHS. For purposes of this subpart, allowable costs must be —

(1) Increased by any risk adjustment charges paid by the issuer for the non-grandfathered health plans under the risk adjustment program established under subpart D of this part.

(2) Reduced by —

(i) Any risk adjustment payments received by the issuer for the non-grandfathered health plans under the risk adjustment program established pursuant to subpart D of this part;

(ii) Any reinsurance payments received by the issuer for the non-grandfathered health plans under the transitional reinsurance program established under subpart C of this part;

(iii) A cost-sharing reduction amount equal to the amount of cost-sharing reductions for the benefit year as calculated under §156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service.

(iv) For the 2015 and 2016 benefit years, any difference between—

(A) The sum of unpaid claims reserves and claims incurred but not reported, as set forth in §§158.103 and 158.140(a)(2) and (3) of this subchapter, that were reported on the MLR and Risk Corridors Annual Reporting Form for the year preceding the benefit year; and

(B) The actual claims incurred during the year preceding the benefit year and paid between March 31 of the benefit year and March 31 of the year following the benefit year.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to the QHP issuer's non-grandfathered health plans in a market within a State in a manner specified by HHS.

(d) *Timeframes.* For each benefit year, a QHP issuer must submit all information required under paragraphs (a) through (c) of this section by July 31 of the year following the benefit year.

(e) *Requirement to submit enrollment data for risk corridors adjustment.* A health insurance issuer in the individual or small group market of a transitional State must submit, in a manner and timeframe specified by HHS, the following:

(1) A count of its total enrollment in the individual market and small group market; and

(2) A count of its total enrollment in individual market and small group market policies that meet the criteria for transitional policies outlined in the CMS letter dated November 14, 2013.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15531, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 79 FR 37662, July 2, 2014; 81 FR 12334, Mar. 8, 2016]

§ 153.540 Compliance with risk corridors standards.

HHS or its designee may audit a QHP issuer to assess its compliance with the requirements of this subpart. HHS will conduct an audit in accordance with the procedures set forth in § 158.402(a) through (e) of this subchapter.

[79 FR 13836, Mar. 11, 2014]

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

§ 153.600 [Reserved]

§ 153.610 Risk adjustment issuer requirements.

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

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

(c) *Issuer contracts.* An issuer that offers risk adjustment covered plans may include in its contract with a provider, supplier, physician, or other practitioner, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframe established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

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

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

(f) *Assessment and collection of user fees for HHS risk adjustment operations.* Where HHS is operating risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan (other than a student health plan or a plan not subject to 45 CFR 147.102, 147.104, 147.106, 156.80, and subpart B of part 156) must, for each benefit year—

(1) Submit or make accessible to HHS its monthly enrollment for the risk adjustment covered plan for the benefit year through the risk adjustment data collection approach established at § 153.610(a), in a manner and timeframe specified by HHS; and

(2) Remit to HHS an amount equal to the product of its monthly billable enrollment in the risk adjustment covered plan multiplied by the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15531, Mar. 11, 2013; 81 FR 94174, Dec. 22, 2016]

§ 153.620 Compliance with HHS risk adjustment standards.

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

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient

to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, for each benefit year for at least 10 years, and must make those documents and records available upon request to HHS, the OIG, the Comptroller General, or their designees, or in a State where the State is operating risk adjustment, the State or its designee to any such entity, for purposes of verification, investigation, audit or other review.

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in §156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding or observation in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following, if required by HHS:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any risk adjustment

(including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 65095, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 86 FR 24287, May 5, 2021; 89 FR 26419, Apr. 15, 2024]

§ 153.630 Data validation requirements when HHS operates risk adjustment.

(a) *General requirement.* An issuer of a risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial and second validation audit performed on its risk adjustment data as described in this section.

(b) *Initial validation audit.* (1) An issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. The issuer must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor, in a timeframe and manner to be specified by HHS.

(2) The issuer must ensure that the initial validation auditors are reasonably capable of performing an initial data validation audit according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

(3) The issuer must ensure that each initial validation auditor is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner and its impartiality is not reasonably open to question.

(4) The issuer must ensure validation of the accuracy of risk adjustment data for a sample of enrollees selected by HHS. The issuer must ensure that the initial validation audit findings are submitted to HHS in a manner and timeframe specified by HHS.

(5) An initial validation audit must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission. Notwithstanding any other provision of this section, a qualified provider that is licensed to diagnose mental illness by the State and that is prohibited from furnishing a complete medical record by applicable State privacy laws concerning any enrollee's treatment for one or more mental or behavioral health conditions may furnish a signed mental or behavioral health assessment that, to the extent permissible under applicable Federal and State privacy laws, should contain: The enrollee's name; sex; date of birth; current status of all mental or behavioral health diagnoses; and dates of service. The mental or behavioral health assessment should be signed by the provider and submitted with an attestation that the provider is prohibited from furnishing a complete medical record by applicable State privacy laws.

(7) The risk score of each enrollee in the sample must be validated by—

(i) Validating the enrollee's enrollment data and demographic data in a manner to be determined by HHS.

(ii) Validating enrollee health status through review of all relevant medical record documentation. Medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers and services. For purposes of this section, ''medical record documentation'' means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health

status is documented and related to accepted risk adjustment services that occurred during a specified period of time. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services;

(iii) Beginning in the 2018 benefit year, validating enrollee health status through review of all relevant paid pharmacy claims;

(iv) Validating medical records according to industry standards for coding and reporting; and

(v) Having a senior reviewer confirm any enrollee risk adjustment error discovered during the initial validation audit. For purposes of this section, a ''senior reviewer'' is a reviewer certified as a medical coder by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, a senior reviewer may possess 3 or more years of experience.

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes, except that for validation of risk adjustment data for the 2015 and 2016 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) HHS may impose civil money penalties in accordance with the procedures set forth in §156.805(b) through (e) of this subchapter if an issuer of a risk adjustment covered plan—

(i) Fails to engage an initial validation auditor;

(ii) Fails to submit the results of an initial validation audit to HHS;

(iii) Engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or

(iv) Intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS.

(10) If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default data validation charge.

(c) *Second validation audit.* HHS will select a subsample of the risk adjustment data validated by the initial validation audit for a second validation audit. The issuer must comply with, and must ensure the initial validation auditor complies with, standards for such audit established by HHS, and must cooperate with, and must ensure that the initial validation auditor cooperates with, HHS and the second validation auditor in connection with such audit.

(d) *Risk adjustment data validation disputes and appeals.* (1) Within 15 calendar days of notification of the initial validation audit sample determined by HHS, in the manner set forth by HHS, an issuer must confirm the sample or file a discrepancy report to dispute the initial validation audit sample determined by HHS.

(2) Within 15 calendar days of the notification of the findings of a second validation audit (if applicable) by HHS, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable), or file a discrepancy report to dispute the findings of a second validation audit (if applicable).

(3) Within 30 calendar days of the notification by HHS of the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the calculation of a risk score error rate as a result of risk adjustment data validation.

(4) An issuer may appeal the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in §156.1220 of this subchapter.

(e) *Adjustment of payments and charges.* HHS may adjust payments and charges for issuers that do not comply with audit requirements and standards, as specified in paragraphs (b) and (c) of this section.

(f) *Data security and transmission.* (1) An issuer must submit the risk adjustment data and source documentation for the initial and second validation audits specified by HHS to HHS or its designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

(g) *Exemptions.* An issuer of a risk adjustment covered plan will be exempted by HHS from the data validation requirement set forth in paragraph (b) of this section for a given benefit year if:

(1) The issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets (as applicable) for the applicable benefit year, calculated on a Statewide basis;

(2) The issuer is at or below the materiality threshold as defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits); or

(3) The issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that:

(i) The issuer provides to HHS, in the manner and timeframe specified by HHS, an attestation that the issuer is in liquidation or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer; and

(ii) The issuer is not a positive error rate outlier under the error estimation methodology in risk adjustment data validation for the prior benefit year of risk adjustment data validation.

(iii) For purposes of this paragraph (g)(3), liquidation means that a State court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest.

(4) The issuer only offered small group market carryover coverage during the benefit year that is being audited.

(5) The issuer was the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13836, Mar. 11, 2014; 81 FR 94174, Dec. 22, 2016; 83 FR 17059, Apr. 17, 2018; 84 FR 17562, Apr. 25, 2019; 86 FR 24287, May 5, 2021; 88 FR 25916, Apr. 27, 2023]

Subpart H—Distributed Data Collection for HHS-Operated Programs

SOURCE: 78 FR 15531, Mar. 11, 2013, unless otherwise noted.

§ 153.700 Distributed data environment.

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

§ 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee

claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

(d) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with §153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(e) *Materiality threshold.* HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds $100,000 or 1 percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less.

(f) *Unresolved discrepancies.* If a discrepancy first identified in a final dedicated distributed data environment report in accordance with paragraph (d)(2) of this section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under §153.310(e) or §153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in §156.1220(a) of this subchapter.

(g) *Evaluation of dedicated distributed data.* If an issuer of a risk adjustment covered plan fails to provide sufficient required data, such that HHS cannot apply the applicable methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely or appropriate fashion, then HHS will assess a default risk adjustment charge under §153.740(b). If an issuer of a reinsurance eligible plan fails to provide data sufficient for HHS to calculate reinsurance payments, the issuer will forfeit reinsurance payments for claims it fails to submit.

(1) *Data quantity.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan must provide, in a format and on a timeline specified by HHS, data on its total enrollment and claims counts by market, which HHS may use in evaluating whether the issuer provided access in the dedicated distributed data environment to a sufficient quantity of data to meet reinsurance and risk adjustment data requirements.

(2) *Data quality.* If, following the deadline for submission of data specified in §153.730, HHS identifies an outlier that would cause the data that a risk adjustment covered plan or a reinsurance-eligible plan made available through a dedicated distributed data environment to fail HHS's data quality thresholds, the issuer may, within 10 calendar days of receiving notification of the outlier, submit an explanation of the outlier for HHS to consider in determining whether the issuer met the reinsurance and risk adjustment data requirements.

(h) *Risk corridors and MLR reporting.* Except as provided in paragraph (h)(3) of this section:

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, any discrepancy filed

under §153.630(d)(2) or (3), or any request for reconsideration under §156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and medical loss ratio (MLR) programs:

(i) The risk adjustment payment to be made or charge assessed, including an assessment of risk adjustment user fees, by HHS in the notification provided under §153.310(e);

(ii) The reinsurance payment to be made by HHS in the notification provided under §153.240(b)(1)(ii);

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under §156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service;

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under §153.510; and

(v) The risk adjustment data validation adjustment calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.

(2) An issuer must report during the current MLR and risk corridors reporting year any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge before August 15, or the next applicable business day, of the current MLR and risk corridors reporting year unless instructed otherwise by HHS. An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge where such adjustment has not been accounted for in a prior MLR and Risk Corridors Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (h)(1) or (2) of this section would lead to unfair or misleading financial reporting, issuers must correct their data submissions in a form and manner to be specified by HHS.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13837, Mar. 11, 2014; 81 FR 12335, Mar. 8, 2016; 86 FR 24288, May 5, 2021; 87 FR 27387, May 6, 2022; 88 FR 25916, Apr. 27, 2023]

§153.720 Establishment and usage of masked enrollee identification numbers.

(a) *Enrollee identification numbers.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must—

(1) Establish a unique masked enrollee identification number for each enrollee; and

(2) Maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year.

(b) *Prohibition on personally identifiable information.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, may not—

(1) Include enrollee's personally identifiable information in the masked enrollee identification number; or

(2) Use the same masked enrollee identification number for different enrollees enrolled with the issuer.

§153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as

applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day.

[87 FR 27387, May 6, 2022]

§ 153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

(a) *Enforcement actions.* If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with §153.700(a) or otherwise fails to comply with the requirements of §§153.700 through 153.730; fails to adhere to the reinsurance data submission requirements set forth in §153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §§153.610 through 153.630, HHS may impose civil money penalties in accordance with the procedures set forth in §156.805 of this subchapter. Civil monetary penalties will not be imposed for non-compliance with these requirements during the 2014 or 2015 calendar years under this paragraph if the issuer has made good faith efforts to comply with these requirements.

(b) *Default risk adjustment charge.* If an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with §153.610(a), §153.700, §153.710, or §153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge.

(c) *Information sharing.* HHS may consult with and share information about issuers of risk adjustment covered plans and reinsurance-eligible plans with other Federal and State regulatory and enforcement entities to the extent the consultation or information is necessary for purposes of Federal or State oversight and enforcement activities.

[78 FR 65095, Oct. 30, 2013, as amended at 80 FR 10863, Feb. 27, 2015]

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

Subpart A—General Provisions

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Subpart B—Disclosure and Review Provisions

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Subpart C—Effective Rate Review Programs

154.301 CMS's determinations of Effective Rate Review Programs.

AUTHORITY: Section 2794 of the Public Health Service Act (42 USC 300gg–94).

SOURCE: 76 FR 29985, May 23, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 154.101 Basis and scope.

(a) *Basis.* This part implements section 2794 of the Public Health Service (PHS) Act.

(b) *Scope.* This part establishes the requirements for health insurance issuers offering health insurance coverage in the small group or individual markets to report information concerning unreasonable rate increases to the Centers for Medicare & Medicaid