this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants, beneficiaries, and enrollees, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants, beneficiaries, and enrollees, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants, beneficiaries, and enrollees, as applicable;

(ii) Average monthly premium amount paid by participants, beneficiaries, and enrollees, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants, beneficiaries, and enrollees, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

Subpart A—General Provisions

Sec.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce PHS Act requirements

AUTHORITY: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

SOURCE: 64 FR 45795, Aug. 20, 1999, unless otherwise noted.

Subpart A—General Provisions

§ 150.101 Basis and scope.

(a) *Basis.* CMS's enforcement authority under sections 2723 and 2761 of the PHS Act and its rulemaking authority under section 2792 of the PHS Act provide the basis for issuing regulations under this part 150.

(b) *Scope*—(1) *Enforcement with respect to group heath plans.* The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by CMS using the procedures described in §150.301 *et seq.*

(2) *Enforcement with respect to health insurance issuers.* The states have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a state is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in parts 146, 147, and 148 of this subchapter, CMS enforces them under subpart C of this part.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13439, Feb. 27, 2013]

§ 150.103 Definitions.

The definitions that appear in part 144 of this subchapter apply to this

part 150, unless stated otherwise. As used in this part:

Amendment, *endorsement*, or *rider* means a document that modifies or changes the terms or benefits of an individual policy, group policy, or certificate of insurance.

Application means a signed statement of facts by a potential insured that an issuer uses as a basis for its decision whether, and on what basis to insure an individual, or to issue a certificate of insurance, or that a non-Federal governmental health plan uses as a basis for a decision whether to enroll an individual under the plan.

Certificate of insurance means the document issued to a person or entity covered under an insurance policy issued to a group health plan or an association or trust that summarizes the benefits and principal provisions of the policy.

Complaint means any expression, written or oral, indicating a potential denial of any right or protection contained in PHS Act requirements (whether ultimately justified or not) by an individual, a personal representative or other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

Group health insurance policy or group policy means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in §144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of parts 147 and 148 of this subchapter. The term ''individual health insurance policy'' includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of parts 146 and 147 of this subchapter.

PHS Act requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146, 147, and 148 of this subchapter.

Plan document means the legal document that provides the terms of the plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

State law means all laws, decisions, rules, regulations, or other State action having the effect of law, of any State as defined in §144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13439, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce PHS Act Requirement

§150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces PHS Act requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§150.203 Circumstances requiring CMS enforcement.

CMS enforces PHS Act requirement to the extent warranted (as determined by CMS) in any of the following circumstances:

(a) *Notification by State.* A State notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing PHS Act requirements.

(b) *Determination by CMS.* If CMS receives or obtains information that a

State may not be substantially enforcing PHS Act requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with §148.128 of this subchapter instead of complying with the guaranteed availability requirements of §148.120, CMS's determination focuses on the following:

(1) Whether the State's mechanism meets the requirements for an acceptable alternative mechanism.

(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§148.101 through 148.126 and §148.170 of this subchapter.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.205 Sources of information triggering an investigation of State enforcement.

Information that may trigger an investigation of State enforcement includes, but is not limited to, any of the following:

(a) A complaint received by CMS.

(b) Information learned during informal contact between CMS and State officials.

(c) A report in the news media.

(d) Information from the governors and commissioners of insurance of the various States regarding the status of their enforcement of PHS Act requirements.

(e) Information obtained during periodic review of State health care legislation. CMS may review State health care and insurance legislation and regulations to determine whether they are:

(1) Consistent with PHS Act requirements.

(2) Not pre-empted as provided in §146.143 (relating to group market provisions) and §148.120 (relating to individual market requirements) on the basis that they prevent the application of a PHS Act requirement.

(f) Any other information that indicates a possible failure to substantially enforce.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.207 Procedure for determining that a State fails to substantially enforce PHS Act requirements.

Sections 150.209 through 150.219 describe the procedures CMS follows to determine whether a State is substantially enforcing PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.209 Verification of exhaustion of remedies and contact with State officials.

If CMS receives a complaint or other information indicating that a State is failing to enforce PHS Act requirements, CMS assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, CMS may contact State officials regarding the questions raised.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.211 Notice to the State.

If CMS is satisfied that there is a reasonable question whether there has been a failure to substantially enforce PHS Act requirements, CMS sends, in writing, the notice described in §150.213 of this part, to the following State officials:

(a) The governor or chief executive officer of the State.

(b) The insurance commissioner or chief insurance regulatory official.

(c) If the alleged failure involves HMOs, the official responsible for regulating HMOs if different from the official listed in paragraph (b) of this section.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.213 Form and content of notice.

The notice provided to the State is in writing and does the following:

(a) Identifies the PHS Act requirement or requirements that have allegedly not been substantially enforced.

(b) Describes the factual basis for the allegation of a failure or failures to enforce PHS Act requirements.

(c) Explains that the consequence of a State's failure to substantially enforce PHS Act requirements is that CMS enforces them.

(d) Advises the State that it has 30 days from the date of the notice to respond, unless the time for response is extended as described in § 150.215 of this subpart. The State's response should include any information that the State wishes CMS to consider in making the preliminary determination described in § 150.217.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.215 Extension for good cause.

CMS may extend, for good cause, the time the State has for responding to the notice described in § 150.213 of this subpart. Examples of good cause include an agreement between CMS and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

§ 150.217 Preliminary determination.

If, at the end of the 30-day period (and any extension), the State has not established to CMS's satisfaction that it is substantially enforcing the PHS Act requirements described in the notice, CMS takes the following actions:

(a) Consults with the appropriate State officials identified in § 150.211 (or their designees).

(b) Notifies the State of CMS's preliminary determination that the State has failed to substantially enforce the requirements and that the failure is continuing.

(c) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.219 Final determination.

If, after providing notice and a reasonable opportunity for the State to show that it has corrected any failure to substantially enforce, CMS finds that the failure to substantially enforce has not been corrected, it will send the State a written notice of its final determination. The notice includes the following:

(a) Identification of the PHS Act requirements that CMS is enforcing.

(b) The effective date of CMS's enforcement.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.221 Transition to State enforcement.

(a) If CMS determines that a State for which it has assumed enforcement authority has enacted and implemented legislation to enforce PHS Act requirements and also determines that it is appropriate to return enforcement authority to the State, CMS will enter into discussions with State officials to ensure that a transition is effected with respect to the following:

(1) Consumer complaints and inquiries.

(2) Instructions to issuers.

(3) Any other pertinent aspect of operations.

(b) CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting issuer compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the State regulatory authority that will assume enforcement responsibility.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

Subpart C—CMS Enforcement With Respect to Issuers and Non-Federal Governmental Plans—Civil Money Penalties

§ 150.301 General rule regarding the imposition of civil money penalties.

If any health insurance issuer that is subject to CMS's enforcement authority under § 150.101(b)(2), or any non-Federal governmental plan (or employer

that sponsors a non-Federal governmental plan) that is subject to CMS's enforcement authority under §150.101(b)(1), fails to comply with PHS Act requirements, it may be subject to a civil money penalty as described in this subpart.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.303 Basis for initiating an investigation of a potential violation.

(a) *Information.* Any information that indicates that any issuer may be failing to meet the PHS Act requirements or that any non-Federal governmental plan that is a group health plan as defined in section 2791(a)(1) of the PHS Act and 45 CFR §144.103 may be failing to meet an applicable PHS Act requirement, may warrant an investigation. CMS may consider, but is not limited to, the following sources or types of information:

(1) Complaints.

(2) Reports from State insurance departments, the National Association of Insurance Commissioners, and other Federal and State agencies.

(3) Any other information that indicates potential noncompliance with PHS Act requirements.

(b) *Who may file a complaint.* Any entity or individual, or any entity or personal representative acting on that individual's behalf, may file a complaint with CMS if he or she believes that a right to which the aggrieved person is entitled under PHS Act requirements is being, or has been, denied or abridged as a result of any action or failure to act on the part of an issuer or other responsible entity as defined in §150.305.

(c) *Where a complaint should be directed.* A complaint may be directed to any CMS regional office.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.305 Determination of entity liable for civil money penalty.

If a failure to comply is established under this part, the responsible entity, as determined under this section, is liable for any civil money penalty imposed.

(a) *Health insurance issuer is responsible entity*—(1) *Group health insurance policy.* To the extent a group health insurance policy issued, sold, renewed, or offered to a private plan sponsor or a non-Federal governmental plan sponsor is subject to applicable PHS Act requirements, a health insurance issuer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraphs (b) or (c) of this section, if the policy itself or the manner in which the policy is marketed or administered fails to comply with an applicable PHS Act requirement.

(2) *Individual health insurance policy.* To the extent an individual health insurance policy is subject to an applicable PHS Act requirement, a health insurance issuer is subject to a civil money penalty if the policy itself, or the manner in which the policy is marketed or administered, violates any applicable PHS Act requirement.

(b) *Non-Federal governmental plan is responsible entity*—(1) *Basic rule.* If a non-Federal governmental plan is sponsored by two or more employers and fails to comply with an applicable PHS Act requirement, the plan is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The plan is the responsible entity irrespective of whether the plan is administered by a health insurance issuer, an employer sponsoring the plan, or a third-party administrator.

(2) *Exception.* In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (b) does not apply to the extent that the non-Federal governmental employers have elected under §146.180 to exempt the plan from applicable PHS Act requirements.

(c) *Employer is responsible entity*—(1) *Basic rule.* If a non-Federal governmental plan is sponsored by a single employer and fails to comply with an applicable PHS Act requirement, the employer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The employer is the responsible entity irrespective of whether the plan is administered by a

health insurance issuer, the employer, or a third-party administrator.

(2) *Exception.* In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (c) does not apply to the extent the non-Federal governmental employer has elected under §146.180 to exempt the plan from applicable PHS Act requirements.

(d) *Actions or inactions of agent.* A principal is liable for penalties assessed for the actions or inactions of its agent.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§150.307 Notice to responsible entities.

If an investigation under §150.303 indicates a potential violation, CMS provides written notice to the responsible entity or entities identified under §150.305. The notice does the following:

(a) Describes the substance of any complaint or other information.

(b) Provides 30 days from the date of the notice for the responsible entity or entities to respond with additional information, including documentation of compliance as described in §150.311.

(c) States that a civil money penalty may be assessed.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005]

§150.309 Request for extension.

In circumstances in which an entity cannot prepare a response to CMS within the 30 days provided in the notice, the entity may make a written request for an extension from CMS detailing the reason for the extension request and showing good cause. If CMS grants the extension, the responsible entity must respond to the notice within the time frame specified in CMS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a violation of PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§150.311 Responses to allegations of noncompliance.

In determining whether to impose a civil money penalty, CMS reviews and considers documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with PHS Act requirements. The following are examples of documentation that a potential responsible entity may submit for CMS's consideration in determining whether a civil money penalty should be assessed and the amount of any civil money penalty:

(a) Any individual policy, group policy, certificate of insurance, application, rider, amendment, endorsement, certificate of creditable coverage, advertising material, or any other documents if those documents form the basis of a complaint or allegation of noncompliance, or the basis for the responsible entity to refute the complaint or allegation.

(b) Any other evidence that refutes an alleged noncompliance.

(c) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(d) Documentation that the policies, certificates of insurance, or non-Federal governmental plan documents have been amended to comply with PHS Act requirements either by revision of the contracts or by the development of riders, amendments, or endorsements.

(e) Documentation of the entity's issuance of conforming policies, certificates of insurance, plan documents, or amendments to policyholders or certificate holders before the issuance of the notice to the responsible entity or entities described in §150.307.

(f) Evidence documenting the development and implementation of internal policies and procedures by an issuer, or non-Federal governmental health plan or employer, to ensure compliance with PHS Act requirements. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's, or non-

Federal governmental health plan's or employer's, commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with PHS Act requirements and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(g) Evidence documenting the entity's record of previous compliance with PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005; 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.313 Market conduct examinations.

(a) *Definition.* A market conduct examination means the examination of health insurance operations of an issuer, or the operation of a non-Federal governmental plan, involving the review of one or more (or a combination) of a responsible entity's business or operational affairs, or both, to verify compliance with PHS Act requirements.

(b) *General.* If, based on the information described in §150.303, CMS finds evidence that a specific entity may be in violation of a PHS Act requirement, CMS may initiate a market conduct examination to determine whether the entity is out of compliance. CMS may conduct the examinations either at the site of the issuer or other responsible entity or a site CMS selects. When CMS selects a site, it may direct the issuer or other responsible entity to forward any documentation CMS considers relevant for purposes of the examination to that site.

(c) *Appointment of examiners.* When CMS identifies an issue that warrants investigation, CMS will appoint one or more examiners to perform the examination and instruct them as to the scope of the examination.

(d) *Appointment of professionals and specialists.* When conducting an examination under this part, CMS may retain attorneys, independent actuaries, independent market conduct examiners, or other professionals and specialists as examiners.

(e) *Report of market conduct examination*—(1) *CMS review.* When CMS receives a report, it will review the report, together with the examination work papers and any other relevant information, and prepare a final report. The final examination report will be provided to the issuer or other responsible entity.

(2) *Response from issuer or other responsible entity.* With respect to each examination issue identified in the report, the issuer or other responsible entity may:

(i) Concur with CMS's position(s) as outlined in the report, explaining the plan of correction to be implemented.

(ii) Dispute CMS's position(s), clearly outlining the basis for its dispute and submitting illustrative examples where appropriate.

(3) *CMS's reply to a response from an issuer or other responsible entity.* Upon receipt of a response from the issuer or other responsible entity, CMS will provide a letter containing its reply to each examination issue. CMS's reply will consist of one of the following:

(i) Concurrence with the issuer's or non-Federal governmental plan's position.

(ii) Approval of the issuer's or non-Federal governmental plan's proposed plan of correction.

(iii) Conditional approval of the issuer's or non-Federal governmental plan's proposed plan of correction, which will include any modifications CMS requires.

(iv) Notice to the issuer or non-Federal governmental plan that there exists a potential violation of PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.315 Amount of penalty—General.

A civil money penalty for each violation of 42 U.S.C. 300gg *et seq.* may not exceed $100 as adjusted annually under 45 CFR part 102 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to

any other penalties prescribed or allowed by law.

[64 FR 45795, Aug. 20, 1999, as amended at 81 FR 61581, Sept. 6, 2016]

§ 150.317 Factors CMS uses to determine the amount of penalty.

In determining the amount of any penalty, CMS takes into account the following:

(a) *The entity's previous record of compliance*. This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation or violations, CMS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of PHS Act requirements.

(2) Documentation that the responsible entity has submitted its policy forms to CMS for compliance review.

(3) Evidence that the responsible entity has never had a complaint for noncompliance with PHS Act requirements filed with a State or CMS.

(4) Such other factors as justice may require.

(b) *The gravity of the violation*. This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.319 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by §150.315 to reflect that fact. As guidelines for taking into account the factors listed in §150.317, CMS considers the following:

(a) *Record of prior compliance*. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under §150.307, implemented and followed a compliance plan as described in §150.311(f).

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s)*. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with PHS Act requirements so that the following occur:

(i) All employers, employees, individuals and non-Federal governmental entities are identified that are or were issued any policy, certificate of insurance or plan document, or any form used in connection therewith that failed to comply.

(ii) All employers, employees, individuals, and non-Federal governmental plans are identified that were denied coverage or were denied a right provided under PHS Act requirements.

(iii) Each employer, employee, individual, or non-Federal governmental plan adversely affected by the violation has been, for example, offered coverage or provided a certificate of creditable coverage in a manner that complies with PHS Act requirements that were violated so that, to the extent practicable, that employer, employee, individual, or non-Federal governmental entity is in the same position that he, she, or it would have been in had the violation not occurred.

(iv) The adjustments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from CMS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.321 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 150.323 Determining the amount of penalty—other matters as justice may require.

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 150.325 Settlement authority.

Nothing in §§ 150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.307 or to compromise on any penalty provided for in §§ 150.315 through 150.323.

§ 150.341 Limitations on penalties.

(a) *Circumstances under which a civil money penalty is not imposed.* CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 150.343 Notice of proposed penalty.

If CMS proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the PHS Act requirements that CMS has determined that the responsible entity violated.

(b) A description of any complaint or other information upon which CMS based its determination, including the basis for determining the number of affected individuals and the number of days for which the violations occurred.

(c) The amount of the proposed penalty as of the date of the notice.

(d) Any circumstances described in §§ 150.317 through 150.323 that were considered when determining the amount of the proposed penalty.

(e) A specific statement of the responsible entity's right to a hearing.

(f) A statement that failure to request a hearing within 30 days permits the assessment of the proposed penalty without right of appeal in accordance with § 150.347.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.345 Appeal of proposed penalty.

Any entity against which CMS has assessed a penalty may appeal that

penalty in accordance with §150.401 *et seq*.

§ 150.347 Failure to request a hearing.

If the responsible entity does not request a hearing within 30 days of the issuance of the notice described in §150.343, CMS may assess the proposed civil money penalty, a less severe penalty, or a more severe penalty. CMS notifies the responsible entity in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment. The responsible entity has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 unless the responsible entity can show good cause, as determined under §150.405(b), for failing to timely exercise its right to a hearing.

Subpart D—Administrative Hearings

§ 150.401 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of the Department of Health and Human Services.

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

Party means CMS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to §150.343.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.403 Scope of ALJ's authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedure Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

§ 150.405 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with §150.407(a), within 30 days after the date of issuance of either CMS's notice of proposed assessment under §150.343 or notice that an alternative dispute resolution process has terminated. The request for hearing should be addressed as instructed in the notice of proposed determination. ''Date of issuance'' is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§ 150.407 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) The request for hearing must identify the relevant notice of assessment by date and attach a copy of the notice.

§ 150.409 Amendment of notice of assessment or request for hearing.

The ALJ may permit CMS to amend its notice of assessment, or permit the respondent to amend a request for hearing that complies with §150.407(a),

if the ALJ finds that no undue prejudice to either party will result.

§ 150.411 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by § 150.405(a) or any extension of time granted by the ALJ pursuant to § 150.405(b).

(b) The request for hearing fails to meet the requirements of § 150.407.

(c) The entity that filed the request for hearing is not a respondent under § 150.401.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 150.413 Settlement.

CMS has exclusive authority to settle any issue or any case, without the consent of the administrative law judge at any time before or after the administrative law judge's decision.

§ 150.415 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor or the IRS may intervene without regard to paragraphs (a)(1) through (a)(3) of this section.

§ 150.417 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Applies the factors that are identified in § 150.317.

(2) May consider evidence of record relating to any factor that CMS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that CMS assessed.

§ 150.419 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.421 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§ 150.423 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice

and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 150.425 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as ''Motion for Discovery'').

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.429 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in §150.401) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in section §150.405(b)).

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

[86 FR 24286, May 5, 2021]

§ 150.435 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in § 150.437(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by § 150.437 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§ 150.437 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in § 150.431, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document (respondent's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 150.439 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 150.437 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 150.441 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 150.437 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 150.441 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 150.437 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.443 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§ 150.445 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under §§ 150.317 and 150.323 of this part to consider the entity's prior

record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether CMS's notice sent in accordance with §§ 150.307 and 150.343 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after CMS's notice under § 150.307.

§ 150.447 The record.

(a) Any testimony that is taken in-person by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.449 Cost of transcripts.

Generally, each party is responsible for 50 percent of the transcript cost. Where there is an intervenor, the ALJ determines what percentage of the transcript cost is to be paid for by the intervenor.

§ 150.451 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§ 150.453 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 150.457.

§ 150.455 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§ 150.457 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this subsection may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under § 150.453.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 150.459 Judicial review.

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to CMS.

(b) *Certification of administrative record.* CMS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of CMS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 150.461 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 150.463 Final order not subject to review.

In an action brought under § 150.461, the validity and appropriateness of the final order described in § 150.459 is not subject to review.

§ 150.465 Collection and use of penalty funds.

(a) Any funds collected under § 150.461 are paid to CMS.

(b) The funds are available without appropriation until expended.

(c) The funds may be used only for the purpose of enforcing the PHS Act

requirements for which the penalty was assessed.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

PART 151 [RESERVED]

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

Subpart A—General Provisions

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152.45 Transition to the exchanges.

AUTHORITY: Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 45029, July 30, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 152.1 Statutory basis.

(a) *Basis.* This part establishes provisions needed to implement section 1101 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which requires the Secretary of the Department of Health and Human Services to establish a temporary high risk health insurance pool program to provide health insurance coverage for individuals described in §152.14 of this part.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for the temporary high risk health insurance pool program, hereafter referred to as the ''Pre-Existing Condition Insurance Plan'' (PCIP) program.

§ 152.2 Definitions.

For purposes of this part the following definitions apply:

Creditable coverage means coverage of an individual as defined in section 2701(c)(1) of the Public Health Service Act as of March 23, 2010 and 45 CFR 146.113(a)(1).

Enrollee means an individual receiving coverage from a PCIP established under this section.

Lawfully present means

(1) A qualified alien as defined in section 431 of the Personal Responsibility and Work Opportunity Act (PRWORA) (8 U.S.C. 1641);

(2) An alien in nonimmigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission;

(3) An alien who has been paroled into the United States pursuant to section 212(d)(5) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(d)(5)) for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings;

(4) An alien who belongs to one of the following classes:

(i) Aliens currently in temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. 1160 or 1255a, respectively);