

**Pt. 149**

writing of CMS’s decision on its application.

(2) If the State applicant is awarded a grant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see part 92 of this title).

(iii) The grantee will be required to submit quarterly progress and financial reports under part 92 of this title and in accordance with section 2745(f) of the Public Health Service Act, requiring the Secretary to make an annual report to Congress that includes information on the use of these grant funds by States.

(b) *Grantees letter of acceptance.* Grantees must submit a letter of acceptance to CMS’ Acquisition and Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

**PART 149—REQUIREMENTS FOR THE EARLY RETIREE REINSURANCE PROGRAM**

**Subpart A—General Provisions**

Sec.

149.1 Purpose and basis.

149.2 Definitions.

**Subpart B—Requirements for Eligible Employment-based Plans**

149.30 General requirements.

149.35 Requirements to participate.

149.40 Application.

149.41 Consequences of Non-Compliance, Fraud, or Similar Fault

149.45 Funding limitation.

**Subpart C—Reinsurance Amounts**

149.100 Amount of reimbursement.

149.105 Transition provision.

149.110 Negotiated price concessions.

149.115 Cost threshold and cost limit.

**45 CFR Subtitle A (10–1–15 Edition)**

**Subpart D—Use of Reimbursements**

149.200 Use of reimbursements.

**Subpart E—Reimbursement Methods**

149.300 General reimbursement rules.

149.310 Timing.

149.315 Reimbursement conditioned upon available funds.

149.320 Universe of claims that must be submitted.

149.325 Requirements for eligibility of claims.

149.330 Content of claims.

149.335 Documentation of costs of actual claims involved.

149.340 Rule for insured plans.

149.345 Use of information provided.

149.350 Maintenance of records.

**Subpart F—Appeals**

149.500 Appeals.

149.510 Content of request for appeal.

149.520 Review of appeals.

**Subpart G—Disclosure of Inaccurate Data**

149.600 Sponsor’s duty to report data inaccuracies.

149.610 Secretary’s authority to reopen and revise reimbursement determination amounts.

**Subpart H—Change of Ownership Requirements**

149.700 Change of ownership requirements.

AUTHORITY: Section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 24466, May 5, 2010, unless otherwise noted.

**Subpart A—General Provisions**

**§ 149.1 Purpose and basis.**

This part implements the Early Retiree Reinsurance Program, as required by section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

**§ 149.2 Definitions.**

For purposes of this part, the following definitions apply:

*Authorized representative* means an individual with legal authority to sign and bind a sponsor to the terms of a contract or agreement.

*Benefit option* means a particular benefit design, category of benefits, or

cost-sharing arrangement offered within an employment-based plan.

*Certified* means that the sponsor and its employment-based plan or plans meet the requirements of this part and the sponsor's application to participate in the program has been approved by the Secretary.

*Chronic and high-cost condition* means a condition for which \$15,000 or more in health benefit claims are likely to be incurred during a plan year by one plan participant.

*Claim or medical claim* means documentation, in a form and manner to be specified by the Secretary, indicating the health benefit provided, the provider or supplier, the incurred date, the individual for whom the health benefit was provided, the date and amount of payment net any known negotiated price concessions, and the employment-based plan and benefit option under which the health benefit was provided. The terms *claim* or *medical claim* include medical, surgical, hospital, prescription drug and other such claims as determined by the Secretary.

*Early retiree* means a plan participant who is age 55 and older who is enrolled for health benefits in a certified employment-based plan, who is not eligible for coverage under title XVIII of the Act, and who is not an active employee of an employer maintaining, or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan. In this part, the term *early retiree* also includes the enrolled spouse, surviving spouse, and dependents of such individuals. The determination of whether an individual is not an active employee is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed to be an active employee if, under the Medicare Secondary Payer rules in 42 CFR 411.104 and related guidance published by the Centers for Medicare & Medicaid Services, the person is considered to be receiving coverage by reason of current employment status. This presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor may also treat a person receiving coverage under its employ-

ment-based plan as a dependent in accordance with the rules of its plan, regardless of whether that individual is considered a dependent for Federal or state tax purposes. For purposes of this definition of early retiree, an employer maintaining, or currently contributing to, the employment-based plan or any employer that has made substantial contributions to fund such plan, means a plan sponsor (as defined in this section).

*Employment-based plan* means a group health plan as defined in this section of the regulation.

*Good cause* means:

(1) New and material evidence exists that was not readily available at the time the reimbursement determination was made;

(2) A clerical error in the computation of the reimbursement determination was made by the Secretary; or

(3) The evidence that was considered in making the reimbursement determination clearly shows on its face that an error was made.

*Group health plan* means group health plan as defined in 42 CFR 423.882 that provides health benefits to early retirees, but excludes Federal governmental plans.

*Health benefits* means medical, surgical, hospital, prescription drug, and other benefits that may be specified by the Secretary, whether self-funded or delivered through the purchase of health insurance or otherwise. Such benefits include benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body. Health benefits do not include benefits specified at 45 CFR 146.145(c)(2) through (4).

*Incurred* means the point in time when the sponsor, health insurance issuer (as defined in 45 CFR 160.103), employment-based plan, plan participant, or a combination of these or similar stakeholders, become responsible for payment of the claim.

*Negotiated price concession* means any direct or indirect remuneration (including discounts, direct or indirect subsidies, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or

## § 149.30

reduced-price services, grants, or other price concessions or similar benefits) offered to some or all purchasers, which may include a sponsor, a health insurance issuer, or an employment-based plan) that would serve to decrease the costs incurred under the employment-based plan.

*Plan participant* means anyone enrolled in an applicable plan including an early retiree, as defined in this section, a retiree, a retiree's spouse and dependent, an active employee and an active employee's spouse and dependent.

*Plan year* means the year that is designated as the plan year in the plan document of an employment-based plan, except that if the plan document does not designate a plan year, if the plan year is not a 12-month plan year, or if there is no plan document, the plan year is:

- (1) The deductible or limit year used under the plan;
- (2) The policy year, if the plan does not impose deductibles or limits on a 12-month basis;
- (3) The sponsor's taxable year, if the plan does not impose deductibles or limits on a 12-month basis, and either the plan is not insured or the insurance policy is not renewed on a 12-month basis, or;
- (4) The calendar year, in any other case.

*Post point-of-sale negotiated price concession* means any negotiated price concession that an employment-based plan or insurer receives with respect to a given health benefit, after making payment for that health benefit.

*Program* means the Early Retiree Reinsurance Program established in section 1102 of the Patient Protection and Affordable Care Act.

*Secretary* means the Secretary of the United States Department of Health & Human Services or the Secretary's designee.

*Sponsor* means a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the pri-

## 45 CFR Subtitle A (10–1–15 Edition)

mary source of financing, the term means the employer.

*Sponsor agreement* means an agreement between the sponsor and the United States Department of Health & Human Services, or its designee, which is made to comply with the provisions of this part.

### Subpart B—Requirements for Eligible Employment-Based Plans

#### § 149.30 General requirements.

A sponsor is eligible to participate in the program if it meets the requirements of section 1102 of the Patient Protection and Affordable Care Act, this part, and guidance developed by the Secretary.

#### § 149.35 Requirements to participate.

(a) A sponsor's employment-based plan must—

- (1) Be certified by the Secretary.
- (2) Include programs and procedures that have generated or have the potential to generate cost-savings with respect to plan participants with chronic and high-cost conditions.

(b) A sponsor must—

- (1) Make available information, data, documents, and records as specified in § 149.350.
- (2) Have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan (as applicable) regarding disclosure of information, data, documents, and records, to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, the information, data, documents and records necessary for the sponsor to comply with the program, this part, and program guidance.
- (3) Ensure that policies and procedures to protect against fraud, waste and abuse under this program are in place, and must comply timely with requests from the Secretary to produce the policies and procedures and any documents or data to substantiate the implementation of the policies and procedures and their effectiveness.
- (4) Submit an application to the Secretary in the manner, and at the time,

required by the Secretary as specified in § 149.40.

**§ 149.40 Application.**

(a) The applicant must submit an application to participate in this program to the Secretary, which is signed by an authorized representative of the applicant who certifies that the information contained in the application is true and accurate to the best of the authorized representative's knowledge and belief.

(b) Applications will be processed in the order in which they are received.

(c) An application that fails to meet all the requirements of this part will be denied and the applicant must submit another application if it wishes to participate in the program. The new application will be processed based on when the new submission is received.

(d) An applicant need not submit a separate application for each plan year but must identify in its application the plan year start and end date cycle (starting month and day, and ending month and day) for which it is applying.

(e) An applicant must submit an application for each plan for which it will submit a reimbursement request.

(f) In connection with each application the applicant must submit the following:

(1) Applicant's Tax Identification Number.

(2) Applicant's name and address.

(3) Contact name, telephone number and email address.

(4) Plan sponsor agreement signed by an authorized representative, which includes—

(i) An assurance that the sponsor has a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan, as applicable, regarding disclosure of information to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, information, data, documents, and records necessary for the sponsor to comply with the requirements of the program.

(ii) An acknowledgment that the information in the application is being provided to obtain Federal funds, and

that all subcontractors acknowledge that information provided in connection with a subcontract is used for purposes of obtaining Federal funds.

(iii) An attestation that policies and procedures are in place to detect and reduce fraud, waste, and abuse, and that the sponsor will produce the policies and procedures, and necessary information, records and data, upon request by the Secretary, to substantiate existence of the policies and procedures and their effectiveness.

(iv) Other terms and conditions required by the Secretary.

(5) A summary indicating how the applicant will use any reimbursement received under the program to meet the requirements of the program, including:

(i) How the reimbursement will be used to reduce premium contributions, co-payments, deductibles, coinsurance, or other out-of-pocket costs for plan participants, to reduce health benefit or health benefit premium costs for the sponsor, or to reduce any combination of these costs;

(ii) What procedures or programs the sponsor has in place that have generated or have the potential to generate cost savings with respect to plan participants with chronic and high-cost conditions; and

(iii) How the sponsor will use the reimbursement to maintain its level of contribution to the applicable plan.

(6) Projected amount of reimbursement to be received under the program for the first two plan year cycles with specific amounts for each of the two cycles.

(7) A list of all benefit options under the employment-based plan that any early retiree for whom the sponsor receives program reimbursement may be claimed.

(8) Any other information the Secretary requires.

(g) An application must be approved, and the plan and the sponsor certified, by the Secretary before a sponsor may request reimbursement under the program.

(h) The Secretary may reopen a determination under which an application had been approved or denied:

(1) Within 1 year of the determination for any reason;

## § 149.41

(2) Within 4 years of the determination if the evidence that was considered in making the determination shows on its face that an error was made; or

(3) At any time in instances of fraud or similar fault.

### § 149.41 Consequences of Non-Compliance, Fraud, or Similar Fault.

Upon failure to comply with the requirements of this part, or if fraud, waste, and abuse, or similar fault are found, the Secretary may recoup or withhold funds, terminate or deny a sponsor's application, or take a combination of these actions.

### § 149.45 Funding limitation.

(a) Based on the projected or actual availability of program funding, the Secretary may deny applications that otherwise meet the requirements of this part, and if an application is approved, may deny all or part of a sponsor's reimbursement request.

(b) The Secretary's decision to stop accepting applications or satisfying reimbursement requests based on the availability of funding is final and binding, and is not appealable.

## Subpart C—Reinsurance Amounts

### § 149.100 Amount of reimbursement.

(a) For each early retiree enrolled in a certified plan in a plan year, the sponsor receives reimbursement in the amount of 80 percent of the costs for health benefits (net of negotiated price concessions for health benefits) for claims incurred during the plan year that are attributed to health benefits costs between the cost threshold and cost limit, and that are paid by the employment-based plan or by the insurer (if an insured plan), and by the early retiree.

(b) Costs are considered paid by an early retiree, if paid by that individual or another person on behalf of the early retiree, and the early retiree (or person paying on behalf of the early retiree) is not reimbursed through insurance or otherwise, or other third party payment arrangement.

(c) Reimbursement is calculated by first determining the costs for health benefits net of negotiated price conces-

## 45 CFR Subtitle A (10–1–15 Edition)

sions, within the applicable plan year for each early retiree, and then subtracting amounts below the cost threshold and above the cost limit within the applicable plan year for each such individual.

(d) For purposes of determining amounts below the cost threshold and above the cost limit for any given early retiree, all costs for health benefits paid by the employment-based plan (or by the insurer, if applicable), or by or on behalf of, an early retiree, for all benefit options the early retiree is enrolled in with respect to a given certified employment-based plan for a given plan year, will be combined. For each early retiree enrolled in an employment-based plan, there is only one cost threshold and one cost limit per plan year regardless of the number of benefit options the early retiree is enrolled in during that plan year.

### § 149.105 Transition provision.

For a certified plan that has a plan year that begins before June 1, 2010 and ends on any date thereafter, the reinsurance amount for the plan year must be determined as follows:

(a) With respect to claims incurred before June 1, 2010, the amount of such claims up to \$15,000 count toward the cost threshold and the cost limit. The amount of claims incurred before June 1, 2010 that exceed \$15,000 are not eligible for reimbursement and do not count toward the cost limit.

(b) The reinsurance amount to be paid is based only on claims incurred on and after June 1, 2010, that fall between the cost threshold and cost limit for the plan year.

### § 149.110 Negotiated price concessions.

(a) The amount of negotiated price concessions that will be taken into account in determining the reinsurance amount will reflect negotiated price concessions that have already been subtracted from the amount the employment-based plan or insurer paid for the cost of health benefits and the amount of post-point-of-sale negotiated price concessions received.

(b) At a time specified by the Secretary, sponsors are required to disclose the amount of post-point-of-sale price concessions that were received

but not accounted for in their submitted claims.

**§ 149.115 Cost threshold and cost limit.**

The following cost threshold and cost limits apply individually, to each early retiree as defined in §149.2:

(a) The cost threshold is equal to \$15,000 for plan years that start on any date before October 1, 2011.

(b) The cost limit is equal to \$90,000 for plan years that start on any date before October 1, 2011.

(c) The cost threshold and cost limit specified in paragraphs (a) and (b) of this section, for plan years that start on or after October 1, 2011, will be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of \$1,000) for the year involved.

**Subpart D—Use of Reimbursements**

**§ 149.200 Use of reimbursements.**

(a) A sponsor must use the proceeds under this program:

(1) To reduce the sponsor's health benefit premiums or health benefit costs,

(2) To reduce health benefit premium contributions, copayments, deductibles, coinsurance, or other out-of-pocket costs, or any combination of these costs, for plan participants, or

(3) To reduce any combination of the costs in (a)(1) and (a)(2) of this section.

(b) Proceeds under this program must not be used as general revenue for the sponsor.

**Subpart E—Reimbursement Methods**

**§ 149.300 General reimbursement rules.**

Reimbursement under this program is conditioned on provision of accurate information by the sponsor or its designee. The information must be submitted, in a form and manner and at the times provided in this subpart and other guidance specified by the Secretary. A sponsor must provide the information specified in section §149.335.

**§ 149.310 Timing.**

(a) An employment-based plan and a sponsor must be certified by the Secretary before claims can be submitted and a reimbursement request may be made. Reimbursement will be made with respect to submitted claims for health benefits at a time and in a manner to be specified by the Secretary, after the sponsor or its designee submits the claims to the Secretary. Claims must satisfy the requirements of this subpart in order to be eligible for reimbursement.

(b) Claims for health benefits may be submitted for a given plan year only upon the approval of an application that references that plan year cycle. Claims for an early retiree for a plan year cannot be submitted until the total paid costs for health benefits for that early retiree incurred for that plan year exceed the applicable cost threshold.

(c) For employment-based plans for which a provider in the normal course of business does not produce a claim, such as a staff-model health maintenance organization, the information required in a claim must be produced and provided to the Secretary, as set out in this regulation and applicable guidance.

**§ 149.315 Reimbursement conditioned upon available funds.**

Notwithstanding a sponsor's compliance with this part, reimbursement is conditioned upon the availability of program funds.

**§ 149.320 Universe of claims that must be submitted.**

(a) Claims submitted for an early retiree, as defined in §149.2, must include claims below the applicable cost threshold for the plan year.

(b) Claims must not be submitted until claims are submitted for amounts that exceed the applicable cost threshold for the plan year for the early retiree.

(c) Sponsors must not submit claims for health benefits for an early retiree to the extent the sponsor has already submitted claims for the early retiree that total more than the applicable cost limit for the applicable plan year.

## § 149.325

### § 149.325 Requirements for eligibility of claims.

A claim may be submitted only if it represents costs for health benefits for an early retiree, as defined in § 149.2, has been incurred during the applicable plan year, and has been paid.

### § 149.330 Content of claims.

Each claim on its face must include the information specified in, and meet, the definition of claim or medical claim found at § 149.2.

### § 149.335 Documentation of costs of actual claims involved.

(a) A submission of claims consists of a list of early retirees for whom claims are being submitted, and documentation of the actual costs of the items and services for claims being submitted, in a form and manner specified by the Secretary.

(b) In order for a sponsor to receive reimbursement for the portion of a claim that an early retiree paid, the sponsor must submit prima facie evidence that the early enrollee paid his or her portion of the claim.

### § 149.340 Rule for insured plans.

With respect to insured plans, the claims and data specified in the subpart may be submitted directly to the Secretary by the insurer.

### § 149.345 Use of information provided.

The Secretary may use data and information collected under this section only for the purpose of, and to the extent necessary in, carrying out this part including, but not limited to, determining reimbursement and reimbursement-related oversight and program integrity activities, or as otherwise allowed by law. Nothing in this section limits the Office of the Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

### § 149.350 Maintenance of records.

(a) The sponsor of the certified plan (or a subcontractor, as applicable) must maintain and furnish to the Secretary, upon request the records enumerated in paragraph (b) of this sec-

## 45 CFR Subtitle A (10-1-15 Edition)

tion. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred, or longer if otherwise required by law.

(b) The records that must be retained are as follows—

(1) All documentation, data, and other information related to this part.

(2) Any other records specified by the Secretary.

(c) The Secretary may issue additional guidance addressing record-keeping requirements, including (but not limited to) the use of electronic media.

(d) The sponsor must require its health insurance issuer or employment-based plan, as applicable, to maintain and produce upon request records to satisfy subparagraph (a) of this regulation.

(e) The sponsor is responsible for ensuring that the records are maintained and provided according to this subpart.

## Subpart F—Appeals

### § 149.500 Appeals.

(a) An adverse reimbursement determination is final and binding unless appealed pursuant to paragraph (e) of this section.

(b) Except as provided in paragraph (c) of this section, a sponsor may request an appeal of an adverse reimbursement determination.

(c) A sponsor may not appeal an adverse reimbursement determination if the denial is based on the unavailability of funds.

(d) An adverse reimbursement determination is a determination constituting a complete or partial denial of a reimbursement request.

(e) If a sponsor appeals an adverse reimbursement determination, the sponsor must submit the appeal in writing to the Secretary within 15 calendar days of receipt of the determination pursuant to guidance issued by the Secretary.

### § 149.510 Content of request for appeal.

The request for appeal must specify the findings or issues with which the sponsor disagrees and the reasons for

the disagreements. The request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider.

**§ 149.520 Review of appeals.**

(a) In conducting review of the appeal, the Secretary reviews the appeal, the evidence and findings upon which the adverse reimbursement determination was made, and any other written evidence submitted by the sponsor or the Secretary's designee and will provide a ruling on the appeal request.

(b) In conducting the review, the Secretary reviews the determination at issue, the evidence and findings upon which it was based, any written documents submitted to the Secretary by the sponsor and the Secretary's designee, and determines whether to uphold, reverse or modify the Secretary's initial reimbursement determination.

(c) A decision by the Secretary under this provision is final and binding.

(d) Regardless of the Secretary's decision, additional reimbursement is contingent upon the availability of funds at the time of the Secretary's determination.

(e) The Secretary informs the sponsor and the applicable Secretary's designee of the decision. The Secretary sends a written decision to the sponsor or the applicable Secretary's designee upon request.

**Subpart G—Disclosure of Data Inaccuracies**

**§ 149.600 Sponsor's duty to report data inaccuracies.**

A sponsor is required to disclose any data inaccuracies upon which a reimbursement determination is made, including inaccurate claims data and negotiated price concessions, in a manner and at a time specified by the Secretary in guidance.

**§ 149.610 Secretary's authority to reopen and revise a reimbursement determination.**

(a) The Secretary may reopen and revise a reimbursement determination upon the Secretary's own motion or upon the request of a sponsor:

(1) Within 1 year of the reimbursement determination for any reason.

(2) Within 4 years of a reimbursement determination for good cause.

(3) At any time, in instances of fraud or similar fault.

(b) For purposes of this section, the Secretary does not find good cause if the only reason for the revision is a change of legal interpretation or administrative ruling upon which the determination to reimburse was made.

(c) A decision by the Secretary not to revise a reimbursement determination is final and binding (unless fraud or similar fault is found) and cannot be appealed.

**Subpart H—Change of Ownership Requirements**

**§ 149.700 Change of ownership requirements.**

(a) *Change of ownership consists of:* (1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable state law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership; exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify the Secretary at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for health benefits, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a

**Pt. 150**

ponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

(f) Failure to notify the Secretary at least 60 days before the anticipated effective date of the change may result in the Secretary recovering funds paid under this program.

**PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS**

**Subpart A—General Provisions**

Sec.

- 150.101 Basis and scope.
- 150.103 Definitions.

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

- 150.201 State enforcement.
- 150.203 Circumstances requiring CMS enforcement.
- 150.205 Sources of information triggering an investigation of State enforcement.
- 150.207 Procedure for determining that a State fails to substantially enforce PHS Act requirements.
- 150.209 Verification of exhaustion of remedies and contact with State officials.
- 150.211 Notice to the State.
- 150.213 Form and content of notice.
- 150.215 Extension for good cause.
- 150.217 Preliminary determination.
- 150.219 Final determination.
- 150.221 Transition to State enforcement.

**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.
- 150.303 Basis for initiating an investigation of a potential violation.
- 150.305 Determination of entity liable for civil money penalty.
- 150.307 Notice to responsible entities.
- 150.309 Request for extension.
- 150.311 Responses to allegations of non-compliance.
- 150.313 Market conduct examinations.
- 150.315 Amount of penalty—General.
- 150.317 Factors CMS uses to determine the amount of penalty.
- 150.319 Determining the amount of the penalty—mitigating circumstances.
- 150.321 Determining the amount of penalty—aggravating circumstances.

**45 CFR Subtitle A (10–1–15 Edition)**

- 150.323 Determining the amount of penalty—other matters as justice may require.
- 150.325 Settlement authority.
- 150.341 Limitations on penalties.
- 150.343 Notice of proposed penalty.
- 150.345 Appeal of proposed penalty.
- 150.347 Failure to request a hearing.

**Subpart D—Administrative Hearings**

- 150.401 Definitions.
- 150.403 Scope of ALJ's authority.
- 150.405 Filing of request for hearing.
- 150.407 Form and content of request for hearing.
- 150.409 Amendment of notice of assessment or request for hearing.
- 150.411 Dismissal of request for hearing.
- 150.413 Settlement.
- 150.415 Intervention.
- 150.417 Issues to be heard and decided by ALJ.
- 150.419 Forms of hearing.
- 150.421 Appearance of counsel.
- 150.423 Communications with the ALJ.
- 150.425 Motions.
- 150.427 Form and service of submissions.
- 150.429 Computation of time and extensions of time.
- 150.431 Acknowledgment of request for hearing.
- 150.435 Discovery.
- 150.437 Submission of briefs and proposed hearing exhibits.
- 150.439 Effect of submission of proposed hearing exhibits.
- 150.441 Prehearing conferences.
- 150.443 Standard of proof.
- 150.445 Evidence.
- 150.447 The record.
- 150.449 Cost of transcripts.
- 150.451 Posthearing briefs.
- 150.453 ALJ decision.
- 150.455 Sanctions.
- 150.457 Review by Administrator.
- 150.459 Judicial review.
- 150.461 Failure to pay assessment.
- 150.463 Final order not subject to review.
- 150.465 Collection and use of penalty funds.

AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92).

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.