

to conduct a compliance review as provided under this section.

(1) A compliance review under this section will be carried out as an onsite or desk review based on the specific circumstances.

(2) Unless otherwise specified, nothing in this section is intended to preempt Federal laws and regulations related to information privacy and security.

(e) *Compliance review timeframe.* A QHP issuer may be subject to a compliance review up to 10 years from the last day of that plan benefit year, or 10 years from the last day that the QHP certification is effective if the QHP is no longer available through a Federally-facilitated Exchange; provided, however, that if the 10 year review period falls during an ongoing compliance review, the review period would be extended until the compliance review is completed.

(f) *Failure to comply.* A QHP issuer that fails to comply with a compliance review under this section may be subject to enforcement remedies under subpart I of this part.

[78 FR 65100, Oct. 30, 2013, as amended at 81 FR 94182, Dec. 22, 2016]

Subpart I—Enforcement Remedies in the Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.800 Available remedies; Scope.

(a) *Kinds of sanctions.* HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

(1) Civil money penalties as specified in § 156.805; and

(2) Decertification of a QHP offered by the non-compliant QHP issuer in a Federally-facilitated Exchange as described in § 156.810.

(b) *Scope.* Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also ap-

plicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.

(c) *Compliance standard.* For calendar years 2014 and 2015, sanctions under this subpart will not be imposed if the QHP issuer has made good faith efforts to comply with applicable requirements.

(d) *Information sharing.* HHS may consult and share information about QHP issuers with other Federal and State regulatory and enforcement entities to the extent that the consultation and information is necessary for purposes of State or Federal oversight and enforcement activities.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 30351, May 27, 2014; 80 FR 10875, Feb. 27, 2015; 86 FR 24293, May 5, 2021]

§ 156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

(a) *Grounds for imposing civil money penalties.* Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

(1) Misconduct in the Federally-facilitated Exchange or substantial non-compliance with the Exchange standards and requirements applicable to issuers offering QHPs in the Federally-facilitated Exchange, including but not limited to issuer standards and requirements under parts 153 and 156 of this subchapter;

(2) Limiting the QHP's enrollees' access to medically necessary items and services that are required to be covered as a condition of the QHP issuer's ongoing participation in the Federally-facilitated Exchange, if the limitation has adversely affected or has a substantial likelihood of adversely affecting one or more enrollees in the QHP offered by the QHP issuer;

(3) Imposing on enrollees premiums in excess of the monthly beneficiary

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premiums permitted by Federal standards applicable to QHP issuers participating in the Federally-facilitated Exchange;

(4) Engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment into a QHP offered by the issuer (except as permitted by this part) by qualified individuals whose medical condition or history indicates the potential for a future need for significant medical services or items;

(5) Intentionally or recklessly misrepresenting or falsifying information that it furnishes—

(i) To HHS or an Exchange; or

(ii) To an individual or entity upon which HHS relies to make its certifications or evaluations of the QHP issuer's ongoing compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange;

(6) Failure to remit user fees assessed under § 156.50(c); or

(7) Failure to comply with the cost-sharing reductions and advance payments of the premium tax credit standards of subpart E of this part.

(b) *Factors in determining the amount of civil money penalties assessed.* In determining the amount of civil money penalties, HHS may take into account the following:

(1) The QHP issuer's previous or ongoing record of compliance;

(2) The level of the violation, as determined in part by—

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

(ii) The magnitude of financial and other impacts on enrollees and qualified individuals; and

(3) Aggravating or mitigating circumstances, or other such factors as justice may require, including complaints about the issuer with regard to the issuer's compliance with the medical loss ratio standards required by the Affordable Care Act and as codified by applicable regulations.

(c) *Maximum penalty.* The maximum amount of penalty imposed for each violation is \$100 as adjusted annually under 45 CFR part 102 for each day for

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each QHP issuer for each individual adversely affected by the QHP issuer's non-compliance; and where the number of individuals cannot be determined, HHS may estimate the number of individuals adversely affected by the violation.

(d) *Request for hearing.* (1) An issuer may appeal the assessment of a civil money penalty under this section by filing a request for hearing under an applicable administrative hearing process.

(2) If an issuer files a request for hearing under this paragraph (d), the assessment of a civil money penalty will not occur prior to the issuance of the final administrative decision in the appeal.

(e) *Failure to request a hearing.* (1) If the QHP issuer does not request a hearing within 30 days of the issuance of the notice described in paragraph (d)(1) of this section, HHS may assess the proposed civil money penalty.

(2) HHS will notify the issuer in writing of any penalty that has been assessed under this subpart and of the means by which the QHP issuer or another responsible entity may satisfy the CMP assessment.

(3) The QHP issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with the requirements of the applicable administrative hearing process unless the QHP issuer can show good cause, as determined under § 156.905(b), for failing to timely exercise its right to a hearing.

(f) *Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform.*

(1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq.* that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.

(2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50,

HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 15245, Mar. 19, 2014; 79 FR 30351, May 27, 2014; 81 FR 12351, Mar. 8, 2016; 81 FR 61581, Sept. 6, 2016; 86 FR 24293, May 5, 2021]

§ 156.806 Notice of non-compliance.

If HHS learns of a potential violation described in § 156.805 or if a State informs HHS of a potential violation, prior to imposing any CMPs, HHS must provide a written notice to the issuer, to include the following:

- (a) Describe the potential violation.
- (b) Provide 30 days from the date of the notice for the QHP issuer to respond and to provide additional information to refute an alleged violation.
- (c) State that a civil money penalty may be assessed if the allegations are not, as determined by HHS, refuted.

[79 FR 30351, May 27, 2014]

§ 156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) *Bases for decertification.* A QHP may be decertified on one or more of the following grounds:

- (1) The QHP issuer substantially fails to comply with the Federal laws and regulations applicable to QHP issuers participating in the Federally-facilitated Exchange;
- (2) The QHP issuer substantially fails to comply with the standards related to the risk adjustment, reinsurance, or risk corridors programs under 45 CFR part 153, including providing HHS with valid risk adjustment, reinsurance or risk corridors data;
- (3) The QHP issuer substantially fails to comply with the transparency and marketing standards in §§ 156.220 and 156.225;
- (4) The QHP issuer substantially fails to comply with the standards regarding advance payments of the premium tax credit and cost-sharing in subpart E of this part;
- (5) The QHP issuer is operating in the Federally-facilitated Exchange in a manner that hinders the efficient and

effective administration of the Exchange;

(6) The QHP no longer meets the applicable standards set forth under subpart C of this part.

(7) Based on credible evidence, the QHP issuer has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data;

(8) The QHP issuer substantially fails to meet the requirements under § 156.230 related to network adequacy standards or, § 156.235 related to inclusion of essential community providers;

(9) The QHP issuer substantially fails to comply with the law and regulations related to internal claims and appeals and external review processes;

(10) The State recommends to HHS that the QHP should no longer be available in a Federally-facilitated Exchange;

(11) The QHP issuer substantially fails to comply with the privacy or security standards set forth in § 156.260;

(12) The QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under subpart K of this part;

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part;

(14) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(15) HHS reasonably believes that the QHP issuer lacks the financial viability to provide coverage under its QHPs until the end of the plan year.

(b) *State sanctions and determinations*—(1) *State sanctions.* HHS may consider regulatory or enforcement actions taken by a State against a QHP issuer as a factor in determining whether to decertify a QHP offered by that issuer.

(2) *State determinations.* HHS may decertify a QHP offered by an issuer in a Federally-facilitated Exchange based on a determination or action by a State as it relates to the issuer offering QHPs in a Federally-facilitated Exchange, including when a State places an issuer or its parent organization