

§ 158.601

records used in compiling data reported and rebates provided under this part and in determining what data to report and rebates to provide under this part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this part.

(b) *Length of time information must be maintained.* All of the documents and other evidence required by this part must be maintained for the current year and six prior years, unless a longer time is required under § 158.501 of this subpart.

Subpart F—Federal Civil Penalties

§ 158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this part, civil penalties, as described in this subpart, may be imposed.

§ 158.602 Basis for imposing civil penalties.

Civil penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in § 158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant to this part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

45 CFR Subtitle A (10–1–20 Edition)

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§ 158.603 Notice to responsible entities.

If HHS learns of a potential violation described in § 158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide 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 responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§ 158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in § 158.602 of this subpart.

§ 158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider 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 Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a