

§ 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.
- (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.