

§ 158.402 Audits.

(a) *Notice of Audit.* HHS will provide 30 days advance notice of its intent to conduct an audit of an issuer.

(b) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(c) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, which will then have 30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) *Final Audit Findings.* If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) *Corrective actions.* HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) *Order to pay rebates.* If HHS determines as the result of an audit that an issuer has failed to pay rebates it is obligated to pay pursuant to this part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with § 158.240(d) of this part.