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the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(c) *Issuer contracts.* An issuer that offers risk adjustment covered plans may include in its contract with a provider, supplier, physician, or other practitioner, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframe established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(d) *Assessment of charges.* An issuer that offers risk adjustment covered plans that has a net balance of risk adjustment charges payable, including adjustments made pursuant to §153.350(c), will be notified by the State, or by HHS on behalf of the State, of those net charges, and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, as applicable.

(e) *Charge submission deadline.* An issuer must remit net charges to the State, or HHS on behalf of the State, within 30 days of notification of net charges payable by the State, or HHS on behalf of the State.

(f) *Assessment and collection of user fees for HHS risk adjustment operations.* Where HHS is operating risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan (other than a student health plan or a plan not subject to 45 CFR 147.102, 147.104, 147.106, 156.80, and subpart B of part 156) must, for each benefit year—

(1) Submit or make accessible to HHS its monthly enrollment for the risk adjustment covered plan for the benefit year through the risk adjustment data collection approach established at §153.610(a), in a manner and timeframe specified by HHS; and

(2) Remit to HHS an amount equal to the product of its monthly billable enrollment in the risk adjustment covered plan multiplied by the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15531, Mar. 11, 2013; 81 FR 94174, Dec. 22, 2016]

45 CFR Subtitle A (10–1–23 Edition)

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* An issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State.

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, for each benefit year for at least 10 years, and must make those documents and records available upon request to HHS, the OIG, the Comptroller General, or their designees, or in a State where the State is operating risk adjustment, the State or its designee to any such entity, for purposes of verification, investigation, audit or other review.

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in §156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.

(i) *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.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the

initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any risk adjustment (including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 65095, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 86 FR 24287, May 5, 2021]

§ 153.630 Data validation requirements when HHS operates risk adjustment.

(a) *General requirement.* An issuer of a risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial and second validation audit performed on its risk adjustment data as described in this section.

(b) *Initial validation audit.* (1) An issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. The issuer must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor, in a timeframe and manner to be specified by HHS.

(2) The issuer must ensure that the initial validation auditors are reasonably capable of performing an initial data validation audit according to the standards established by HHS for such audit, and must ensure that the audit is so performed.