

(2) Remit to HHS an amount equal to the product of its monthly 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]

§ 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.* HHS or its designee may audit an issuer of a risk adjustment covered plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart H of this part, the issuer must complete all of the following:

(1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(2) Implement that plan.

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

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

§ 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.

(3) The issuer must ensure that each initial validation auditor is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner and its impartiality is not reasonably open to question.

(4) The issuer must ensure validation of the accuracy of risk adjustment data for a sample of enrollees selected by HHS. The issuer must ensure that the initial validation audit findings are submitted to HHS in a manner and timeframe specified by HHS.

(5) An initial validation audit must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission.

(7) The risk score of each enrollee in the sample must be validated by—

(i) Validating the enrollee’s enrollment data and demographic data in a manner to be determined by HHS.

(ii) Validating enrollee health status through review of all relevant medical record documentation. Medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers and services. For purposes of this section, “medical record documentation” means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health status is documented and related to accepted risk adjustment services that occurred during a specified period of time. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services;

(iii) Validating medical records according to industry standards for coding and reporting; and

(iv) Having a senior reviewer confirm any enrollee risk adjustment error discovered during the initial validation audit. For purposes of this section, a “senior reviewer” is a reviewer certified as a medical coder by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, a senior reviewer may possess 3 or more years of experience.

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) Enforcement actions. If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter.

(10) Default data validation charge. If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default risk adjustment charge.

(c) *Second validation audit.* HHS will select a subsample of the risk adjustment data validated by the initial validation audit for a second validation audit. The issuer must comply with, and must ensure the initial validation auditor complies with, standards for such audit established by HHS, and must cooperate with, and must ensure that the initial validation auditor cooperates with, HHS and the second validation auditor in connection with such audit.

(d) *Data validation appeals.* An issuer may appeal the findings of a second validation audit or the application of a risk score error rate to its risk adjustment payments and charges.

(e) *Adjustment of payments and charges.* HHS may adjust payments and charges for issuers that do not comply with audit requirements and standards, as specified in paragraphs (b) and (c) of this section.

(f) *Data security and transmission.* (1) An issuer must submit the risk adjustment data and source documentation for the initial and second validation audits specified by HHS to HHS or its

designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

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Subpart H—Distributed Data Collection for HHS-Operated Programs

SOURCE: 78 FR 15531, Mar. 11, 2013, unless otherwise noted.

§ 153.700 Distributed data environment.

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

§ 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or rein-

urance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

(d) *Interim dedicated distributed data environment reports.* Within 30 calendar days of the date of an interim dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the interim report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the timeframe specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the interim dedicated distributed data environment report.

(e) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(f) *Unresolved discrepancies.* If a discrepancy first identified in an interim