

(i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.

(ii) After the final risk adjustment data submission deadline, which is a date announced by CMS that is no earlier than January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

(3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

[73 FR 48757, Aug. 19, 2008, as amended at 79 FR 29956, May 23, 2014; 79 FR 50358, Aug. 22, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 88 FR 6665, Feb. 1, 2023]

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

(b) *RADV audit results.* (1) MA organizations that undergo RADV audits will be issued an audit report post medical record review that describes the results of the RADV audit as follows:

(i) Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.

(ii) The contract-level RADV payment error estimate in dollars.

(iii) The contract-level payment adjustment amount to be made in dollars.

(iv) An approximate timeframe for the payment adjustment.

(v) A description of the MA organization's RADV audit appeal rights.

(2) *Compliance date.* The compliance date for meeting RADV medical record submission requirements for the validation of risk adjustment data is the due date when MA organizations selected for RADV audit must submit medical records to the Secretary.

(c) *RADV audit appeals—(1) Appeal rights.* MA organizations that do not agree with their RADV audit results may appeal.

(2) *Issues eligible for RADV appeals—(i) General rules.* MA organizations may appeal RADV medical record review determinations and the Secretary's RADV payment error calculation. In order to be eligible for RADV appeal, MA organizations must adhere to the following:

(A) Established RADV audit procedures and requirements.

(B) RADV appeals procedures and requirements.

(ii) *Failure to follow RADV rules.* Failure to follow the Secretary's RADV audit procedures and requirements and the Secretary's RADV appeals procedures and requirements will render the MA organization's request for appeal invalid.

(iii) *RADV appeal rules.* The MA organization's written request for medical record review determination appeal must specify the following:

(A) The audited HCC(s) that the Secretary identified as being in error.

(B) A justification in support of the audited HCC selected for appeal.

(iv) *Number of medical records eligible for appeal.* For each audited HCC, MA organizations may appeal one medical record that has undergone RADV review. If an attestation was submitted to cure a signature or credential-related error, the attestation may be included in the HCC appeal.

(v) *Selection of medical record for appeal.* The MA organization must select the medical record that undergoes appeal.

(vi) *Written request for RADV payment error calculation appeal.* The written request for RADV payment error calculation appeal must clearly specify the following:

(A) The MA organization's own RADV payment error calculation.

(B) Where the Secretary's RADV payment error calculation was erroneous.

(3) *Issues ineligible for RADV appeals.*

(i) MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, RADV-reviewed medical record, and any accompanying attestation that the MA organization chooses for appeal.

(ii) MA organizations may not appeal the Secretary's medical record review determination methodology or RADV payment error calculation methodology.

(iii) As part of the RADV payment error calculation appeal—MA organizations may not appeal RADV medical record review-related errors.

(iv) MA organizations may not appeal RADV errors that result from an MA organization's failure to submit a medical record.

(4) *Burden of proof.* The MA organization bears the burden of proof by a preponderance of the evidence in demonstrating that the Secretary's medical record review determination(s) or payment error calculation was incorrect.

(5) *Manner and timing of a request for RADV appeal.* (i) At the time the Secretary issues its RADV audit report, the Secretary notifies audited MA organizations of the following:

(A) That they may appeal RADV HCC errors that are eligible for medical record review determination appeal.

(B) That they may appeal the Secretary's RADV payment error calculation.

(ii) MA organizations have 60 days from date of issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify one of the following:

(A) Whether the MA organization requests medical record review determination appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(B) Whether the MA organization requests RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(C) Whether the MA organization requests both medical record review de-

termination appeal and RADV payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements.

(iii) For MA organizations that appeal both medical record review determination appeal and RADV payment error calculation appeal:

(A) The Secretary adjudicates the request for RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.

(B) An MA organization's request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final for that stage of appeal.

(6) *Reconsideration stage*—(i) *Written request for medical record review reconsideration.* A MA organization's written request for medical record review determination reconsideration must specify the following:

(A) The audited HCC that the Secretary identified as being in error that the MA organization wishes to appeal.

(B) A justification in support of the audited HCC chosen for appeal.

(ii) *Written request for payment error calculation.* The MA organization's written request for payment error calculation reconsideration—

(A) Must include the MA organization's own RADV payment error calculation that clearly specifies where the Secretary's RADV payment error calculation was erroneous; and

(B) May include additional documentary evidence pertaining to the calculation of the payment error that the MA organization wishes the reconsideration official to consider.

(iii) *Conduct of the reconsideration.* (A) For medical record review determination reconsideration, a medical record review professional who was not involved in the initial medical record review determination of the disputed audited HCCs does the following:

(1) Reviews the medical record and accompanying dispute justification.

(2) Reconsiders the initial audited medical record review determination.

(B) For payment error calculation reconsideration, CMS ensures that a third party not involved in the initial RADV payment error calculation does the following:

(1) Reviews the Secretary's RADV payment error calculation.

(2) Reviews the MA organization's RADV payment error calculation;

(3) Recalculates the payment error in accordance with CMS's RADV payment error calculation procedures.

(iv) *Effect of the reconsideration official's decision.* (A) The reconsideration official issues a written reconsideration decision to the MA organization.

(B) The reconsideration official's decision is final unless the MA organization disagrees with the reconsideration official's decision.

(C) If the MA organization disagrees with the reconsideration official's decision, they may request a hearing in accordance with paragraph (c)(7) of this section.

(7) *Hearing stage*—(i) *Errors eligible for hearing.* At the time the reconsideration official issues his or her reconsideration determination to the MA organization, the reconsideration official notifies the MA organization of any RADV HCC errors or payment error calculations that are eligible for RADV hearing.

(ii) *General hearing rules.* A MA organization that requests a RADV hearing must do so in writing in accordance with procedures established by CMS.

(iii) *Written request for hearing.* The written request for a hearing must be filed with the Hearing Officer within 60 days of the date the MA organization receives the reconsideration officer's written reconsideration decision.

(A) If the MA organization appeals medical record review reconsideration determination, the written request for RADV hearing must—

(1) Include a copy of the written decision of the reconsideration official;

(2) Specify the audited HCCs that the reconsideration official confirmed as being in error; and

(3) Specify a justification why the MA organization disputes the reconsideration official's determination.

(B) If the MA organization appeals the RADV payment error calculation reconsideration determination, the

written request for RADV hearing must include the following:

(1) A copy of the written decision of the reconsideration official.

(2) The MA organization's own RADV payment error calculation that clearly specifies where the Secretary's payment error calculation was erroneous.

(iv) *Designation of hearing officer.* A hearing officer will conduct the RADV hearing.

(v) *Disqualification of the hearing officer.* (A) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(B) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(C) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(D) If the hearing officer withdraws, another hearing officer conducts the hearing.

(E) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to the Secretary.

(vi) *Hearing Officer review.* The hearing officer reviews the following:

(A) For a medical record review determination appeal, the hearing officer reviews all of the following:

(1) The RADV-reviewed medical record and any accompanying attestation that the MA organization selected for review.

(2) The reconsideration official's written determination.

(3) The written brief submitted by the MA organization or the Secretary in response to the reconsideration official's determination.

(B) For a payment error calculation appeal, the hearing officer reviews all of the following:

(1) The reconsideration official's written determination.

(2) Briefs addressing the reconsideration decision.

(vii) *Hearing procedures*—(A) *Authority of the Hearing Officer*. The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and the Secretary rulings. These powers include the authority to dismiss the appeal with prejudice and take any other action which the hearing officer considers appropriate, including for failure to comply with such rules and procedures.

(B) *The hearing is on the record*. (1) Except as specified in paragraph (c)(viii)(B)(2) of this section, the hearing officer is limited to the review of the record.

(2)(i) Subject to the hearing officer's full discretion, the parties may request a live or telephonic hearing regarding some or all of the disputed medical records.

(ii) The hearing officer may, on his or her own-motion, schedule a live or telephonic hearing.

(3) The record is comprised of the following:

(i) *Written decisions* described at paragraphs (c)(6)(iv) and (7)(vi) of this section.

(ii) Written briefs from the MA organization explaining why they believe the reconsideration official's determination was incorrect.

(iii) The Secretary's optional brief that responds to the MA organization's brief—

(4) The hearing officer neither receives testimony nor accepts any new evidence that is not part of the record.

(5) Either the MA organization or the Secretary may ask the hearing officer to rule on a motion for summary judgment.

(viii) *Hearing Officer decision*. The hearing officer decides whether to uphold or overturn the reconsideration official's decision, and sends a written determination to CMS and the MA organization, explaining the basis for the decision.

(ix) *Computations based on hearing decision*. (A) Once the hearing officer's decision is considered final in accordance with paragraph (c)(7)(x) of this section, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV

audit report to the appellant MA organization and CMS.

(B) For MA organizations appealing the RADV error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS.

(x) *Effect of the Hearing Officer's decision*. The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

(8) *CMS Administrator review stage*. (i) A request for CMS Administrator review must be made in writing and filed with the CMS Administrator.

(ii) CMS or a MA organization that has received a hearing officer's decision and requests review by the CMS Administrator must do so within 60 days of receipt of the hearing officer's decision.

(iii) After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the notification; and

(B) The CMS Administrator is limited to the review of the record. The record is comprised of the following:

(1) The record is comprised of documents described at paragraph (c)(7)(vii)(B)(3) of this section.

(2) The hearing record.

(3) Written arguments from the MA organization or CMS explaining why either or both parties believe the hearing officer's determination was correct or incorrect.

(C) The CMS Administrator reviews the record and determines whether the hearing officer's determination should be upheld, reversed, or modified.

(v) The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision.

§ 422.312

42 CFR Ch. IV (10–1–23 Edition)

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not make a decision within 60 days.

[75 FR 19806, Apr. 15, 2010; 75 FR 32859, June 10, 2010; as amended at 79 FR 29956, May 23, 2014; 88 FR 6665, Feb. 1, 2023]

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement.* Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement.* Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology.* (1) No later than 60 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 30 days to comment on the proposed changes.

[70 FR 4729, Jan. 28, 2005, as amended at 85 FR 33908, June 2, 2020]

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA).* A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees.* An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA.* (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with $\frac{1}{12}$ of the annual capitation rate applied under this section for the.

(ii) If the monthly MA MSA premium is less than $\frac{1}{12}$ of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

[70 FR 4729, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005]

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section