as required by CMS. There may be penalties for submission of false data.

(f) *Use of data.* CMS uses the data obtained under this section to determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c). CMS also may use the data for updating risk adjustment models, calculating Medicare DSH percentages, conducting quality review and improvement activities, and for Medicare coverage purposes.

(g) *Deadlines for submission of risk adjustment data.* Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate. CMS may adjust these deadlines, as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting items and services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the March deadline until January 31 of the year following the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual January 31 late data submission deadline will not be accepted for the purposes of reconciliation.

[73 FR 48757, Aug. 19, 2008]

§ 422.311 RADV audit dispute and appeal processes.

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

(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 CMS or its contractors.

(3) *Medical record review appeal.* MA organizations that do not agree with the medical record review determinations for audited HCCs may appeal the medical record review determinations of the initial validation contractor to CMS in accordance with paragraph (c)(2) of this section.

(c) *RADV audit dispute and appeal processes*—(1) *Attestation process*—(i) *Submission requirements for attestations.* MA organizations—

(A) May submit CMS-generated attestations from physician/practitioner(s) in order to dispute signature-related or credential-related RADV errors in accordance with the attestations provisions of this section.

(B) Are not obligated to submit attestations to CMS.

(ii) *RADV audit-related errors eligible for attestation process.* CMS will only accept an attestation to support a physician or outpatient medical record with a missing signature or missing credential or both.

(iii) *RADV audit-related errors and documentation ineligible for attestation process.*

(A) Attestations from providers for anything other than signature-related and credential-related errors will not be permitted.

(B) Inpatient provider-type medical records are not eligible for attestation.

(iv) *Manner and timing of a request for attestation.* (A) CMS will provide MA

organizations selected for RADV audits with attestations and accompanying instructions at the time the organization receives its audit instructions.

(B) If an organization decides to submit attestations completed by physicians or other practitioners, the MA organization must submit the attestations to CMS at the same time that the MA organization is required to submit related medical records for RADV audit.

(v) *Attestation content.* An attestation must accompany and correspond to the medical record submitted for RADV audit and must meet the following requirements:

(A) Contain only CMS-generated attestations.

(B) The CMS attestation form may not be altered unless otherwise instructed and agreed-upon in writing by CMS.

(C) Attestations must be completed and be signed and dated by the eligible risk adjustment physician/practitioner whose medical record accompanies the attestation.

(D) Attestations must be based upon medical records that document face-to-face encounters between beneficiaries and RADV-eligible physicians/practitioners.

(vi) *Attestation review and determination procedures.* CMS—(A) Reviews each submitted attestation to determine if it meets CMS requirements and is acceptable for use during the medical record review; and

(B) Provides written notice of its determination(s) regarding submitted attestations to the MA organization at the time CMS issues its RADV audit report.

(vii) *Effect of CMS's attestation determination.* (A) CMS' attestation determination is final.

(B) An MA organization may choose to appeal its medical record review determinations for audited HCCs following initial validation contractor review using a CMS-administered medical record review determination appeal process.

(2) *RADV-related medical record review errors and documentation eligible for medical record review determination appeal process:* (i) *General rules.* (A) In order to be eligible for medical record review determination appeal, MA organizations must adhere to established RADV audit procedures and RADV appeals requirements. Failure to follow CMS rules regarding the RADV medical record review audit procedures and RADV appeals requirements may render the MA organization's request for appeal invalid.

(B) The medical record review determination appeal process applies only to error determinations from review of the one best medical record submitted by the MA organization and audited by the RADV initial validation contractor (IVC).

(C) MA organizations that choose to appeal the IVC's medical record review determination(s) may only submit the IVC-audited one best medical record and IVC-reviewed attestation, previously submitted in accordance with paragraph (c)(1) of this section, to CMS for re-review.

(D) MA organizations' request for medical record review determination appeal may not include additional documentary evidence beyond the IVC-audited one best medical record and IVC-reviewed attestation.

(ii) *RADV-related audit errors and documentation ineligible for medical record review appeal process.* (A) MA organizations may not appeal errors that resulted because MA organizations failed to adhere to established RADV audit procedures and RADV appeals requirements. This includes failure by the MA organization to meet the medical record submission deadline established by CMS.

(B) Any other documentation submitted to CMS beyond the one best medical record and attestation submitted to and audited by the IVC will not be reviewed by CMS under the medical record review determination appeal process.

(C) The MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that CMS identified as being in error and eligible for medical record review determination appeal, and that the MA organization wishes to appeal.

(iii) *Manner and timing of a request for medical record review determination appeal.* (A) At the time CMS issues its

IVC RADV audit report to audited MA organizations, CMS notifies these MA organizations of any RADV HCC errors that are eligible for medical record review determination appeal.

(B) MA organizations have 30 calendar days from date of issuance of the RADV audit report to file a written request with CMS for medical record review determination appeal.

(C) A request for medical record review determination appeal must specify the determinations with which the MA organization disagrees and the reasons for the request for appeal.

(iv) *Medical record review determination appeal review and notification procedures.* (A) *Designation of a hearing officer.* CMS designates a hearing officer to conduct the medical record review determination appeal. The hearing officer need not be an ALJ.

(B) *Disqualification of hearing officer.* (*1*) 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.

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

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

(*i*) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(*ii*) 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 CMS.

(v) *Hearing officer's review.* The hearing officer reviews the IVC-audited one best medical record and the IVC-reviewed attestation submitted by the MA organization to determine whether it supports overturning medical record review determination errors listed in the MA organization's IVC-level RADV audit report.

(vi) *Hearing procedures.* (A) CMS provides written notice of the time and place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented to the IVC. The CMS hearing officer is limited to the review of the record that was before the IVC.

(vii) *Hearing officer's decision.* As soon as practical after the hearing, the hearing officer issues a decision which provides written notice of the hearing officer's review of the appeal of medical record review determination(s) to the MA organization and to CMS.

(viii) *Computations based on hearing decision.* In accordance with the hearing officer's decision, CMS recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization.

(ix) *Effect of hearing decision.* The hearing officer's decision is final and binding, unless the MA organization requests review of the hearings officer appeal determination by the CMS Administrator.

(x) *Review by the CMS Administrator.* (A) A MA organization that has received a hearing officer decision may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's determination. A request for CMS Administrator review must be made in writing and filed with CMS.

(B) 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 decision.

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

(*1*) Acknowledges the decision to review the hearing decision in writing; and

(*2*) Reviews the decision and determine based upon all of the following whether the determination should be upheld, reversed, or modified:

(*i*) The hearing record.

(*ii*) Written arguments submitted by the MA organization or CMS.

(xi) *Notification of Administrator determination.* (A) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of acknowledging his or her decision to review the hearing decision.

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

(*1*) Declines to review the hearing decision; or

(*2*) Does not make a determination regarding review within 30 calendar days.

(3) *RADV payment error calculation appeal process.* (i) MA organizations may appeal CMS' RADV payment error calculation.

(ii) *RADV payment error-related issues ineligible for appeal.* MA organizations may not—

(A) Appeal RADV medical record review-related errors as part of the RADV payment error calculation appeal process. In accordance with paragraph (c)(2) of this section, MA organizations that wish to appeal medical record review determinations may do so following issuance of the IVC RADV audit report of findings.

(B) Introduce new HCCs to CMS for payment consideration in the context of their RADV payment error calculation appeal.

(C) Appeal RADV errors that result from an MA organization's failure to submit a medical record.

(D) Appeal CMS' RADV payment error calculation methodology.

(iii) *Manner and timing of a request for appeal.* (A) MA organizations may not appeal their RADV error calculation until any appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are final.

(B) At the time CMS issues either its IVC or post-medical record review appeal RADV audit report, CMS notifies affected MA organizations in writing of their appeal rights around the RADV payment error calculation.

(C) MA organizations have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation.

(iv) *Burden of proof.* The MA organization bears the burden of proof in demonstrating that CMS failed to follow its stated RADV payment error calculation methodology.

(v) *Content of request.* The written request for reconsideration must specify the issues with which the MA organization disagrees and the reasons for the disagreements.

(A) The written request for reconsideration may include additional documentary evidence the MA organization wishes CMS to consider.

(B) CMS does not accept reconsiderations for issues with the methodology applied in any part of the RADV audit.

(vi) *Conduct of written reconsideration.* (A) In conducting the written reconsideration, CMS reviews all of the following information:

(*1*) The RADV payment error calculation.

(*2*) The evidence and findings upon which they were based.

(*3*) Any other written evidence submitted by the MA organization.

(B) CMS ensures that a third party—either within CMS or a CMS contractor—not otherwise involved in the initial RADV payment error calculation reviews the written request for reconsideration.

(C) The third party recalculates the payment error in accordance with CMS RADV payment calculation procedures described in CMS' RADV payment error calculation standard operating procedures.

(D) The third party described in paragraph (c)(3)(vi)(B) of this section provides his or her determination to a CMS reconsideration official not otherwise involved in the RADV payment error calculation to review the reconsideration determination.

(vi) *Decision of the CMS reconsideration official.* The CMS reconsideration official informs the MA organization and CMS in writing of the decision of the CMS reconsideration official.

(vii) *Effect of the CMS reconsideration official.* The written reconsideration decision is final and binding unless a request for a hearing is filed by CMS or the appellant MA organization in accordance with paragraph (c) (4) of this section.

(4) *Right to a hearing.* CMS or a MA organization dissatisfied with the written decision of the CMS reconsideration official is entitled to a hearing as provided in this section.

(i) *Manner and timing for request.* A request for a hearing must be made in writing and filed with CMS within 30 calendar days of the date CMS and the MA organization receives the CMS reconsideration officer's written reconsideration decision.

(ii) *Content of request.* The written request for hearing must include a copy of the written decision of the CMS reconsideration official and must specify the findings or issues in the reconsideration decision with which either CMS or the MA organization disagrees and the reasons for the disagreement.

(iii) *Hearing procedures.* (A) CMS provides written notice of the time and place of the hearing at least 30 calendar days before the scheduled date.

(B) The hearing will be held on the record, unless the parties request, subject to the hearing officer's discretion, a live or telephonic hearing. The hearing officer may schedule a live or telephonic hearing on his/her own motion.

(C) The hearing is conducted by the CMS hearing officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made either its initial RADV payment error calculation determination or its post-medical record review appeal payment error calculation determination and when the CMS reconsideration official issued the written reconsideration decision.

(D) The hearing officer has full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers include the authority to dismiss the appeal with prejudice or take any other action which the hearing officer considers appropriate for failure to comply with such rules and procedures.

(iv) *Decision of the CMS Hearing Officer.* The CMS hearing officer decides whether the reconsideration official's decision was correct, and sends a written decision to CMS and the MA organization, explaining the basis for the decision.

(v) *Effect of the Hearing Officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the Administrator in accordance with paragraph (c)(5) of this section.

(vi) *Review by the CMS Administrator.* (A) CMS or a MA organization that has received a hearing officer's decision upholding or overturning a CMS initial or reconsideration-level RADV payment error calculation determination may request review by the CMS Administrator within 30 calendar days of receipt of the hearing officer's decision.

(B) At his or her discretion, the CMS Administrator can choose to either review or not review a case.

(C) If the CMS Administrator chooses to review the case, the CMS Administrator—

(*1*) Acknowledges his or her decision to review the hearing officer's decision in writing; and

(*2*) Determines whether to uphold, reverse, or modify the Hearing Officer's decision based on his or her review of the following:

(*i*) The Hearing Officer's decision.

(*ii*) Written documents submitted by CMS or the MA organization to the Hearing Officer.

(*iii*) Any other any other information included in the record of the Hearing Officer's decision.

(D) The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review.

(E) If the Administrator chooses to review, the Administrator's determination is final and binding.

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

(*1*) Declines to review the hearing decision; or

(*2*) Does not make a determination regarding review within 30 calendar days.

[75 FR 19806, Apr. 15, 2010; 75 FR 32859, June 10, 2010]