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(2) All prospective payment system hospitals in the State must agree to the reclassification to a statewide wage index through a signed affidavit on the application.

(3) All prospective payment system hospitals in the State must agree, through an affidavit, to withdrawal of an application or to termination of an approved statewide wage index reclassification.

(4) All hospitals in the State must waive their rights to any wage index classification that they would otherwise receive absent the statewide wage index classification, including a wage index that any of the hospitals might have received through individual geographic reclassification.

(5) New hospitals that open within the State prior to the deadline for submitting an application for a statewide wage index reclassification (September 1), regardless of whether a group application has already been filed, must agree to the use of the statewide wage index as part of the group application. New hospitals that open within the State after the deadline for submitting a statewide wage index reclassification application or during the approved reclassification period will be considered a party to the statewide wage index application and reclassification.

(b) *Effect on payments.* (1) An individual hospital within the State may receive a wage index that could be higher or lower under the statewide wage index reclassification in comparison to its otherwise redesignated wage index.

(2) Any new prospective payment system hospital that opens in the State during the effective period of an approved statewide wage index reclassification will be designated to receive the statewide wage index for the duration of that period.

(c) *Terms of the decision.* (1) A decision by the MGCRB on an application for a statewide wage index reclassification will be effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the hospitals filed a complete application.

(2) The procedures and timeframes specified in § 412.273 apply to with-

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drawals of applications for redesignation to a statewide wage index and terminations of approved statewide wage index reclassifications, including the requirement that, to withdraw an application or terminate an approved reclassification, the request must be made in writing by all hospitals that are party to the application, except hospitals reclassified into the State for purposes of receiving the statewide wage index.

[66 FR 39935, Aug. 1, 2001]

COMPOSITION AND PROCEDURES

§ 412.246 MGCRB members.

(a) *Composition.* The Medicare Geographical Classification Review Board (MGCRB) consists of five members, including a Chairman, all of whom are appointed by the Secretary. The members include two members who are representative of prospective payment system hospitals located in rural areas, and at least one individual who is knowledgeable in analyzing the costs of inpatient hospital services.

(b) *Term of office.* The term of office for an MGCRB member may not exceed 3 years. A member may serve more than one term. The Secretary may terminate a member's tenure prior to its full term.

[55 FR 36766, Sept. 6, 1990, as amended at 61 FR 46224, Aug. 30, 1996; 61 FR 51217, Oct. 1, 1996]

§ 412.248 Number of members needed for a decision or a hearing.

(a) *A quorum.* A quorum, consisting of at least a majority of the MGCRB members, one of whom is representative of rural hospitals if possible, is required for making MGCRB decisions.

(b) *Number of members for a hearing.* If less than a quorum is present for an oral hearing, the chairman with the consent of the hospital may allow those members present to conduct the hearing and to prepare a recommended decision, which is then submitted to a quorum.

§ 412.250 Sources of MGCRB's authority.

(a) *Compliance.* The MGCRB, in issuing decisions under section 1886(d)(10)(C) of the Act, complies with

all the provisions of title XVIII and related provisions of the Act and implementing regulations, including the criteria and conditions located at § 412.230 through § 412.236, issued by the Secretary under the authority of section 1886(d)(10)(D) of the Act; and CMS Rulings issued under the authority of the Administrator.

(b) *Affords great weight.* The MGCRB affords great weight to other interpretive rules, general statements of policy and rules of agency organization, procedure, and practice established by CMS.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991]

§ 412.252 Applications.

(a) *By one hospital.* An individual prospective payment system hospital seeking redesignation to a different rural or urban area has the right to submit an application to the MGCRB.

(b) *By a group of hospitals.* A group of hospitals has the right to submit an application to the MGCRB requesting redesignation of all prospective payment hospitals in a county if all prospective payment hospitals located in a county agree to the request.

[55 FR 36766, Sept. 6, 1990, as amended at 69 FR 49250, Aug. 11, 2004]

§ 412.254 Proceedings before MGCRB.

(a) *On-the-record decision.* The MGCRB will ordinarily issue an on-the-record decision without conducting an oral hearing. The MGCRB will issue a decision based upon all documents, data, and other written evidence and comments submitted timely to the MGCRB by the parties.

(b) *Oral hearing.* The MGCRB may hold an oral hearing on its own motion or if a party demonstrates to the MGCRB's satisfaction that an oral hearing is necessary.

§ 412.256 Application requirements.

(a) *Written application.* A request for reclassification must be in writing and must constitute a complete application in accordance with paragraph (b) of this section.

(1) An application must be submitted to the MGCRB according to the method prescribed by the MGCRB.

(2) A complete application must be received not later than the first day of the 13-month period preceding the Federal fiscal year for which reclassification is requested.

(3) The filing date of an application is the date the application is received by the MGCRB.

(b) *Criteria for a complete application.* An application is complete if the application from an individual hospital or from all hospitals in a county includes the following information:

(1) The Federal fiscal year for which the hospital is applying for redesignation.

(2) Which criteria constitute the basis of the request for reclassification.

(3) An explanation of how the hospital or hospitals meet the relevant criteria in §§ 412.230 through 412.236, including any necessary data to support the application.

(c) *Opportunity to complete a submitted application.* (1) The MGCRB will review an application within 15 days of receipt to determine if the application is complete. If the MGCRB determines that an application is incomplete, the MGCRB will notify the hospital, with a copy to CMS, within the 15 day period, that it has determined that the application is incomplete and may dismiss the application if a complete application is not filed by September 1.

(2) At the request of the hospital, the MGCRB may, for good cause, grant a hospital that has submitted an application by September 1, an extension beyond September 1 to complete its application.

(d) *Appeal of MGCRB dismissal.* (1) The hospital may appeal the MGCRB dismissal to the Administrator within 15 days of the date of the notice of dismissal.

(2) Within 20 days of receipt of the hospital's request for appeal, the Administrator will affirm the dismissal or reverse the dismissal and remand the case to the MGCRB to determine whether reclassification is appropriate.

(e) *Notification of complete application.* When the MGCRB determines that the hospital's application contains all the necessary elements for a complete application, it notifies the hospital in writing, with a copy to CMS, that the application is complete and that the

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case may proceed to an MGCRB decision.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991; 62 FR 46031, Aug. 29, 1997; 63 FR 26357, May 12, 1998; 64 FR 41541, July 30, 1999; 81 FR 57268, Aug. 22, 2016; 84 FR 42614, Aug. 16, 2019]

§ 412.258 Parties to MGCRB proceeding.

(a) The party or parties to an MGCRB proceeding are the hospital or group of hospitals requesting a change in geographic designation.

(b) CMS has 30 days from the date of receipt of notice of a complete application to submit written comments and recommendations (with a copy to the hospital) for consideration by the MGCRB.

(c) The hospital has 15 days from the date of receipt of CMS's comments to submit written comments to the MGCRB, with a copy to CMS, for the purpose of responding to CMS's comments.

§ 412.260 Time and place of the oral hearing.

If the MGCRB decides that an oral hearing is necessary, it sets the time and place for the hearing and notifies the parties in writing, with a copy to CMS, not less than 10 days before the time scheduled for the hearing. The MGCRB may reschedule, adjourn, postpone, or reconvene the hearing provided that reasonable written notice is given to the parties, with a copy to CMS.

§ 412.262 Disqualification of an MGCRB member.

(a) *Grounds for disqualification.* An MGCRB member may not participate in any decision in a case in which he or she may be prejudiced or partial with respect to a party or has any other interest in the case.

(b) *Request for disqualification.* If a party believes that an MGCRB member should not participate in a decision, the party submits the objection in writing to the MGCRB at its earliest opportunity, explaining the grounds for the request. CMS may also submit such a suggestion to the MGCRB.

(c) *Consideration by the MGCRB member.* The MGCRB member will consider

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the objection and, at his or her discretion, either will proceed or withdraw.

(d) *Consideration by the MGCRB.* If the member does not withdraw, a party may petition the MGCRB for withdrawal and the MGCRB will consider the objection and rule on whether the member may participate in the decision before it decides the case.

§ 412.264 Evidence and comments in MGCRB proceeding.

(a) *Submission by the parties.* Before a decision is issued and during an oral hearing, the parties may present evidence or comments to the MGCRB regarding the matters at issue in the case.

(b) *Content of evidence and comments.* The MGCRB may receive evidence and comments without regard for the rules of evidence applicable to court procedures.

(c) *Ex parte communications.* (1) The members of the MGCRB and its staff may not consult or be consulted by an individual representing the interests of an applicant hospital or by any other individual on any matter in issue before the MGCRB without notice to the hospital or CMS. If such communication occurs, the MGCRB will disclose it to the hospital or CMS, as appropriate, and make it part of the record after the hospital or CMS has had an opportunity to comment. MGCRB members and staff may not consider any information outside the record about matters concerning a hospital's application for reclassification.

(2) The provisions in paragraph (c)(1) of this section do not apply to the following:

(i) Communications among MGCRB members and staff.

(ii) Communications concerning the MGCRB's administrative functions or procedures.

(iii) Requests from the MGCRB to a party or CMS for a document.

(iv) Material that the MGCRB includes in the record after notice and an opportunity to comment.

(d) *MGCRB rulings on evidence and comments.* The MGCRB rules upon the admissibility of evidence and comments and excludes irrelevant, immaterial, or unduly repetitious evidence and comments.

§ 412.266 Availability of wage data.

A hospital may obtain the average hourly wage data necessary to prepare its application to the MGCRB from FEDERAL REGISTER documents published in accordance with the provisions of § 412.8(b).

[60 FR 45849, Sept. 1, 1995]

§ 412.268 Subpoenas.

(a) *In general.* When reasonably necessary for the full presentation of a case, and only after a pre-decision request for information or data has failed to produce the necessary evidence, either upon its own motion or upon the request of a party, the MGCRB may issue subpoenas for the attendance and testimony of witnesses, for an oral hearing or the production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(b) *Content of request.* The request must designate which witnesses or documents are to be produced, and describe addresses or locations with sufficient particularity to permit these witnesses or documents to be found. The request for a subpoena must state the pertinent facts that the party expects to establish by the requested witnesses or documents and whether these facts could be established by other evidence without the use of a subpoena.

(c) *Issuance.* Subpoenas are issued as provided in section 205(d) of the Act.

(d) *Payment for subpoena cost.* CMS pays for the cost of issuing subpoenas and the fees and mileage of any witness who is subpoenaed, as provided in section 205(d) of the Act.

§ 412.270 Witnesses.

Witnesses at an oral hearing testify under oath or affirmation, unless excused by the MGCRB for cause. The MGCRB may examine the witnesses and may allow the parties or their representatives to also examine any witnesses called.

§ 412.272 Record of proceedings before the MGCRB.

A complete record of the proceedings before the MGCRB is made in all cases. The record will not be closed until a decision has been issued by the

MGCRB. A transcription of an oral hearing will be made at a party's request, at the expense of the requesting party.

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

(a) *Definitions.* For purposes of this section, the following definitions apply.

Termination refers to the termination of an already existing 3-year MGCRB reclassification where such reclassification has already been in effect for 1 or 2 years, and there are 1 or 2 years remaining on the 3-year reclassification. A termination is effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year are not considered.

Withdrawal refers to the withdrawal of a 3-year MGCRB reclassification that has not yet gone into effect or where the MGCRB has not yet issued a decision on the application.

(b) *General rule.* The MGCRB allows a hospital, or group of hospitals, to withdraw its application or to terminate an already existing 3-year reclassification, in accordance with this section.

(c) *Timing.* (1) A request for withdrawal must be received by the MGCRB—

(i) At any time before the MGCRB issues a decision on the application; or

(ii) After the MGCRB issues a decision, provided that the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the FEDERAL REGISTER concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed.

(2) A request for termination must be received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the FEDERAL REGISTER concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the termination is to apply.

(d) *Reapplication within the approved 3-year period, cancellations of terminations and withdrawals, and prohibition on overlapping reclassification approvals*—(1) *Cancellation of terminations or withdrawals.* Subject to the provisions of this section, a hospital (or group of hospitals) may cancel a withdrawal or termination in a subsequent year and request the MGCRB to reinstate the wage index reclassification for the remaining fiscal year(s) of the 3-year period. (Withdrawals may be cancelled only in cases where the MGCRB issued a decision on the geographic reclassification request.)

(2) *Timing and process of cancellation request.* Cancellation requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

(3) *Reapplications.* A hospital may apply for reclassification to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, regardless of whether the withdrawal or termination request is made within 3 years from the date of the withdrawal or termination.

(4) *Termination of existing 3-year reclassification.* In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1.

(e) *Written request only.* (1) A request to withdraw an application must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by all hospitals that are party to the application.

(2) A request to terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by an individual hospital

or by an individual hospital that is party to a group classification.

(f) *Appeal of the MGCRB's denial of a hospital's request for withdrawal or termination, or for cancellation of a withdrawal or termination.* (1) A hospital may file an appeal of the MGCRB's denial of its request for withdrawal or termination, or of the MGCRB's denial of its request for a cancellation of such withdrawal or termination, to the Administrator. The appeal must be received within 15 days of the date of the notice of the denial.

(2) Within 20 days of receipt of the hospital's request for appeal, the Administrator affirms or reverses the denial.

[75 FR 50415, Aug. 16, 2010, as amended at 82 FR 38512, Aug. 14, 2017; 87 FR 49404, Aug. 10, 2022]

§ 412.274 Scope and effect of an MGCRB decision.

(a) *Scope of decision.* The MGCRB may affirm or change a hospital's geographic designation. The MGCRB's decision is based upon the evidence of record, including the hospital's application and other evidence obtained or received by the MGCRB.

(b) *Effective date and term of the decision.* (1) For reclassifications prior to fiscal year 2005, a standardized amount classification change is effective for 1 year beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the complete application is filed and ending effective at the end of that Federal fiscal year (the end of the next September 30).

(2) A wage index classification change is effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year in which the complete application is filed.

[55 FR 36766, Sept. 6, 1990, as amended at 62 FR 46031, Aug. 29, 1997; 66 FR 39935, Aug. 1, 2001; 69 FR 49250, Aug. 11, 2004]

§ 412.276 Timing of MGCRB decision and its appeal.

(a) *Timing.* The MGCRB notifies the parties in writing, with a copy to CMS, and issues a decision within 180 days

after the first day of the 13-month period preceding the Federal fiscal year for which a hospital has filed a complete application. The hospital has 15 days from the date of the decision to request Administrator review.

(b) *Appeal.* The decision of the MGCRB is final and binding upon the parties unless it is reviewed by the Administrator and the decision is changed by the Administrator in accordance with §412.278.

[55 FR 36766, Sept. 6, 1990, as amended at 64 FR 41541, July 30, 1999]

§412.278 Administrator's review.

(a) *Hospitals requests for review.* A hospital or group of hospitals dissatisfied with the MGCRB's decision regarding its geographic designation may request the Administrator to review the MGCRB decision. (A hospital or group of hospitals may also request that the Administrator review the MGCRB's dismissal of an application as untimely filed or incomplete, as provided in §412.256(d).)

(b) *Procedures for hospital's request for review.* (1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. The hospital must also submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

(2) The request for review may contain proposed findings of fact and conclusions of law, exceptions to the MGCRB's decision, and supporting reasons therefor.

(3) Within 15 days of receipt of the hospital's request for review, CMS may submit to the Administrator, in writing, with a copy to the party, comments and recommendations concerning the hospital's submission.

(4) Within 10 days of receipt of CMS's submission, the hospital may submit in writing, with a copy to CMS, a response to the Administrator.

(c) *Discretionary review by the Administrator.* (1) The Administrator may, at his or her discretion, review any final decision of the MGCRB.

(2) The Administrator promptly notifies the hospital that he or she has decided to review a decision of the MGCRB. The notice of review indicates the particular issues to be considered and includes copies of any comments submitted to the Administrator by CMS staff concerning the MGCRB decision.

(3) Within 15 days of the receipt of the Administrator's notice of review, the hospital may submit a response in writing to the Administrator, with a copy of CMS.

(d) *Criteria for discretionary review.* In deciding whether to review an MGCRB decision, the Administrator normally considers whether it appears that any of the following situations apply:

(1) The MGCRB made an erroneous interpretation of law, regulation, or CMS Ruling.

(2) The MGCRB's decision is not supported by substantial evidence.

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to issuance of a CMS Ruling or other directive needed to clarify a provision in the law or regulations.

(4) The decision of the MGCRB requires clarification, amplification, or an alternative legal basis.

(5) The MGCRB has incorrectly extended its authority to a degree not provided for by law, regulation, or CMS Ruling.

(e) *Communication procedures.* All communications between CMS staff and the Administrator concerning the Administrator's review of an MGCRB decision must be in writing. As specified in paragraphs (b) and (c) of this section, copies of comments by CMS staff are sent to applicant hospitals within 15 days of receipt of a hospital's request for review, or, in cases in which the Administrator decides to review a case at his or her discretion, are included with the Administrator's notice of review. In the event there are additional communications between CMS staff and the Administrator concerning MGCRB decisions reviewed by the Administrator under paragraphs (b) or (c) of this section, CMS furnishes copies of the communications to the hospital or group of hospitals.

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(f) *Administrator's decision.* (1) The Administrator may not receive or consider any new evidence and must issue a decision based only upon the record as it appeared before the MGCRB and comments submitted under paragraphs (b)(2), (b)(3), (b)(4), (c)(2), and (c)(3) of this section.

(2) The Administrator issues a decision in writing to the party with a copy to CMS—

(i) Not later than 90 days following receipt of the party's request for review, except the Administrator may, at his or her discretion, for good cause shown, toll such 90 days; or

(ii) Not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator, except the Administrator may, at his or her discretion, for good cause shown, toll such 105 days.

(3) The Administrator's decision issued under § 412.278 (a) or (c) is the final Departmental decision, unless it is amended under § 412.278(g). The final Departmental decision is not subject to judicial review.

(4) The Administrator's decision is not subject to judicial review.

(g) *Amendment of Administrator decision*—(1) *Hospital's request for amendment.* The hospital may request the Administrator to amend the decision for the limited purpose of correcting mathematical or computational errors, or to correct the decision if the evidence that was considered in making the decision clearly shows on its face that an error was made. The following procedure is followed:

(i) The hospital's request for amendment must be received by the Administrator within 10 days after the date the Administrator issues a decision. The request for amendment must be in writing, with a copy to CMS.

(ii) The Administrator promptly reviews the hospital's request and amends the decision, if necessary, within 5 days following receipt of the hospital's request for amendment.

(2) *Discretionary review by the Administrator.* Within 15 days following the issuance of the Administrator's decision, the Administrator, at his or her discretion, may amend the decision to correct mathematical or computational errors, or to correct the decision

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if the evidence that was considered in making the decision clearly shows on its face that an error was made. The Administrator's amended decision is final and is not subject to judicial review.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25489, June 4, 1991; 57 FR 39826, Sept. 1, 1992; 68 FR 45471, Aug. 1, 2003; 70 FR 47487, Aug. 12, 2005; 85 FR 59023, Sept. 18, 2020; 86 FR 45520, Aug. 13, 2021]

§ 412.280 Representation.

(a) *General.* A party may be represented by legal counsel or by any other person appointed to act as its representative at any proceeding before the MGCRB or the Administrator.

(b) *Rights of a representative.* A representative appointed by a party may accept or give on behalf of the party any request or notice connected with any proceeding before the MGCRB or the Administrator. A representative is entitled to present evidence and argument as to facts and law in any MGCRB proceeding affecting the party represented and to obtain information to the same extent as the party represented. Notice of any action or decision sent to the representative of a party has the same effect as if it had been sent to the party itself.

Subpart M—Prospective Payment System for Inpatient Hospital Capital Costs

SOURCE: 56 FR 43449, Aug. 30, 1991, unless otherwise noted.

GENERAL PROVISIONS

§ 412.300 Scope of subpart and definition.

(a) *Purpose.* This subpart implements section 1886(g)(1)(A) of the Act by establishing a prospective payment system for inpatient hospital capital-related costs. Under this system, payment is made on the basis described in § 412.304 through § 412.374 for inpatient hospital capital-related costs furnished by hospitals subject to the prospective payment system under subpart B of this part.

(b) *Definition.* For purposes of this subpart, a new hospital means a hospital that has operated (under previous