

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.