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hospital operated by the IHS or a Tribe.

(2) Subject to the requirements set forth in § 405.1885 of this chapter, a hospital may request the application of the policy described in paragraph (e)(1) of this section for discharges occurring in FY 2011 through FY 2017.

[75 FR 50414, Aug. 16, 2010, as amended at 78 FR 50965, Aug. 19, 2013; 49 FR 15030, Mar. 18, 2014; 79 FR 50352, Aug. 22, 2014; 80 FR 49767, Aug. 17, 2015; 82 FR 38511, Aug. 14, 2017; 83 FR 41702, Aug. 17, 2018; 84 FR 42613, Aug. 16, 2019; 88 FR 59332, Aug. 28, 2023; 89 FR 69911, Aug. 28, 2024]

§ 412.102 Special treatment: Hospitals located in areas that are changing from urban to rural as a result of a geographic redesignation.

An urban hospital that was part of an MSA, but was redesignated as rural as a result of the most recent OMB standards for delineating statistical areas adopted by CMS, may receive an adjustment to its rural Federal payment amount for operating costs for 2 successive fiscal years as provided in paragraphs (a) and (b) of this section.

(a) *First year adjustment.* (1) Effective on or after October 1, 1983 and before October 1, 2014, the hospital's rural average standardized amount and disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its geographic redesignation and the rural standardized amount and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(2) Effective on or after October 1, 2014, the hospital's rural disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the disproportionate share payments as an urban hospital applicable to the hospital before its geographic redesignation to a rural area as a result of implementation of the most recent OMB standards for delineating statistical areas adopted by CMS and the rural disproportionate share payment other-

wise applicable to the Federal fiscal year for which the adjustment is made.

(b) *Second year adjustment.* (1) Effective on or after October 1, 1983 and before October 1, 2014, if a hospital's status continues to be rural as a result of geographic redesignation, its rural average standardized amount and disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its redesignation and the rural standardized amounts and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(2) Effective on or after October 1, 2014, if a hospital's status continues to be rural as a result of geographic redesignation, its disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the disproportionate share payments applicable to the hospital before its geographic redesignation to a rural area as a result of implementation of the most recent OMB standards for delineating statistical areas adopted by CMS and the rural disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

[79 FR 50353, Aug. 22, 2014]

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) *General criteria.* A prospective payment hospital that is located in an urban area (as defined in subpart D of this part) may be reclassified as a rural hospital if it submits an application in accordance with paragraph (b) of this section and meets any of the following conditions:

(1) The hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, using the Rural-Urban Commuting Area codes and additional criteria, as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA),

which is available at the web link provided in the most recent FEDERAL REGISTER notice issued by HRSA defining rural areas.

(2) The hospital is located in an area designated by any law or regulation of the State in which it is located as a rural area, or the hospital is designated as a rural hospital by State law or regulation.

(3) The hospital would qualify as a rural referral center as set forth in §412.96, or as a sole community hospital as set forth in §412.92, if the hospital were located in a rural area.

(4) For any period after September 30, 2004 and before October 1, 2006, a CAH in a county that, in FY 2004, was not part of a MSA as defined by the Office of Management and Budget, but as of FY 2005 was included as part of an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement in §485.610(b) of this chapter if it meets any of the requirements in paragraphs (a)(1), (a)(2), or (a)(3) of this section.

(5) For any period after September 30, 2009, and before October 1, 2011, a CAH in a county that, in FY 2009, was not part of an MSA as defined by the Office of Management and Budget, but, as of FY 2010, was included as part of an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on November 20, 2008, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement in §485.610(b) of this chapter if it meets any of the requirements under paragraph (a)(1), (a)(2), or (a)(3) of this section.

(6) For any period on or after October 1, 2014, a CAH in a county that was not in an urban area as defined by the Office of Management and Budget (OMB), but was included in an urban area as a result of the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement at §485.610(b) of this chap-

ter for a period of 2 years, beginning with the date of the implementation of the new labor market area delineations, if it meets any of the requirements under paragraph (a)(1), (a)(2), or (a)(3) of this section.

(7) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at §413.65 of this chapter as a main campus and a remote location of a hospital, the hospital is required to demonstrate that the main campus and its remote location(s) each independently satisfy the location conditions specified in paragraphs (a)(1) and (2) of this section.

(8) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at §413.65 of this chapter as a main campus and a remote location of a hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area (as defined in §412.64(b) and including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act).

(b) *Application requirements*—(1) *Written application*. A hospital seeking reclassification under this section must submit a complete application in writing to CMS in accordance with paragraphs (b)(2) and (b)(3) of this section.

(2) *Contents of application*. An application is complete if it contains an explanation of how the hospital meets the condition that constitutes the basis of the request for reclassification set forth in paragraph (a) of this section, including data and documentation necessary to support the request.

(3) *Submission of application*. An application may be submitted to the CMS Regional Office by the requesting hospital by mail or by facsimile or other electronic means.

(4) *Notification by CMS*. Within 5 business days after receiving the hospital's application, the CMS Regional Office

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will send the hospital a letter acknowledging receipt, with a copy to the CMS Central Office.

(5) *Filing date.* The filing date of the application is the date CMS receives the application.

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for the payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of this section no later than 60 days after the public display date at the Office of the Federal Register of the inpatient prospective payment system proposed rule for the next Federal fiscal year.

(c) *CMS review.* The CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date.

(d) *Effective dates of reclassification.* (1) Except as specified in paragraphs (d)(2) and (3) of this section, CMS will consider a hospital that satisfies any of the criteria set forth in paragraph (a) of this section as being located in the rural area of the State in which the hospital is located as of that filing date.

(2) If a hospital's complete application is received in CMS by September 1, 2000, and satisfies any of the criteria set forth in paragraph (a) of this section, CMS will consider the filing date to be January 1, 2000.

(3) CMS will consider a hospital that satisfies the criteria set forth in paragraph (a)(3) of this section and which qualifies for sole community hospital status in accordance with the requirements of § 412.92(b)(2)(vi) as being located in the rural area of the State in which the hospital is located as of the effective date set forth in § 412.92(b)(2)(vi).

(e) *Withdrawal of application.* A hospital may withdraw an application at any time prior to the date of CMS's decision as set forth in paragraph (c) of this section.

(f) *Duration of classification.* An approved reclassification under this section remains in effect without need for

reapproval unless there is a change in the circumstances under which the classification was approved.

(g) *Cancellation of classification—(1) Hospitals other than rural referral centers.* Except as provided in paragraph (g)(2) of this section—

(i) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of its current cost reporting period.

(ii) The hospital's cancellation of the classification is effective beginning with the next full cost reporting period.

(iii) The provisions of paragraphs (g)(1)(i) and (ii) of this section are effective for all written requests submitted by hospitals before October 1, 2019 to cancel rural reclassifications.

(2) *Hospitals classified as rural referral centers.* For a hospital that was classified as a rural referral center under § 412.96 based on rural reclassification under this section—

(i) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year and after being paid as rural for at least one 12-month cost reporting period.

(ii) The hospital's cancellation of the classification is not effective until it has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the Federal fiscal year following such 12-month cost reporting period.

(iii) The provisions of paragraphs (g)(2)(i) and (ii) of this section are effective for all written requests submitted by hospitals on or after October 1, 2007 and before October 1, 2019, to cancel rural reclassifications.

(3) *Cancellation of rural reclassification on or after October 1, 2019, and before October 1, 2021.* For all written requests submitted by hospitals on or after October 1, 2019, and before October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a

Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(4) *Cancellation of rural reclassification on or after October 1, 2021.* For all written requests submitted by hospitals on or after October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification and not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(5) *Special rule for hospitals that opt to receive county out-migration adjustment.* A rural reclassification will be considered canceled effective for the next Federal fiscal year when a hospital, by submitting a request to CMS within 45 days of the date of public display of the proposed rule for the next Federal fiscal year at the Office of the Federal Register, opts to accept and receives its county out-migration wage index adjustment determined under section 1886(d)(13) of the Act in lieu of its geographic reclassification described under section 1886(d)(8)(B) of the Act.

[65 FR 47048, Aug. 1, 2000, as amended at 69 FR 49244, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47486, Aug. 12, 2005; 72 FR 47411, Aug. 22, 2007; 74 FR 43997, Aug. 27, 2009; 79 FR 50353, Aug. 22, 2014; 81 FR 57267, Aug. 22, 2016; 83 FR 41703, Aug. 17, 2018; 84 FR 42613, Aug. 16, 2019; 86 FR 45519, Aug. 13, 2021; 87 FR 49403, Aug. 10, 2022; 88 FR 59332, Aug. 28, 2023; 89 FR 69911, Aug. 28, 2024]

§412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* CMS provides an additional payment to a hospital for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into any of the following MS-DRGs, where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges:

(1) MS-DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis).

(2) MS-DRGs 650 and 651 (Kidney Transplant with Hemodialysis with MCC, without MCC, respectively).

(3) MS-DRGs 682, 683, and 684 (Renal Failure with MCC, with CC, without CC/MCC, respectively).

(b) *Additional payment.* A hospital that meets the criteria of paragraph (a) of this section is paid an additional payment for each ESRD beneficiary discharge except those excluded under paragraph (a) of this section.

(1) The payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD beneficiaries for the hospital.

(2)(i) Effective for cost reporting periods beginning before October 1, 2024, the estimated weekly cost of dialysis is the average number of dialysis sessions furnished per week during the 12-month period that ended June 30, 1983, multiplied by the average cost of dialysis for the same period.

(ii) Effective for cost reporting periods beginning on or after October 1, 2024, the estimated weekly cost of dialysis is calculated as 3 dialysis sessions per week multiplied by the applicable ESRD prospective payment system (PPS) base rate (as defined in 42 CFR 413.171) that corresponds with the fiscal year in which the cost reporting period begins.

(3) The average cost of dialysis used for purposes of determining the estimated weekly cost of dialysis for cost reporting periods beginning before October 1, 2024, includes only those costs determined to be directly related to the renal dialysis services. (These costs include salary, employee health and welfare, drugs, supplies, and laboratory services.)

(4) Effective for cost reporting periods beginning before October 1, 2024, the average cost of dialysis is reviewed and adjusted, if appropriate, at the time the composite rate reimbursement for outpatient dialysis is reviewed.

(5) The payment to a hospital equals the average length of stay of ESRD beneficiaries in the hospital, expressed