DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1762–IFC]

RIN 0938-AU56

Medicare Program; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services, (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) amends our current regulations to allow hospitals with a rural redesignation under the Social Security Act (the Act) to reclassify through the Medicare Geographic Classification Review Board (MGCRB) using the rural reclassified area as the geographic area in which the hospital is located. These regulatory changes align our policy with the decision in Bates County Memorial Hospital v. Azar, effective with reclassifications beginning with fiscal year (FY) 2023. We would also apply the policy in this IFC when deciding timely appeals before the Administrator of applications for reclassifications beginning with FY 2022 that were denied by the MGCRB due to the current policy, which does not permit hospitals with rural redesignations to use the rural area’s wage data for purposes of reclassifying under the MGCRB.

DATES: Effective date: These regulations are effective on May 10, 2021.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below by June 28, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1762–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.
Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the “submit a comment” tab.

2. By regular mail. You may mail written comments to the following address ONLY:

   Centers for Medicare & Medicaid Services,
   Department of Health and Human Services,
   Attention: CMS–1762–IFC,
   P.O. Box 8013,
   Baltimore, MD 21244–1850.

   Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY:

   Centers for Medicare & Medicaid Services,
   Department of Health and Human Services,
   Attention: CMS–1762–IFC,
   Mail Stop C4–26–05,
   7500 Security Boulevard,
   Baltimore, MD 21244–1850.

   For information on viewing public comments, we refer readers to the beginning of the SUPPLEMENTARY INFORMATION section.
FOR FURTHER INFORMATION CONTACT: Tehila Lipschutz, (410) 786–1344 or Dan Schroder, (410) 786–7452.

SUPPLEMENTARY INFORMATION:

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: [http://regulations.gov](http://regulations.gov). Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Wage Index for Acute Care Hospitals Paid Under the Hospital Inpatient Prospective Payment System (IPPS)

Under section 1886(d) of the Social Security Act (the Act), hospitals are paid based on prospectively set rates. To account for geographic area wage level differences, section 1886(d)(3)(E) of the Act requires that the Secretary of the Department of Health and Human Services (the Secretary) adjust the standardized amounts by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital, as compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No.
Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index of hospitals annually, and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS, after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act, regarding geographic reclassification of hospitals, are equal to the aggregate prospective payments that would have been made absent these provisions.

B. Hospital Reclassifications under Sections 1886(d)(8)(E) and 1886(d)(10) of the Act

Hospitals may seek to have their geographic designation reclassified. Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status. Specifically, section 1886(d)(8)(E) of the Act states that “[f]or purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the state in which the hospital is located.” The regulations governing these geographic redesignations are codified in § 412.103, and such hospitals are commonly referred to as “§ 412.103 hospitals”.

In a separate process, hospitals may also reclassify for purposes of the wage index under the IPPS under section 1886(d)(10) of the Act by applying to the Medicare Geographic Classification Review Board (MGCRB). Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought,
generally by September 1. (However, we note that this deadline has been extended for applications for FY 2022 reclassifications to 15 days after the public display date of the FY 2021 IPPS/LTCH final rule at the Office of the Federal Register, using our authority under section 1135(b)(5) the Act due to the COVID-19 Public Health Emergency.) Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280.

Prior to a court decision in Geisinger Community Medical v. Secretary, United States Department of Health and Human Services, 794 F.3d 383 (3d Cir. 2015) (“Geisinger”), hospitals were only able to hold one reclassification at a time: either under § 412.103 or through the MGCRB under section 1886(d)(10) of the Act. The Court of Appeals in Geisinger ruled that CMS’s prohibition of dual § 412.103 and MGCRB reclassifications was unlawful, since section 1886(d)(8)(E)(i) of the Act requires that “the Secretary shall treat the hospital as being located in the rural area,” inclusive of MGCRB reclassification purposes. Therefore, on April 21, 2016, we published an interim final rule with comment period (the April 21, 2016 IFC) in the Federal Register (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications.

II. Provisions of the Interim Final Rule With Comment Period

Pursuant to our April 21, 2016 IFC, for reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using the distance and average hourly wage criteria designated for rural hospitals. Hospitals with a § 412.103 redesignation seeking additional reclassification under the MGCRB use the rural distance and average hourly wage criteria under § 412.230(b)(1), (d)(1)(iii)(C), and (d)(1)(iv)(E). For example, under our current policy, a § 412.103 hospital
geographically located in the urban CBSA of Buffalo-Cheektowaga, NY seeking to reclassify under the MGCRB would demonstrate that their wages are at least 106 percent (and not 108 percent, as urban hospitals must demonstrate) of the average hourly wage of Buffalo-Cheektowaga, NY, to meet the criteria at § 412.230(d)(1)(iii)(C).

However, our current policy compares the average hourly wage of a § 412.103 hospital to its geographic urban location, rather than the rural reclassified area, for purposes of satisfying certain wage comparison criteria. In response to a comment on our April 21, 2016 IFC (81 FR 56925), we stated: “The commenter is correct that the rural distance and average hourly wage criteria will be used for hospitals with a § 412.103 redesignation. However, the commenter’s statement that the average hourly wage of a hospital with a § 412.103 redesignation is compared to the average hourly wage of hospitals in the State’s rural area under §412.230(d)(1)(iii)(C) is incorrect. Instead, the hospital’s average hourly wage would be compared to the average hourly wage of all other hospitals in its urban geographic location using the rural distance and average hourly wage criteria.”

On May 14, 2020, the United States District Court for the District of Columbia issued a decision in Bates County Memorial Hospital v. Azar, 464 F. Supp. 3d 43 (D.D.C. 2020) (Bates). Bates County Memorial Hospital and five other geographically urban hospitals were reclassified to rural under § 412.103. They also applied for reclassification under the MGCRB, but were denied because their wages were not at least 106 percent of the geographic urban area in which the hospitals were located. Each of the hospitals’ average hourly wages were at least 106 percent of the 3-year average hourly wage of all other hospitals in the rural area of the state in which the hospitals are located.

The Court agreed with the Plaintiffs that the statute at section 1886(d)(8)(E)(i) of Act requires that CMS treat qualifying hospitals as being located in the rural area for purposes of section 1886(d) of the Act, including MGCRB reclassification. The Bates decision requires that CMS consider the rural area to be the area in which the hospital is located for the wage
comparisons required for MGCRB reclassifications. For example, pursuant to Bates, a § 412.103 hospital geographically located in the urban CBSA of Buffalo-Cheektowaga, NY seeking to reclassify under the MGCRB would demonstrate that their wages are at least 106 percent of the average hourly wage of rural NY, rather than that of Buffalo-Cheektowaga.

As a result of the Bates court’s decision, we are revising our policy so that the redesignated rural area, and not the hospital’s geographic urban area, will be considered the area a § 412.103 hospital is located in for purposes of meeting MGCRB reclassification criteria. Similarly, we are revising the regulations to consider the redesignated rural area, and not the geographic urban area, as the area a § 412.103 hospital is located in for the prohibition at § 412.230(a)(5)(i) on reclassifying to an area with a pre-reclassified average hourly wage lower than the pre-reclassified average hourly wage for the area in which the hospital is located.

Specifically, to align our policy with the court’s decision in Bates, we are amending the regulations at § 412.230(a)(1) by adding (a)(1)(iii) to state that an urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of this section. We are also making conforming changes to the regulation at § 412.230(a)(5)(i) because § 412.230(a)(1) excepts paragraph (a)(5). Because § 412.230(a)(1) excepts paragraph (a)(5), we believe it is necessary to make a specific conforming revision to § 412.230(a)(5)(i), in addition to the general rule at § 412.230(a)(1)(iii), to clarify that the general rule at § 412.230(a)(1)(iii) applies to § 412.230(a)(5)(i) as well. That is, we are amending the regulation at § 412.230(a)(5)(i) to add language stating that an urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of paragraph (a)(5)(i).

These changes implement the Bates court’s interpretation of the requirement at section 1886(d)(8)(E)(i) of the Act that “the Secretary shall treat the hospital as being located in the rural area.” That is, a § 412.103 hospital would be considered to be located in the rural area of the state for all purposes of MGCRB reclassification, including the average hourly wage
comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C). For example, for purposes of § 412.230(d)(1)(iii)(C), the § 412.103 hospital would compare its average hourly wage to the average hourly wage of all other hospitals in the state’s rural area. In addition, for purposes of § 412.230(a)(5)(i), a § 412.103 hospital may not be redesignated to another area if the pre-classified average hourly wage for that area is lower than the pre-reclassified average hourly wage of the rural area of the state in which the hospital is located (thus, a § 412.103 hospital could potentially reclassify to any area with a pre-reclassified average hourly wage that is higher than the pre-reclassified average hourly wage for the rural area of the state, if it meets all other applicable reclassification criteria).

Therefore, effective for reclassification applications due to the MGCRB on September 1, 2021, for reclassification first effective for FY 2023, a § 412.103 hospital could apply for a reclassification under the MGCRB using the state’s rural area as the area in which the hospital is located. We would also apply the policy in this IFC when deciding timely appeals before the Administrator under § 412.278 for reclassifications beginning in FY 2022 that were denied by the MGCRB due to existing policy, which did not permit § 412.103 hospitals to be considered located in the state’s rural area.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended, in response to public comments and take effect, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79-404), 5 U.S.C. 553 and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of proposed rulemaking in the Federal Register that includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public
comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the Federal Register and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under Title XVIII of the Act. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(d) of the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the Federal Register. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. Finally, the Congressional Review Act (CRA) (Pub. L. 104-121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines 5 U.S.C. 801(a)(3) and 808(2).

We find good cause for waiving notice-and-comment rulemaking and a delay in effective date given the decision of the district court and the public interest in expeditious implementation of the court’s interpretation of the statute. Revising the regulation text by adding § 412.230(a)(1)(iii) and revising the regulation at § 412.230(a)(5)(i) through an IFC rather than through the normal notice-and-comment rulemaking cycle and waiving the delay of effective date will ensure an expeditious implementation of the court’s interpretation by allowing this
policy to be applied to FY 2023 MGCRB reclassification decisions and cases before the Administrator for reclassifications effective beginning FY 2022. Absent this IFC, the earliest effective date of this revision to the regulations would be October 1, 2021 (FY 2022) following the normal IPPS/LTCH PPS notice-and-comment rulemaking cycle. An effective date of FY 2022 would only allow the MGCRB to approve hospitals’ applications qualifying under this policy for applications due September 1, 2022 for reclassifications effective beginning FY 2024 (applications are due to the MGCRB 13 months prior to the start of the fiscal year).

Additionally, implementing the court’s interpretation via an IFC allows this policy to be applied to cases before the Administrator for reclassifications effective beginning in FY 2022, which supports an expeditious implementation of this policy. Therefore, we find good cause to waive the notice of proposed rulemaking as well as the delay of effective date and to issue this final rule on an interim basis. Even though we are waiving notice of proposed rulemaking requirements and are issuing these provisions on an interim basis, we are providing a 60-day public comment period.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).
Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this IFC would not have a significant economic impact on a substantial number of small entities. Also, our revision to the regulatory text is a consequence of a court decision. We are amending the regulations to align our policy with the court’s decision in Bates and implement the Bates court’s interpretation of the requirement at section 1886(d)(8)(E)(i) of the Act that “the Secretary shall treat the hospital as being located in the rural area.”

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital for Medicare payment regulations as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this IFC would not have a significant impact on the operations of a substantial number of small rural hospitals.
Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We estimate that this rule is “significant” but not “economically significant,” as measured by the $100 million threshold. However, we have prepared an impact analysis that presents our best estimate of the costs and benefits of this rule for FY 2022 since section 3(f) of Executive
Order 12866 defines a “significant regulatory action” as a rule that raises novel legal or policy issues arising out of legal mandates.

With regard to our impact analysis, as a result of this IFC, for FY 2022, there are approximately 22 hospitals that may qualify for a reclassification to a new or different urban area with a higher wage index than they might otherwise have received based on the information currently available to us (for example, applications submitted to the MGCRB.) For FY 2022, if these hospitals qualify for and accept reclassification to a new or different urban area with a higher wage index than they might otherwise have received, we estimate a total increase in payments to these hospitals of approximately $50 million in aggregate. However, wage index adjustments such as these are made in a manner that ensures that aggregate payments to hospitals are unaffected. This is accomplished through the application of a wage index budget neutrality adjustment as described more fully in the FY 2022 IPPS/LTCH proposed rule. Therefore, as a consequence of the court’s decision in Bates, even though an urban hospital may be able to qualify for a reclassification to a new or different urban area with a higher wage index, this would not increase aggregate hospital payments. We estimate that in FY 2022 the wage index budget neutrality adjustment could increase by one-half of a percentage point as a result of an increase in the wage index to these 22 hospitals.

We do not know as a result of this IFC: (1) how many additional hospitals will elect to apply to the MGCRB by September 1, 2021 for reclassification beginning FY 2023 that would not otherwise have applied; (2) how many hospitals that apply will qualify for a wage index higher than they otherwise would have received; (3) for those that qualify for a higher wage index how much higher that wage index will be; and, (4) how many hospitals may elect to retain or acquire § 412.103 urban-to rural reclassification that would not otherwise have done so. The MGCRB makes determinations on reclassification requests, and hospitals make final decisions whether to accept reclassifications approved by the MGCRB.
We also note that OMB requested public comment on the recommendations it received from the Metropolitan and Micropolitan Statistical Area Standards Review Committee for changes to OMB's metropolitan and micropolitan statistical area standards (86 FR 5263). These standards determine the procedures for delineating and updating the statistical areas as new data become available. If changes to the standards are adopted by OMB and if those changes would affect the OMB delineations used for the IPPS wage index, we would address any such changes and impacts in future rulemaking.

In accordance with the provisions of Executive Order 12866, this IFC was reviewed by the Office of Management and Budget.

VI. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 16, 2021.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, part 412, as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.
2. Section 412.230 is amended by adding paragraph (a)(1)(iii) and revising paragraph (a)(5)(i) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

(a) * * *
(1) * * *

(iii) An urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of this section.

* * * * *

(5) * * *

(i) An individual hospital may not be redesignated to another area for purposes of the wage index if the pre-reclassified average hourly wage for that area is lower than the pre-reclassified average hourly wage for the area in which the hospital is located. An urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of this paragraph (a)(5)(i).

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Dated: April 23, 2021

Xavier Becerra,
Secretary,
Department of Health and Human Services.

[FR Doc. 2021-08889 Filed: 4/27/2021 4:45 pm; Publication Date: 5/10/2021]