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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

#### **42 CFR Part 412**

**[CMS-1664-IFC]**

**RIN 0938-AS88**

### **Medicare Program; Temporary Exception for Certain Severe Wound Discharges from Certain Long-Term Care Hospitals Required by the Consolidated Appropriations Act, 2016; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Interim final rule with comment period.

**SUMMARY:** This interim final rule with comment period (IFC) implements section 231 of the Consolidated Appropriations Act of 2016 (CAA), which provides for a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) for certain long-term care hospitals. This IFC also amends our current regulations to allow hospitals nationwide to reclassify based on their acquired rural status, effective with reclassifications beginning with fiscal year (FY) 2018. Hospitals with an existing Medicare Geographic Classification Review Board (MGCRB) reclassification would also have the opportunity to seek rural reclassification for IPPS payment and other purposes and keep their existing MGCRB reclassification. We would also apply the policy in this IFC when deciding timely appeals before the Administrator under our regulations for FY 2017 that were denied by the MGCRB due to existing regulations, which do not permit simultaneous rural reclassification for IPPS payment and other purposes and MGCRB reclassification. These regulatory changes implement the decisions in *Geisinger*

*Community Medical Center v. Secretary, United States Department of Health and Human Services*, 794 F.3d 383 (3d Cir. 2015) and *Lawrence + Memorial Hospital v. Burwell*, No. 15-164, 2016 WL 423702 (2d Cir. Feb. 4, 2015) in a nationally consistent manner.

**DATES:** Effective date: These regulations are effective on [insert the date of publication in the **Federal Register**].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 17, 2016.

**ADDRESSES:** In commenting, please refer to file code CMS-1664-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

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--1664-IFC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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 to the following address ONLY:

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS--1664-IFC,  
Mail Stop C4-26-05,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

**FOR FURTHER INFORMATION CONTACT:**

Emily Lipkin, (410) 786-3633 for the Temporary Exception to Site-Neutral Payments for Certain Long-Term Care Hospital Discharges.

Tehila Lipschutz, (410) 786-1344 or Dan Schroder, (410) 786-7452 for the Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board.

**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>. 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. Long-Term Care Hospital Prospective Payment System

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) provides for payment for both the operating and capital related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a "per discharge" system with a diagnosis related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register** (67 FR 55954), we issued the Medicare Program; Prospective Payment System for Long-Term Care Hospitals: Implementation and FY 2003 Rates final rule that implemented the LTCH PPS authorized under the BBRA and BIPA. For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis related groups (LTC-DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis related groups (MS-LTC-DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS-LTC-DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97-248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98-21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost-reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this interim final rule with comment, when we refer to discharges, we describe Medicare discharges.)

The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the federal rate.

In addition, in the August 30, 2002 final rule, we presented an in depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, Subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51733 through 51743) for a chronological summary of the main legislative and regulatory developments affecting the LTCH PPS through the annual update cycles prior to the FY 2014 rulemaking cycle. In addition, the FY 2016 IPPS/LTCH PPS final rule, we implemented the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67), which mandated the application of

the "site neutral" payment rate for discharges in cost reporting periods beginning in FY 2016. Section 1886(m)(6)(A) of the Act provides that, for cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria are paid the site neutral payment rate. Discharges which do meet the statutory criteria continue to receive reimbursement at the LTCH PPS standard federal payment rate. The application of the site neutral payment rate, which resulted in a dual rate payment structure under the LTCH PPS, is implemented in the regulations at § 412.522. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, refer to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).

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

Under section 1886(d) of 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 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. 13-01. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the new OMB labor market area delineations beginning with the FY 2015 wage index.

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.

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 found in § 412.103. We also refer readers to the final rule published in the August 1, 2000 **Federal Register** entitled, "Medicare Program; Provisions of the Balanced Budget Refinement Act of 1999; Hospital Inpatient Payments and Rates and Costs of Graduate Medical Education" (65 FR 47029 through 47031) for a discussion of the general criteria for reclassifying from urban to rural under this statute. In addition, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51596), we discussed the effects on the wage index of an urban hospital reclassifying to a rural area of its state, if the urban hospital meets the requirements under § 412.103. Hospitals that are located in states without any geographically rural areas are ineligible to apply for rural reclassification in accordance with the provisions of § 412.103.

In addition, under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. 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). 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. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies applicable to reclassifications under the MGCRB process are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

## **II. Provisions of the Interim Final Rule with Comment Period**

### **A. Long Term Care Hospital Prospective Payment System**

#### **1. Section 231 of the Consolidated Appropriations Act, 2016**

Section 231 of the Consolidated Appropriations Act, 2016 (CAA) (Pub. L. 114-113) amends section 1886(m)(6) of the Act by revising subparagraph (A)(i) and adding new subparagraph (E), which establishes a temporary exception for certain wound care discharges from the site neutral payment rate for certain LTCHs. Specifically, under this statutory provision, the exception applies for discharges occurring prior to January 1, 2017 from LTCHs "identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997" and "located in a rural area (as defined in subsection (d)(2)(D)) or treated as being so located pursuant to subsection (d)(8)(E)" when the individual discharged "has a severe wound". In this interim final rule with comment period (IFC), we are amending § 412.522 to implement this provision. Because the statute contained no effective date and required rulemaking to

implement, we determined that an IFC was the appropriate mechanism to use to provide the longest period of relief under the statute.

In implementing the provisions of section 231 of the CAA, we found that, in light of the unique nature of LTCHs as a category of Medicare provider, some of the terminology in the provision is internally inconsistent. Therefore, we were required to interpret the provisions in the way we believe reasonably reconciles seemingly inconsistent provisions and that results in an application of the provisions that is logical and workable. We discuss our interpretations in this section of this IFC.

Section 1886(m)(6)(E)(i)(I)(aa) of the Act, as added by the CAA, specifies that the temporary exclusion for certain discharges from the site neutral payment rate is applicable to an LTCH that is "identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997." The phrase "identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997" has been interpreted by CMS in previous rulemaking. Section 114 of the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) (Pub. L. 110–173) used the phrase to delay the implementation of the 25 percent policy at §§ 412.534 and 412.536 for LTCHs "identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997" which we interpreted in the May 22, 2008 interim final rule with comment period (IFC). In that IFC (73 FR 29703) (finalized in our FY 2010 IPPS/RV 2010 LTCH PPS final rule (74 FR 43980)) we interpreted the phrase to mean hospitals which were described in § 412.23(e)(2)(i) that meet the criteria of § 412.22(f). (We note that we received no comments in response to this interpretation). Section 412.22(f) requires that, in order to maintain grandfathered status, a hospital-within-hospital (HwH) must continue to operate under the same terms and conditions including but not limited to number of beds. In revising § 412.22(f) in the FY 2004 IPPS final rule (68 FR 45463), we created a "hold harmless" provision which allowed a

grandfathered HwH to increase beds or change terms and maintain grandfathered status so long as beds were not increased on or after October 1, 2003 (meaning that if a hospital increased beds between October 1, 1995 and September 30, 2003 it would maintain its grandfathered status). As we have already interpreted this exact phrase in previous rulemaking, for purposes of implementing section 231 of the CAA we are interpreting the phrase consistent with our implementation of MMSEA, meaning that "identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997" requires that the LTCH participated in Medicare as an LTCH and was co-located with another hospital as of September 30, 1995, and must currently meet the requirements of § 412.22(f).

Section 4417(a) of the BBA of 1997 permanently exempted certain LTCHs from our regulations governing separateness and control requirements for HwHs (which we established in the FY 1995 IPPS final rule (59 FR 45389)). We implemented section 4417(a) of the BBA in the FY 1998 IPPS final rule (62 FR 46012). As finalized, our regulations implementing section 4417(a) of the BBA exempted hospitals excluded from the hospital inpatient prospective payment system on or before September 30, 1995 from our separateness and control HwH requirements. An HwH is defined in our regulations at § 412.22(e) as a hospital which occupies space in a building also used by another hospital or on the campus of another hospital. The provisions governing HwH exemption from the separateness and control requirements remained unchanged until the FY 2003 rulemaking cycle in which we proposed and finalized revisions to § 412.22(f) to specify that, effective with cost reporting periods beginning on or after October 1, 2003, a hospital operating as an HwH on or before September 30, 1995, would only be exempt from the criteria in §§ 412.22(e)(1) through (5) if the hospital-within-a-hospital continued to operate under the same terms and conditions that were in effect as of September 30, 1995 (68 FR 45463). The intent of this modification to the grandfathering

provision was to limit the separateness and control exemption to those HwHs that continued to operate as they had when the Congress provided for an exemption from the requirements. Those HwHs that met this requirement would continue to be shielded as the Congress had intended. But, in recognition of the need not to allow these facilities undue advantage over facilities not benefiting from the exemption, and in recognition that some grandfathered HwHs no longer resembled the entities they had been in 1995 (for example, by changing the nature of their operations such as by adding more beds), we proposed to limit grandfathering to those HwHs that continued to operate under the same terms and conditions that were in effect as of September 30, 1995, the date identified in the BBA.

Several commenters disagreed with our proposal to limit grandfathering to HwH that continue to operate under the same terms and conditions that were in place on September 30, 1995. These commenters believed that the adoption of this proposal could result in a decertification of a number of LTCHs, thus depriving Medicare beneficiaries of specialized services and unique programs. They asserted that CMS was requiring grandfathered HwHs that had changed the terms and conditions under which they operated to either reverse their previously approved changes or lose their certification, which would retroactively reverse prior governmental approvals of LTCH changes. The commenters further asserted that there was no good reason to treat these hospitals any differently from other providers participating in the Medicare program, a practice that the commenters believed would result in inequitable treatment of patients as well as employees. Furthermore, the commenters expressed concern that the proposed effective date timeframe for implementation (which was 60 days from the publication of the final rule) was too short because it would not allow adequate time for providers to undo previous changes to the terms and conditions under which they operated.

In response to these comments, in the FY 2003 LTCH PPS final rule, we reiterated that, in establishing grandfathering regulations, the intent had been to protect existing hospitals from the potentially adverse impact of subsequent, specific regulations that they could not have foreseen, and, using their existing operational structures, could not have abided by. If those entities later proved able to change their operational structures, we saw no policy basis for not applying the separateness and control provisions that had since proven essential to the goals of the Medicare program – after all, the entity benefiting from the grandfathering would no longer resemble the entity the Congress had grandfathered in statute. That said, we understood commenters' concerns about after-the-fact changes, and so we finalized a policy that grandfathered any facility that continued to operate as it had as of September 30, 1995 (our original proposal), or that operated under the terms and conditions that had been put into effect no later than October 1, 2003, and codified these provisions in a revised § 412.22(f). An LTCH that met these revised grandfathering requirements would still need to comply with the general HwH requirements set forth in § 412.22(e) (see 68 FR 45463).

Later, in recognition of requests for modification relating to the need to update a hospital's medical equipment, in the FY 2007 IPPS proposed rule, we proposed further revisions to the requirements of § 412.22(f) to allow grandfathered hospitals to increase square footage or decrease the number of beds for cost reporting periods beginning on or after October 1, 2006 without a loss of grandfathered status. These proposals generated comments requesting further amendments to allow a grandfathered hospital to increase beds without loss of grandfathered status. As we explained in response to those comments in the FY 2007 IPPS final rule (71 FR 48106), grandfathered hospitals are generally organized and operated in ways that do not meet the separateness and control requirements applicable to non-grandfathered facilities, so that they effectively function as units of their host facilities, an arrangement prohibited by the Act.

Therefore, although we finalized regulations that allowed grandfathered HwHs (and satellite facilities) the ability to increase their square footage and retain grandfathered status to allow the hospitals to be able to provide care using the most appropriate medical equipment and techniques (which may require more space than was required in 1995 and 2003), we did not allow grandfathered hospitals an increase in the number of beds (71 FR 48111).

As discussed previously, there are several reasons for which an LTCH described in § 412.23(e)(2)(i) may not meet the criteria in § 412.22(f). For example, the LTCH may have more than one location, meaning that each co-located location would be a satellite, not an HwH, or the hospital may have increased beds after September 30, 2003 (we note that the preceding provides only examples and is not an exhaustive list of the reasons an LTCH may not meet the criteria in § 412.22(f)). Also as previously explained, the requirement that grandfathered HwHs meet the criteria in § 412.22(f) was established through previous notice-and-comment rulemaking. Therefore, in order to identify which LTCHs are grandfathered HwHs, Medicare Administrative Contractors (MACs) will be verifying which LTCHs described in § 412.23(e)(2)(i) meet the criteria in § 412.22(f). Section 1886(m)(6)(E)(i)(I)(bb) of the Act, as added by the CAA, further limits the temporary statutory exclusion for certain discharges from the site neutral payment rate to LTCHs that are "located in a rural area (as defined in subsection (d)(2)(D)) or treated as being so located pursuant to subsection (d)(8)(E)". In general, section 1886(d)(2)(D) of the Act defines the term "rural area" as any area outside an urban area, which is an area within a Metropolitan Statistical Area (MSA) (as defined by the OMB). This definition of rural area is consistent with the existing definition of rural area under the LTCH PPS set forth at § 412.503. Therefore, in this IFC, we are establishing that "located in a rural area" in section 1886(m)(6)(E)(i)(I)(bb) refers to LTCHs which are currently located in a rural area as defined under § 412.503. (For information on the current labor market area geographic classifications

used under the LTCH PPS, refer to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

The phrase "treated as being so located pursuant to subsection (d)(8)(E)" is internally inconsistent given the unique nature of LTCHs as a category of Medicare provider. There is currently no mechanism which an LTCH may use to be treated as rural pursuant to section 1886(d)(8)(E) of the Act because that section only applies to subsection (d) hospitals, and LTCHs, by definition at section 1886(b)(1) of the Act are not subsection (d) hospitals.

For urban subsection (d) hospitals, we implemented the rural reclassification provision in the regulations at § 412.103. In general, the provisions of § 412.103 provides that a hospital that is located in an urban area may be reclassified as a rural hospital if it submits an application in accordance with our established criteria and meets certain conditions, which include the hospital being located in a rural census tract of a MSA as determined under the most recent version of the Goldsmith Modification, the Rural-Urban Commuting Area (RUCA) codes, as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration (HRSA), or that 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. Paragraph (b) of § 412.103 sets forth application requirements for a hospital seeking reclassification as rural under that section, which includes a written application mailed to the Center for Medicare and Medicaid Services (CMS) regional office (RO) that contains an explanation of how the hospital meets the condition that constitutes the request for reclassification, including data and documentation necessary to support the request. As provided in paragraphs (c) and (d) of § 412.103, the RO reviews the application and notifies the hospital of its approval or disapproval of the request within 60 days of the filing date (that is, the date the CMS RO receives the application), and a hospital (that satisfies any of the criteria set forth

§ 412.103(a) is considered as being located in the rural area of the state in which the hospital is located as of that filing date (meaning that the hospital would be treated as rural for the purposes of exclusion from the site neutral payment rate for severe wound discharges as of the filing date). For additional information on our policies for hospitals located in urban areas and that apply for reclassification as rural under § 412.103, refer to the FY 2001 IPPS/LTCH PPS final rule (65 FR 47029).

For the purposes of implementing subparagraph (E) of section 1886(m)(6) of the Act as provided by the CAA, we are revising our regulations to –

- "Borrow" the existing rural reclassification process for urban subsection (d) hospitals under § 412.103; and
- Allow grandfathered LTCH HwHs (previously defined in this IFC) to apply to their RO for treatment as being located in a rural area for the sole purpose of qualifying for this temporary exclusion from the application of the site neutral payment rate.

We note that this policy would only allow grandfathered LTCH HwHs to apply for this reclassification. The rural treatment would only extend to this temporary exception for certain wound care discharges from the site neutral payment rate (meaning a grandfathered HwH LTCH will not be treated as rural for any other reason including, but not limited to, the 25 percent policy and wage index). We also note that the any rural treatment under § 412.103 for a grandfathered HwH LTCH will expire at the same time as this temporary provision (that is, December 31, 2016).

Section 1886(m)(6)(E)(i)(II) of the Act, as added by the CAA, provides that the temporary exclusion for certain discharges from the site neutral payment rate for certain LTCHs is applicable when "the individual discharged has a severe wound." The use of the present tense in "has" a severe wound is also internally inconsistent. A strictly literal read of the statute would

require exception from the site neutral payment rate only for an individual who, presently, "has severe a wound" at the time of their discharge from the LTCH, and thus payments for patients whose wounds were either healed or no longer severe at the time of their discharge would be made under our existing regulations (that is, they would receive payment at the site neutral payment rate unless they met the existing exclusion criteria). We do not believe that the Congress meant to exclude only discharges where the patient, at the time of discharge, still "has" a severe wound from the site neutral payment rate while making site neutral payment rate payments for discharges of patients whose wounds healed during the course of their treatment in the LTCH (that is, a patient who "had" a severe wound as opposed to "has" one). Therefore, in order to resolve this inconsistency, and in accordance with our interpretation of other provisions of the statute, we are implementing this provision of the statute so that discharges for patients who received treatment for a "severe wound" at the LTCH (as discussed later in this section will meet the criteria for exclusion from the site neutral payment rate under section 1886(m)(6)(E)(i)(II) of the Act regardless of whether the wound was still present and severe at the time of discharge.

Section 1886(m)(6)(E)(ii) of the Act, as added by the CAA, defines a "severe wound" as "a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis or wound with morbid obesity as identified in the claim from the long-term care hospital." To implement this statutory definition, in consultation with our medical officers we are defining a wound as: "an injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment". In this IFC, we are also establishing that "as identified in the claim" means "identified based on the ICD-10 diagnosis codes on the claim where--

- The ICD-10 diagnosis codes contain sufficient specificity for this purpose; or

- Through the use of a payer-specific condition code where the ICD-10 diagnosis codes lack sufficient specificity for this purpose".

For six of the eight statutory categories included in the definition of "severe wound" (stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, fistula, and osteomyelitis), we believe severe wounds can be identified through the use of specific ICD-10 codes which are reported in the LTCH claim. The list of ICD-10 diagnosis codes that we will use to identify severe wounds for this group of the six statutory categories can be found in the table "Severe Wound Diagnosis Codes by Category for Implementation of Section 231 of Public Law 114-113" posted on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html> under the regulation "CMS-1664-IFC". Our medical officers compiled this list of codes by reviewing ICD-10 diagnosis codes for the statutorily enumerated categories of severe wounds and selected those codes for diagnoses which met our definition of "wound" (previously stated in this IFC). We note that under our definition of wound, the ICD-10 diagnosis codes used to identify severe wounds in the osteomyelitis category are also part of the ICD-10 diagnosis codes used to identify severe wounds in the fistula category so no separate identification of ICD-10 codes for osteomyelitis is necessary.

The remaining two statutory categories included in the definition of "severe wound" (infected wound and wound with morbid obesity) lack ICD-10 diagnosis codes with sufficient specificity to identify the presence of a "severe wound". This is because the number of codes which are used to identify wounds and infections are too numerous to identify in an exhaustive list. Furthermore, the presence of codes for infection (or morbid obesity) and wound on the claim do not in and of themselves demonstrate that the discharge was for a "severe wound." In other words, the ICD-10 diagnosis codes for infection (or morbid obesity) and wound do provide any information on the severity of such diagnosis, that is, ICD-10 diagnosis codes do not

differentiate between such diagnoses that are "severe" or "non-severe" wounds. Because we cannot specify ICD-10 diagnosis codes to identify wounds in these categories, for the purposes of this provision we are defining a "wound with morbid obesity" as "a wound in those with morbid obesity that require complex, continuing care including local wound care occurring multiple times a day" and we are defining an "infected wound" as "a wound with infection requiring complex, continuing care including local wound care occurring multiple times a day."

In order to operationalize these definitions in the absence of ICD-10 diagnosis codes, we will utilize "payer-only" condition codes. These payer-only condition codes are a type of condition code (which are currently reported on claims) issued by the National Uniform Billing Committee (NUBC), which is the governing body for forms and codes used in medical claims billing for hospitals and other institutional providers. In this IFC, we are establishing that if an LTCH has a discharge meeting our definition of "wound with morbid obesity" or "infected wound" the LTCH would inform its MAC, and the MAC will then place the designated payer-only condition code on the claim for processing. The presence of the designated payer-only condition code on the claim for qualifying grandfathered HwH LTCHs will generate a standard federal payment rate payment for the claim (that is, exclusion from the site neutral payment rate) consistent with this statutory provision. We intend to issue additional operational instructions regarding the use of the designated payer-only condition code. We note that while the use of this payer-only condition code is the most expedient operational method we have of implementing the statutory definition in the time frame allowed, the continued use of a payer-only condition code may not be feasible if the scope of this provision is expanded. Given the current limitations on the number of LTCHs which can qualify for this provision under the statutory criteria (that is, grandfathered HwHs that are located in a rural area or reclassify as rural, as previously described in this IFC), the ability to identify the other statutory categories of

severe wounds, and the limited timeframe of the exception, we expect the number of claims necessitating the use of this payer-only condition code will be minimal.

B. Wage Index for Acute Care Hospitals Paid Under the Inpatient Prospective Payment System (IPPS): Criteria for an Individual Hospital Seeking Redesignation to Another Area (§ 412.103)

Our current policy limits certain redesignations in order to preclude hospitals from obtaining urban to rural reclassification under § 412.103, and then using that obtained rural status to receive an additional reclassification through the MGCRB. We refer readers to § 412.230(a)(5)(iii), which states that an urban hospital that has been granted redesignation as rural under § 412.103 cannot receive an additional reclassification by the MGCRB based on this acquired rural status for a year in which such redesignation is in effect. In other words, § 412.230(a)(5)(iii) prohibits a hospital from simultaneously receiving an urban to rural reclassification under § 412.103 and a reclassification under the MGCRB.

On July 23, 2015 the Court of Appeals for the Third Circuit issued a decision in *Geisinger Community Medical Center v. Secretary, United States Department of Health and Human Services*, 794 F.3d 383 (3d Cir. 2015). Geisinger Community Medical Center ("Geisinger"), a hospital located in a geographically urban Core-Based Statistical Area (CBSA), obtained rural status under § 412.103, but was unable to receive additional reclassification through the MGCRB while still maintaining its rural status under § 412.230(a)(5)(iii). To receive reclassification through the MGCRB under existing regulations, Geisinger would have had to first cancel its § 412.103 urban-to-rural reclassification and use the proximity requirements for an urban hospital rather than take advantage of the broader proximity requirements for reclassification granted to rural hospitals. (We refer readers to § 412.230(b)(1), which states that a hospital demonstrates a close proximity with the area to which it seeks redesignation if the distance from the hospital to the area is no more than 15 miles for an urban

hospital and no more than 35 miles for a rural hospital.) Geisinger challenged as unlawful the regulation at § 412.230(a)(5)(iii) requiring cancelation of its rural reclassification prior to applying for reclassification through the MGCRB. In *Geisinger Community Medical Center v. Burwell*, 73 F. Supp.3d 507 (M.D. Pa. 2014), the United States District Court for the Middle District of Pennsylvania upheld the regulation at § 412.230(a)(5)(iii) and granted summary judgment in favor of CMS. The Court of Appeals for the Third Circuit reversed the decision of the District Court, holding that the language of section 1886(d)(8)(E)(i) of the Act is unambiguous in its plain intent that "the Secretary shall treat the hospital as being located in the rural area," inclusive of MGCRB reclassification purposes, thus invalidating the regulation at § 412.230(a)(5)(iii). On February 4, 2016, the Court of Appeals for the Second Circuit issued its decision in *Lawrence + Memorial Hospital v. Burwell*, No. 15-164, 2016 WL 423702 (2d Cir. February 4, 2016), essentially following the reasoning of the Third Circuit *Geisinger* decision.

While these decisions currently apply only to hospitals located within the jurisdictions of the Second and Third Circuits, we believe that maintaining the regulations at § 412.230(a)(5)(iii) in other places nationally would constitute inconsistent application of reclassification policy based on jurisdictional regions. In the interest of creating a uniform national reclassification policy, we are removing the regulation text at § 412.230(a)(5)(iii). We are also revising the regulation text at § 412.230(a)(5)(ii) to allow more than one reclassification for those hospitals redesignated as rural under § 412.103 and – simultaneously seeking reclassification through the MGCRB. Specifically, we are revising § 412.230(a)(5)(ii) to state that a hospital may not be redesignated to more than one area, except for an urban hospital that has been granted redesignation as rural under § 412.103 and receives an additional reclassification by the MGCRB. Therefore, effective for reclassification applications due to the MGCRB on September 1, 2016, for reclassification first effective for FY 2018, a hospital could apply for a

reclassification under the MGCRB while still being reclassified from urban to rural under § 412.103. Such hospitals would be eligible to use distance and average hourly wage criteria designated for rural hospitals at § 412.230(b)(1) and (d)(1). In addition, effective with the display date of this IFC, a hospital that has an active MGCRB reclassification and is then approved for reclassification under § 412.103 would not lose its MGCRB reclassification; that is, a hospital with an active MGCRB reclassification can simultaneously maintain rural status under § 412.103, and receive a reclassified urban wage index during the years of its active MGCRB reclassification and would still be considered rural under section 1886(d) of the Act and for other purposes. We would also apply the policy in this IFC when deciding timely appeals before the Administrator under § 412.278 for FY 2017 that were denied by the MGCRB due to existing § 412.230(a)(5)(ii) and (iii), which do not permit simultaneous §412.103 and MGCRB reclassifications.

Apart from the direct impact on reclassifying hospitals previously discussed in this section, we also considered how to treat the wage data of hospitals that maintain simultaneous reclassifications under both the § 412.103 and MGCRB processes. Under current wage index calculation procedures, the wage data for a hospital geographically located in an urban area with a § 412.103 reclassification is included in the wage index for its home geographic area. It is also included in its state rural wage index, if including wage data for hospitals with rural reclassification raises the state's rural floor. In addition, the wage data for a hospital located in an urban area, and that is approved by the MGCRB to reclassify to another urban area (or another state's rural area), would be included in its home area wage index calculation, and in the calculation for the reclassified "attaching" area. We refer readers to the FY 2012 IPPS final rule (76 FR 59595 through 59596) for a full discussion of the effect of reclassification on wage index calculations. Furthermore, as discussed in the FY 2007 IPPS final rule (71 FR 48020 through

48022), hospitals currently cannot simultaneously maintain more than one wage index status (for example, a hospital cannot simultaneously maintain a § 412.103 rural reclassification and an MGCRB reclassification, nor can a hospital receive an outmigration adjustment while also maintaining MGCRB or Lugar status). However, as a consequence of the court decisions previously discussed, we are revising our current regulations and creating a rule that would apply to all hospitals nationally, regarding the treatment of the wage data of hospitals that have both a § 412.103 reclassification and an MGCRB reclassification. Under this IFC, if a hospital with a § 412.103 reclassification is approved for an additional reclassification through the MGCRB process, and the hospital accepts its MGCRB reclassification, the CBSA to which the hospital is reclassified under the MGCRB prescribes the area wage index that the hospital would receive; the hospital would not receive the wage index associated with the rural area to which the hospital is reclassified under § 412.103. That is, for wage index calculation and payment purposes, when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification would control for wage index calculation and payment purposes. Therefore, although we are amending our policy with this IFC so that a hospital can simultaneously have a reclassification under the MGCRB and an urban to rural reclassification under § 412.103, we are separately clarifying that we will exclude hospitals with § 412.103 reclassifications from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. In these circumstances, we believe it is appropriate to rely on the urban MGCRB reclassification to include the hospital's wage data in the calculation of the urban CBSA wage index. Further, we believe it is appropriate to rely on the urban MGCRB reclassification to ensure that the hospital be paid based on its urban MGCRB wage index. While rural reclassification confers other rural benefits besides the wage index under section 1886(d) of the Act, a hospital that chooses to pursue reclassification under the MGCRB (while

also maintaining a rural reclassification under § 412.103) would do so solely for wage index payment purposes.

As previously stated, for wage index calculation and payment purposes, when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification would control for wage index calculation and payment purposes. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we would consider, as is current practice, the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. The hospital's geographic CBSA and reclassified CBSA would be reflected accordingly in Tables 2 and 3 of the annual IPPS/LTCH PPS proposed and final rules. (We note that these tables are referenced in the IPPS/LTCH proposed and final rules and are available only through the Internet on the CMS Website.) However, in the absence of an active MGCRB reclassification, if the hospital has an active § 412.103 reclassification, CMS would treat the hospital as rural under § 412.103 reclassification for IPPS payment and other purposes, including purposes of calculating the wage indices reflected in Tables 2 and 3 of the annual IPPS/LTCH PPS proposed and final rules.

In summary, for reclassifications effective beginning FY 2018, a hospital could acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. Additionally, effective with the display date of this IFC, a hospital with an active MGCRB reclassification could also acquire rural status under § 412.103 for IPPS payment and other purposes. We would also apply the policy in this IFC when deciding timely appeals before the Administrator under § 412.278 for FY 2017 that were denied by the MGCRB due to existing § 412.230(a)(5)(ii) and (iii), which do not permit simultaneous §412.103 and MGCRB reclassifications. When there is

both an MGCRB reclassification and a § 412.103 reclassification, the MGCRB reclassification would control for wage index calculation and payment purposes. For a discussion regarding budget neutrality adjustments for FY 2017 and subsequent years for hospitals that have a reclassification under § 412.103 and an MGCRB reclassification, we refer readers to the FY 2017 IPPS/LTCH proposed rule. Also, we intend to issue instructions to explain the revisions of the regulation text at § 412.230(a)(5)(ii) and the removal of the regulation text at § 412.230(a)(5)(iii) to ensure that MACs properly update the Provider Specific File (PSF) in the instance where a hospital would have a simultaneous reclassification to an urban area under the MGCRB and to a rural area under § 412.103.

### **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. The notice of proposed rulemaking 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. In addition, in accordance with section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act, we ordinarily provide a delay in the effective date of a substantive rule. For substantive rules that constitute major rules, in accordance with 5 U.S.C. 801, we ordinarily provide a 60-day delay in the effective date. None of the processes or effective date requirements apply, however, when the rule in question is interpretive, a general statement of policy, or a rule of agency organization, procedure, or practice. They also do not apply when the statute establishes rules to be applied, leaving no discretion or gaps for an agency to fill in through rulemaking. Furthermore, an agency may waive notice-and-comment rulemaking, as well as any delay in effective date, when the agency finds good cause that a notice and public comment on the rule as well the effective date delay are

impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

For the LTCH wound care exception, we find notice-and-comment rulemaking and a delay in the effective date to be both unnecessary as well as impracticable and contrary to public interest. Section 231 of CAA requires the implementation of the LTCH wound care exception, limiting any discretion we might otherwise have, thereby making procedure unnecessary. In addition, given the statutory expiration of the provisions of section 231 of CAA on January 1, 2017 due to a congressionally imposed deadline, notice-and-comment and the resulting delay would significantly limit the set of discharges to which the statute would apply. By implementing the statute through an IFC rather than through the normal notice-and-comment rulemaking cycle and waiving the 60-day delay of effective date, we are ensuring the period of relief granted is consistent with our interpretation of the statute. We find, on these bases, that there is good cause to waive notice and comment and the delay in effective date that would otherwise be required by the provisions previously cited in this section.

In the case of the portion of this IFC regarding the wage index for acute care hospitals paid under the IPPS, we find good cause for waiving notice-and-comment rulemaking and a delay in effective date given the decisions of the courts of appeals and the public interest in consistent application of a Federal policy nationwide. Revising the regulation text at § 412.230(a)(5)(ii) and removing the regulation text at § 412.230(a)(5)(iii) through an IFC rather than through the normal notice-and-comment rulemaking cycle and waiving the 60-day delay of effective date will ensure a uniform national reclassification policy, since this policy has already been effective as of July 23, 2015 in the Third Circuit and February 4, 2016 in the Second Circuit. Absent such a policy, the wage index for acute care hospitals paid under the IPPS will remain confusingly inconsistent across jurisdictions. Therefore, we find good cause to waive the

notice of proposed rulemaking as well as the 60-day 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**

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

However, we are requesting an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting an emergency review and approval under 5 CFR 1320.13(a)(2)(i) of the implementing regulations of the PRA in order to implement Section 231 of the CAA as expeditiously as possible. Public harm is reasonably likely to ensue if the normal clearance procedures are followed since the approval of this information collection is essential to ensuring that otherwise qualifying grandfathered urban HWHs are not unduly delayed in attempting to obtain the temporary exception by applying to be treated as rural before the temporary exception expires on December 31, 2016.

For the purposes of implementing subparagraph (E) of section 1886(m)(6) of the Act as provided by the CAA, we are revising our regulations at § 412.522(b)(2)(ii)(B)(2) to utilize the same administrative mechanisms used in the existing rural reclassification process for urban subsection (d) hospitals under § 412.103, described later in this section. We also will allow grandfathered LTCH HwHs (previously defined in this IFC) to apply to their RO for treatment as being located in a rural area for the sole purpose of qualifying for this temporary exclusion from the application of the site neutral payment rate.

For urban subsection (d) hospitals, and now temporarily LTCHs, we implemented the rural reclassification provision in the regulations at § 412.103. In general, the provisions of § 412.103 provides that a hospital that is located in an urban area may be reclassified as a rural hospital if it submits an application in accordance with our established criteria. It must also meet certain conditions which include the hospital being located in a rural census tract of a MSA or that the hospital is located in an area designated by any law or regulation of the state as a rural area or the hospital is designated as a rural hospital by state law or regulation. Paragraph (b) of § 412.103 sets forth application requirements for a hospital seeking reclassification as rural under that section, which includes a written application mailed to the CMS regional office (RO) that contains an explanation of how the hospital meets the condition that constitutes the request for reclassification, including data and documentation necessary to support the request. As provided in paragraphs (c) and (d) of § 412.103, the RO reviews the application and notifies the hospital of its approval or disapproval of the request within 60 days of the filing date, and a hospital that satisfies any of the criteria set forth § 412.103(a) is considered as being located in the rural area of the state in which the hospital is located as of that filing date.

We note that this policy would only allow grandfathered LTCH HwHs to apply for this reclassification, and the rural treatment would only extend to this temporary exception for certain

wound care discharges from the site neutral payment rate (meaning a grandfathered HwH LTCH will not be treated as rural for any other reason including, but not limited to, the 25 percent policy and wage index). We also note that the any rural treatment under § 412.103 for a grandfathered HwH LTCH will expire at the same time as this temporary provision (that is, December 31, 2016).

We estimate that each application will require 2.5 hours of work from each LTCH (0.5 hours to fill out the application and 2 hours of recordkeeping). Based on the current information we have received from the MACs, out of the approximately 120 current LTCHs that existed in 1995, which is a necessary but not sufficient condition to be a grandfathered HWH, there are approximately 5 hospitals that currently meet the criteria of being a grandfathered HWH and would not be precluded from submitting an application. We note that as the MACs continue to update the list of grandfathered HWH that the number of potential applicants could increase. Since it is possible that the number of applicants could rise to 10 or more, in an abundance of caution, we treating this information collection as being subject to the PRA. Therefore, we estimate that the aggregate number of hours associated with this request across all currently estimated eligible hospitals will be 12.5 (2.5 hours per hospital for 5 hospitals). We estimate a current, average salary of \$29 per hour (based on the "2015 Median usual weekly earnings (second quartile), Employed full time, Wage and salary workers, Management, professional, and related occupations" from the Current Population Survey, available here <http://www.bls.gov/webapps/legacy/cpswktab4.htm>) plus 100 percent for fringe benefits (\$58 per hour). Therefore, we estimate the total one-time costs associated with this request will be \$725 (12.5 hours x \$58 per hour).

Written comments and recommendations from the public will be considered for this emergency information collection request if received by **Insert date 7 days after date of**

**publication in the Federal Register**]. We are requesting OMB review and approval of this information collection request by **[Insert date 14 days after date of publication in the Federal Register]**, with a 180-day approval period.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at  
<http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in the ADDRESSES section of this interim final rule with comment period.

## **V. Regulatory Impact Analysis**

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 Social Security 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). Executive Order 13563 emphasizes the

importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We project that two rural LTCHs would qualify for the temporary exception to the site neutral payment rate for certain LTCHs for certain discharges provided by section 231 of the CAA, based on the best data available at this time. We are not able to determine which, if any, LTCHs may be treated as rural in the future by applying and being approved for a reclassification as rural under the provisions of § 412.103. Given that LTCHs are generally concentrated in more densely populated areas, we do not expect any LTCHs to qualify under § 412.103. As such, at this time, our projections related to the temporary exception to the site neutral payment rate for certain LTCHs for certain discharges provided by section 231 of the CAA, are limited to LTCHs that are geographically located in a rural area. As such, at this time, our projections related to the temporary exception to the site neutral payment rate for certain LTCHs for certain discharges provided by section 231 of the CAA, are limited to LTCHs that are geographically located in a rural area. Based on the most recent data for these two LTCHs, including the identification of FY 2014 LTCH discharges with a "severe wound" we estimate the monetary impact of this IFC with respect to that LTCH PPS provision is approximately a \$5 million increase in aggregate LTCH PPS payments had this statutory provision not been enacted. This does not reach the economic threshold and this provision does not cause this IFC to be considered a major rule.

For the IPPS wage index portion of this IFC, we did not conduct an in-depth impact analysis because our revision to the regulatory text is a consequence of court decisions. The *Geisinger* decision invalidated the regulation at § 412.230(a)(5)(iii) effective July 23, 2015 for hospitals in states within the Third Circuit's jurisdiction, and the *Lawrence + Memorial* decision invalidated the regulation at § 412.230(a)(5)(iii) effective February 4, 2016 for hospitals in states

within the Second Circuit's jurisdiction. That is, we did not have a choice to maintain the previously uniform regulations at § 412.230(a)(5)(iii) for hospitals in states within the Second and Third Circuits.

Furthermore, we do not believe we could necessarily estimate the national impact of removing the regulation at § 412.230(a)(5)(iii). We note that already in the FY 2017 IPPS/LTCH proposed rule, of the 3,586 IPPS hospitals listed on wage index Table 2, 867 hospitals have an MGCRB reclassification, and 57 hospitals have a reclassification to a rural area under § 412.103. (This table is discussed in the FY 2017 IPPS/LTCH proposed rule and is available on the CMS Website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>. Click on the link on the left side of the screen titled, “FY 2017 IPPS Proposed Rule Home Page.”) We cannot estimate how many additional hospitals will elect to apply to the MGCRB by September 1, 2016 for reclassification beginning FY 2018, and we cannot predict how many hospitals may elect to retain or acquire § 412.103 urban-to-rural reclassification over and above the hospitals that have already reclassified.

We also note that under §412.64(e)(1)(ii), (e)(2), and (e)(4), increases in the wage index due to reclassification are implemented in a budget neutral manner (that is, wage index adjustments are made in a manner that ensures that aggregate payments to hospitals are unaffected through the application of a wage index budget neutrality adjustment described more fully in the FY 2017 IPPS/LTCH proposed rule). Therefore, as a result of the Third Circuit’s decision in *Geisinger*, even though an urban hospital that may or may not already have a reclassification to another urban area under the MGCRB may be able to qualify for a reclassification to a more distant urban area with an even higher wage index, this would not increase aggregate IPPS payments (although the wage index budget neutrality factor applied to

IPPS hospitals could be larger as a result of additional reclassifications occurring to higher wage index areas.)

However, there are other Medicare payment provisions potentially impacted by rural status, such as payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA, under which payments are not made in a budget neutral manner. Additional hospitals acquiring rural status under § 412.103 could, therefore, potentially increase Federal expenditures. Nevertheless, taking all of these factors into account, we cannot accurately determine an impact analysis as a result of the Third Circuit's decision in *Geisinger* and the Second Circuit's decision in *Lawrence + Memorial*.

The RFA also requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.5 million to \$38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: [https://www.sba.gov/sites/default/files/files/Size\\_Standards\\_Table.pdf](https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf).)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and states are not included in the definition of a small entity. We believe that the provisions of this IFC may have an impact on some small entities, but for the reasons previously discussed in this IFC, we cannot conclusively determine the number of such

entities impacted. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the RFA. MACs are not considered to be small entities.

Because we acknowledge that many of the potentially affected entities are small entities, the discussion in this section regarding potentially impacted hospitals constitutes our regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a metropolitan statistical area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. For the IPPS portion of this IFC, no geographically rural hospitals are directly affected since only urban hospitals can reclassify to a rural area under § 412.103. However, we note that with regard to the wage index budget neutrality adjustments applied under §412.64(e)(1)(ii), (e)(2), and (e)(4), rural IPPS hospitals would be affected to the extent that the reclassification budget neutrality adjustment increases, but this impact is no different than on urban IPPS hospitals, as the same budget neutrality factor is applied to all IPPS hospitals.

The provisions of section 231 of the CAA, which we are implementing in this IFC, by definition affect rural LTCHs that qualify, and will result in an increase in payment for those qualifying LTCHs' discharges that meet the definition of a severe wound. However, as

previously discussed in this section, based on the data currently available, we estimate there are only two LTCHs that currently meet the criteria. Therefore, we do not believe the provision of section 231 of the CAA will have a significant impact on the operations of a substantial number of small rural LTCHs.

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 2016, that threshold is approximately \$146 million. This IFC will have no consequential effect on state, local, or tribal governments, nor will it affect private sector costs.

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

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.

**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 as follows:

**PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES**

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

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332), sec. 1206 of Pub. L. 113-67, and sec. 112 of Pub. L. 113-93.

2. Section 412.230 is amended by—

- a. Revising paragraph (a)(5)(ii).
- b. Removing paragraph (a)(5)(iii).
- c. Redesignating paragraph (a)(5)(iv) as paragraph (a)(5)(iii).

The revision reads as follows:

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

(a) \* \* \*

(5) \* \* \*

(ii) A hospital may not be redesignated to more than one area, except for an urban hospital that has been granted redesignation as rural under §412.103 and receives an additional reclassification by the MGCRB.

\* \* \* \* \*

3. Section 412.522 is amended by –

a. Redesignating paragraphs (b)(1) introductory text, (b)(1)(i) and (ii), and (b)(2) and (3) as paragraphs (b)(1)(i) introductory text, (b)(1)(i)(A) and (B), and (b)(1)(ii) and (iii), respectively.

b. Adding a paragraph heading for paragraph (b)(1).

c. Revising the paragraph heading for newly redesignated paragraph (b)(1)(i) introductory text.

d. In newly redesignated paragraph (b)(1)(i)(B), by removing the reference "paragraph (b)(2)" and adding the reference "paragraph (b)(1)(ii)" in its place and by removing the reference "paragraph (b)(3)" and adding the reference "paragraph (b)(1)(iii)" in its place.

d. In newly redesignated paragraph (b)(1)(ii), by removing the reference "paragraph (b)(1)" and adding the reference "paragraph (b)(1)(i)" in its place.

e. In newly redesignated paragraph (b)(1)(iii), by removing the reference "paragraph (b)(1)" and adding the reference "paragraph (b)(1)(i)" in its place.

f. Adding paragraph (b)(2).

The revision and additions read as follows:

**§ 412.522 Application of site neutral payment rate.**

(b) \* \* \*

(1) General criteria--(i) Basis and scope. \* \* \*

\* \* \* \* \*

(2) Special criteria--(i) Definitions. For purposes of this paragraph (b)(2) the following definitions are applicable:

Severe wound means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis or wound with

morbid obesity as identified by the applicable code on the claim from the long-term care hospital.

Wound means an injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.

(ii) Discharges for severe wounds. A discharge that occurs on or after [insert date of publication in the **Federal Register**] and before January 1, 2017 for a patient that was treated for a severe wound that meets the all of following criteria is excluded from the site neutral payment rate specified under this section:

(A) The severe wound meets the definition specified in paragraph (b)(2)(i) of this section.

(B) The discharge is from a long term care hospital that is--

(1) Described in § 412.23(e)(2)(i) and meets the criteria of § 412.22(f); and

(2) Located in a rural area (as defined at § 412.503) or reclassified as rural by meeting the requirements set forth in § 412.103.

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**Dated:** April 7, 2016.

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**Andrew M. Slavitt,**

Acting Administrator,

Centers for Medicare & Medicaid Services.

**Dated:** April 14, 2016.

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**Sylvia M. Burwell,**

Secretary,

Department of Health and Human Services.

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