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42 CFR Part 405, 410, 411, et al.

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 405, 410, 411, 414, 425, and 495**

[CMS-1631-FC]

RIN 0938-AS40

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period.

SUMMARY: This major final rule with comment period addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Effective date:* The provisions of this final rule with comment period are effective on January 1, 2016, except the definition of “ownership or investment interest” in § 411.362(a), which has an effective date of January 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 29, 2015. (See the

SUPPLEMENTARY INFORMATION section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS-1631-FC. 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 www.regulations.gov. Follow the instructions for “submitting a comment.”

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-1631-FC, 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-1631-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

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

FOR FURTHER INFORMATION CONTACT:

Donta Henson, (410) 786-1947 for issues related to pathology and ophthalmology services or any physician payment issues not identified below.

Abdihakim Abdi, (410) 786-4735, for issues related to portable X-ray transportation fees.

Gail Addis, (410) 786-4522, for issues related to the refinement panel.

Lindsey Baldwin, (410) 786-1694, for issues related to valuation of moderate sedation and colonoscopy services.

Jessica Bruton, (410) 786-5991, for issues related to potentially misvalued code lists.

Roberta Epps, (410) 786-4503, for issues related to PAMA section 218(a) policy.

Ken Marsalek, (410) 786-4502, for issues related to telehealth services.

Ann Marshall, (410) 786-3059, for issues related to advance care planning, and for primary care and care management services.

Geri Mondowney, (410) 786-4584, for issues related to geographic practice cost indices, malpractice RVUs, target, and phase-in provisions.

Chava Sheffield, (410) 786-2298, for issues related to the practice expense methodology, impacts, and conversion factor.

Michael Soracoe, (410) 786-6312, for issues related to the practice expense methodology and the valuation and coding of the global surgical packages.

Regina Walker-Wren, (410) 786-9160, for issues related to the “incident to” proposals.

Pamela West, (410) 786-2302, for issues related to therapy caps.

Emily Yoder, (410) 786-1804, for issues related to valuation of radiation treatment services.

Amy Gruber, (410) 786-1542, for issues related to ambulance payment policy.

Corinne Axelrod, (410) 786-5620, for issues related to rural health clinics or federally qualified health centers and payment to grandfathered tribal FQHCs.

Simone Dennis, (410) 786-8409, for issues related to rural health clinics HCPCS reporting.

Edmund Kasaitis (410) 786-0477, for issues related to Part B drugs, biologicals, and biosimilars.

Alesia Hovatter, (410) 786-6861, for issues related to Physician Compare.

Deborah Krauss, (410) 786-5264 and Alexandra Mugge, (410) 786-4457, for issues related to the physician quality reporting system and the merit-based incentive payment system.

Alexandra Mugge, (410) 786-4457, for issues related to EHR Incentive Program.

Sarah Arceo, (410) 786-2356 or Patrice Holtz, (410) 786-5663 for issues related to EHR Incentive Program-Comprehensive Primary Care (CPC) initiative and Medicare EHR Incentive Program aligned reporting.

Rabia Khan or Terri Postma, (410) 786-8084 or ACO@cms.hhs.gov, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786-3232, or Sabrina Ahmed (410) 786-7499, for issues related to value-based Payment Modifier and Physician Feedback Program.

Frederick Grabau, (410) 786-0206, for issues related to changes to opt-out regulations.

Lisa Ohrin Wilson (410) 786-8852, or Matthew Edgar (410) 786-0698, for issues related to physician self-referral updates.

Christiane LaBonte, (410) 786-7234, for issues related to Comprehensive Primary Care (CPC) initiative.

JoAnna Baldwin (410) 786-7205, or Sarah Fulton (410) 786-2749, for issues

2. Applying Therapy Caps to Maryland Hospitals

Since October 1, 2012, the therapy caps and related provisions have applied to the outpatient therapy services furnished by hospitals as recognized under section 1833(a)(8)(B) of the Act. Before then, outpatient therapy services furnished by hospitals had been exempted from the statutory therapy caps. Since 1999, hospitals have been paid for the outpatient therapy services they furnish at PFS rates—the applicable fee schedule established under section 1834(k)(3) of the Act.

Beginning October 1, 2012, CMS has been required to apply the therapy caps and related provisions to outpatient therapy services under section 1833(g) of the Act furnished in hospitals. As with other statutory provisions on therapy caps, this provision has been extended several times by additional legislation. Most recently, section 202(a) of the MACRA extended this broadened application of the therapy caps to include outpatient therapy services furnished by hospitals through December 31, 2017.

When we first implemented the statutory provision that extended application of the therapy caps to outpatient therapy services furnished by hospitals, we did not apply the therapy caps to most hospitals in Maryland. Originally, this omission was linked to our longstanding waiver policy under section 1814(b) of the Act, which allowed Maryland to set the payment rates for hospital services, including those for the outpatient therapy services they furnish. Since 2014, most hospitals in Maryland are paid at rates determined under the Maryland All-Payer Model, which is being tested under the authority of section 1115A of the Act.

To correct this oversight, we recently issued instructions through Change Request 9223 (available online at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3367CP.pdf>) to our Maryland MAC to revise our systems to ensure the application of the therapy caps and related provisions to the outpatient therapy services provided in all Maryland hospitals. These instructions included the direction to use the rates established under the Maryland All-Payer Model rather than the PFS rates to accrue towards the per-beneficiary therapy caps and thresholds. We believe using the Maryland All-Payer Model rates rather than the PFS rates is consistent with the statute at sections 1833(g)(1) and (3) of the Act that requires us to count the actual

expenses incurred in any calendar year towards the beneficiary's therapy caps. These instructions will become effective January 1, 2016.

III. Other Provisions of the Final Rule With Comment Period

A. Provisions Associated With the Ambulance Fee Schedule

1. Overview of Ambulance Services

a. Ambulance Services

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—
- ++ Basic Life Support (BLS) (emergency and non-emergency)
- ++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency)
- ++ Advanced Life Support, Level 2 (ALS2)
- ++ Paramedic ALS Intercept (PI)
- ++ Specialty Care Transport (SCT)
- For Air—
- ++ Fixed Wing Air Ambulance (FW)
- ++ Rotary Wing Air Ambulance (RW)

b. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong.,

1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

c. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40 and § 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the MIPPA amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Most recently, section 203(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons through December 31, 2017. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2018. We proposed to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439) and the CY 2015 PFS final rule with comment period (79 FR 67743)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary. We received several comments regarding this proposal. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the implementation of the extension of the ambulance payment add-ons. These commenters also agreed that these provisions are self-implementing. One commenter encouraged CMS to seek to make these add-on payments permanent.

Response: We appreciate the commenters' support of these provisions, but we do not have the authority to make these provisions permanent.

After consideration of the public comments received, we are finalizing our proposal to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a "qualified rural area," that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of

rural census tract). This rural bonus is sometimes referred to as the "Super Rural Bonus" and the qualified rural areas (also known as "super rural" areas) are identified during the claims adjudicative process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 203(b) of the Medicare Access and CHIP Reauthorization Act of 2015 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2017. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2018 where transportation originates in a qualified rural area. Accordingly, we proposed to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440) and the CY 2015 PFS final rule with comment period (79 FR 67743 through 67744)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary through December 31, 2017, and does not require any substantive exercise of discretion on the part of the Secretary. We received several comments regarding this proposal. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the continued implementation of the percent increase in the base rate of the fee schedule for transports in areas defined as super rural. These commenters also agreed with CMS that these provisions are self-implementing. One commenter encouraged CMS to seek to make these add-on payments permanent.

Response: We appreciate the commenters' support of these provisions, but we do not have the authority to make these provisions permanent.

After consideration of the public comments received, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

3. Changes in Geographic Area Delineations for Ambulance Payment

a. Background

In the CY 2015 PFS final rule with comment period (79 FR 67744 through

67750) as amended by the correction issued December 31, 2014 (79 FR 78716 through 78719), we adopted, beginning in CY 2015, the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13-01) and the most recent modifications of the Rural-Urban Commuting Area (RUCA) codes for purposes of payment under the ambulance fee schedule. With respect to the updated RUCA codes, we designated any census tracts falling at or above RUCA level 4.0 as rural areas. In addition, we stated that none of the super rural areas would lose their status upon implementation of the revised OMB delineations and updated RUCA codes. After publication of the CY 2015 PFS final rule with comment period and the correction, we received feedback from stakeholders expressing concerns about the implementation of the new geographic area delineations finalized in that rule (as corrected). In response to these concerns, in the CY 2016 PFS proposed rule (80 FR 41788 through 41792), we clarified our implementation of the revised OMB delineations and the updated RUCA codes in CY 2015, and re-proposed the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent calendar years. We requested public comment on our proposals, which comments are further discussed in section III A.3.b. of this final rule with comment period.

b. Provisions of the Final Rule With Comment Period

Under section 1834(l)(2)(C) of the Act, the Secretary is required to consider appropriate regional and operational differences in establishing the ambulance fee schedule. Historically, the Medicare ambulance fee schedule has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to take into account appropriate regional (urban and rural) differences. This use of consistent geographic standards for Medicare payment purposes provides for consistency across the Medicare program.

The geographic areas used under the ambulance fee schedule effective in CY 2007 were based on OMB standards published on December 27, 2000 (65 FR 82228 through 82238), Census 2000 data, and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10-02). For a discussion of OMB's delineation of Core-Based Statistical Areas (CBSAs) and our implementation of the CBSA definitions under the ambulance fee schedule, we refer readers to the preamble of the CY

2007 Ambulance Fee Schedule proposed rule (71 FR 30358 through 30361) and the CY 2007 PFS final rule with comment period (71 FR 69712 through 69716). On February 28, 2013, OMB issued OMB Bulletin No. 13-01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf>. According to OMB, this bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published in the June 28, 2010 **Federal Register** (75 FR 37246-37252) and Census Bureau data. OMB defines an MSA as a CBSA associated with at least one urbanized area that has a population of at least 50,000, and a Micropolitan Statistical Area (referred to in this discussion as a Micropolitan Area) as a CBSA associated with at least one urban cluster that has a population of at least 10,000 but less than 50,000 (75 FR 37252). Counties that do not qualify for inclusion in a CBSA are deemed "Outside CBSAs." We note that, when referencing the new OMB geographic boundaries of statistical areas, we are using the term "delineations" consistent with OMB's use of the term (75 FR 37249).

Although the revisions OMB published on February 28, 2013 were not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2007, the February 28, 2013 OMB bulletin did contain a number of significant changes. For example, there are new CBSAs, urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart. As we stated in the CY 2015 PFS final rule with comment period (79 FR 67745), we reviewed our findings and impacts relating to the new OMB delineations, and found no compelling reason to further delay implementation. We stated in the CY 2015 final rule with comment period, and in the CY 2016 PFS proposed rule (80 FR 41788), that it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible to maintain a more accurate and up-to-date payment system

that reflects the reality of population shifts.

Additionally, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49952), we adopted OMB's revised delineations to identify urban areas and rural areas for purposes of the IPPS wage index. For the reasons discussed in this section, we believe that it was appropriate to adopt the same geographic area delineations for use under the ambulance fee schedule as are used under the IPPS and other Medicare payment systems. Thus, in the CY 2016 PFS proposed rule (80 FR 41788), we proposed to continue implementation of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13-01 for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We stated in the CY 2016 PFS proposed rule (80 FR 41788) that we continue to believe that the updated OMB delineations more realistically reflect rural and urban populations, and that the use of such delineations under the ambulance fee schedule would result in more accurate payment. Under the ambulance fee schedule, consistent with our current definitions of urban and rural areas (§ 414.605), in CY 2016 and subsequent CYs, MSAs would continue to be recognized as urban areas, while Micropolitan and other areas outside MSAs, and rural census tracts within MSAs (as discussed below in this section), would continue to be recognized as rural areas. We invited public comments on this proposal.

In addition to the OMB's statistical area delineations, the current geographic areas used in the ambulance fee schedule also are based on rural census tracts determined under the most recent version of the Goldsmith Modification. These rural census tracts within MSAs are considered rural areas under the ambulance fee schedule (see § 414.605). For certain rural add-on payments, section 1834(l) of the Act requires that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs. In the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716), we adopted the most recent (at that time) version of the Goldsmith Modification, designated as RUCA codes. RUCA codes use urbanization, population density, and daily commuting data to categorize every census tract in the country. For a discussion about RUCA codes, we refer the reader to the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716), the CY 2015 PFS final rule with comment period (79 FR 67745

through 67746) and the CY 2016 PFS proposed rule (80 FR 41788 through 41789). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13-01, which established revised delineations for MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service Web site for a detailed listing of updated RUCA codes found at <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx>. The updated RUCA code definitions were introduced in late 2013 and are based on data from the 2010 decennial census and the 2006-2010 American Community Survey. Information regarding the American Community Survey can be found at <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx> and at <http://www.census.gov/programs-surveys/acs/guidance/training-presentations/acs-basics.html>. We stated in the CY 2016 PFS proposed rule (80 FR 41789) that we believe the most recent RUCA codes provide more accurate and up-to-date information regarding the rurality of census tracts throughout the country. Accordingly, we proposed to continue to use the most recent modifications of the RUCA codes for CY 2016 and subsequent CYs, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the ambulance fee schedule. We stated that if we continue to use the most recent RUCA codes, many counties that are designated as urban at the county level based on population would continue to have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67745) and in the CY 2016 PFS proposed rule (80 FR 41789), the 2010 Primary RUCA codes are as follows:

- (1) Metropolitan area core: Primary flow with an urbanized area (UA).
- (2) Metropolitan area high commuting: Primary flow 30 percent or more to a UA.
- (3) Metropolitan area low commuting: Primary flow 10 to 30 percent to a UA.
- (4) Micropolitan area core: Primary flow within an Urban Cluster of 10,000 to 49,999 (large UC).

(5) Micropolitan high commuting: Primary flow 30 percent or more to a large UC.

(6) Micropolitan low commuting: Primary flow 10 to 30 percent to a large UC.

(7) Small town core: Primary flow within an Urban Cluster of 2,500 to 9,999 (small UC).

(8) Small town high commuting: Primary flow 30 percent or more to a small UC.

(9) Small town low commuting: Primary flow 10 to 30 percent to a small UC.

(10) Rural areas: Primary flow to a tract outside a UA or UC.

Based on this classification, and consistent with our current policy as set forth in the CY 2015 PFS final rule with comment period (79 FR 67745), we proposed to continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas for purposes of payment for ambulance services under the ambulance fee schedule. As discussed in the CY 2007 PFS final rule with comment period (71 FR 69715), the CY 2015 PFS final rule with comment period (79 FR 67745), and the CY 2016 PFS proposed rule (80 FR 41789), the Office of Rural Health Policy within the Health Resources and Services Administration (HRSA) determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, HRSA designates any census tract that falls in RUCA level 4.0 or higher as a rural census tract. In addition to designating any census tracts falling at or above RUCA level 4.0 as rural areas, under the updated RUCA code definitions, HRSA has also designated as rural census tracts those census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We refer readers to HRSA's Web site at <ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf> for additional information. Consistent with the HRSA guidelines discussed above and the policy we adopted in the CY 2015 PFS final rule with comment period (79 FR 67750), we proposed for CY 2016 and subsequent CYs, to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We stated that we continue to believe that this HRSA guideline accurately identifies rural census tracts throughout the country, and thus, would be appropriate to apply for ambulance fee schedule payment purposes.

Also, consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67749), we did not propose in the CY 2016 PFS

proposed rule (80 FR 41789) to designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We stated in the CY 2016 PFS proposed rule (80 FR 41789) that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We stated that we do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. Also, payment under the ambulance fee schedule is based on ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We stated that we believe payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system. For example, there are circumstances where ZIP codes cross county or census tract borders and where counties or census tracts cross ZIP code borders. Such overlaps in geographic designations would complicate our ability to appropriately assign ambulance transportation services to geographic areas for payment under the ambulance fee schedule if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas. Therefore, we stated in the proposed rule (80 FR 41789) that, under the ambulance fee schedule, we would not designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people.

We invited public comments on our proposals, as discussed in the CY 2016 PFS proposed rule, to continue to use the revised OMB delineations and updated RUCA codes under the ambulance fee schedule for CY 2016 and subsequent CYs.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41789 through 41790), the adoption of the most current OMB delineations and the updated RUCA codes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because urban and rural transports are paid differently. The determination of whether a transport is urban or rural is based on the point of pick-up for the transport; thus, a transport is paid differently depending on whether the point of pick-up is in an

urban or a rural area. During claims processing, a geographic designation of urban, rural, or super rural is assigned to each claim for an ambulance transport based on the point of pick-up ZIP code that is indicated on the claim.

The continued implementation of the revised OMB delineations and the updated RUCA codes would continue to affect whether or not transports would be eligible for rural adjustments under the ambulance fee schedule statute and regulations. For ground ambulance transports where the point of pick-up is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles (§ 414.610(c)(5)(i)). For air ambulance services where the point of pick-up is in a rural area, the total payment (base rate and mileage rate) is increased by 50 percent (§ 414.610(c)(5)(i)).

Section 1834(l)(12) of the Act (as amended most recently by section 203(b) of the Medicare Access and CHIP Reauthorization Act of 2015) specifies that, for services furnished during the period July 1, 2004 through December 31, 2017, the payment amount for the ground ambulance base rate is increased by a "percent increase" (Super Rural Bonus) where the ambulance transport originates in a "qualified rural area," which is a rural area that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density (also known as a "super rural area"). We implement this Super Rural Bonus in § 414.610(c)(5)(ii). As discussed in section III.A.2.b. of this final rule with comment period, we are revising § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41790), adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. Furthermore, under section 1834(l)(13) of the Act (as amended most recently by section 203(a) of the Medicare Access and CHIP Reauthorization Act of 2015), for ground ambulance transports furnished through December 31, 2017, transports originating in rural areas are paid based on a rate (both base rate and mileage rate) that is 3 percent higher than otherwise is applicable. (See also § 414.610(c)(1)(ii)). As discussed in section III.A.2.a. of this final rule with comment period, we are revising § 414.610(c)(1)(ii) to conform the

regulations to this statutory requirement.

Similar to our discussion in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41790), if we continue to use OMB's revised delineations and the updated RUCA codes for CY 2016 and subsequent CYs, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but were within urban areas under the geographic delineations in effect in CY 2014) would continue to experience increases in payment for such transports (as compared to the CY 2014 geographic delineations) because they may be eligible for the rural adjustment factors discussed in this section. In addition, those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but were previously in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA under the geographic delineations in effect in CY 2014) would continue to experience decreases in payment for such transports (as compared to the CY 2014 geographic delineations) because they would no longer be eligible for the rural adjustment factors discussed in this section.

The continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs would mean the continued recognition of urban and

rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. As discussed in this section, we proposed to continue to use the updated RUCA codes to identify rural census tracts within MSAs, such that any census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas. To determine which ZIP codes are included in each such rural census tract, we proposed to continue to use the ZIP code approximation file developed by HRSA. This file includes the 2010 RUCA code designation for each ZIP code and can be found at <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx>. If ZIP codes are added over time to the USPS ZIP code file (and thus are not included in the 2010 ZIP code approximation file provided to us by HRSA) or if ZIP codes are revised over time, we stated that we would determine the appropriate urban/rural designation for such ZIP code based on any updates provided on the HRSA and OMB Web sites, located at <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx> and <http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf>.

Based on the August 2015 USPS ZIP code file that we are using in this final rule with comment period to assess the impacts of the revised geographic delineations, there are a total of 42,927 ZIP codes in the U.S. Table 23 sets forth an analysis of the number of ZIP codes that changed urban/rural status in each U.S. state and territory after CY 2014 due to our implementation of the revised OMB delineations and the

updated RUCA codes beginning in CY 2015, using the August 2015 USPS ZIP code file, the revised OMB delineations, and the updated RUCA codes (including the RUCA ZIP code approximation file discussed above). Based on this data, the geographic designations for approximately 95.22 percent of ZIP codes are unchanged by OMB's revised delineations and the updated RUCA codes. Similar to the analysis set forth in the CY 2015 PFS final rule with comment period, as corrected (79 FR 78716 through 78719), and the CY 2016 PFS proposed rule (80 FR 41790 through 41791), as reflected in Table 23, more ZIP codes have changed from rural to urban (1,600 or 3.73 percent) than from urban to rural (451 or 1.05 percent). In general, it is expected that ambulance providers and suppliers in 451 ZIP codes within 42 states may continue to experience payment increases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from urban to rural. The state of Ohio has the most ZIP codes that changed from urban to rural with a total of 54, or 3.63 percent of all zip codes in the state. Ambulance providers and suppliers in 1,600 ZIP codes within 44 states and Puerto Rico may continue to experience payment decreases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from rural to urban. The state of West Virginia has the most ZIP codes that changed from rural to urban (149 or 15.92 percent of all zip codes in the state). As discussed in this section, these findings are illustrated in Table 23.

TABLE 23—ZIP CODE ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State/ territory *	Total ZIP Codes	Total ZIP Codes changed rural to urban	Percentage of total ZIP Codes	Total ZIP Codes changed urban to rural	Percentage of total ZIP Codes	Total ZIP Codes not changed	Percentage of total ZIP Codes not changed
AK	276	0	0.00	0	0.00	276	100.00
AL	854	43	5.04	8	0.94	803	94.03
AR	725	19	2.62	9	1.24	697	96.14
AS	1	0	0.00	0	0.00	1	100.00
AZ	569	21	3.69	7	1.23	541	95.08
CA	2,723	85	3.12	43	1.58	2,595	95.30
CO	677	4	0.59	9	1.33	664	98.08
CT	445	37	8.31	0	0.00	408	91.69
DC	303	0	0.00	0	0.00	303	100.00
DE	99	6	6.06	0	0.00	93	93.94
EK	63	0	0.00	0	0.00	63	100.00
EM	857	35	4.08	4	0.47	818	95.45
FL	1,513	69	4.56	9	0.59	1,435	94.84
FM	4	0	0.00	0	0.00	4	100.00
GA	1,032	47	4.55	4	0.39	981	95.06
GU	21	0	0.00	0	0.00	21	100.00
HI	143	9	6.29	3	2.10	131	91.61
IA	1,080	20	1.85	3	0.28	1,057	97.87
ID	335	0	0.00	0	0.00	335	100.00
IL	1,629	68	4.17	7	0.43	1,554	95.40

TABLE 23—ZIP CODE ANALYSIS BASED ON OMB’S REVISED DELINEATIONS AND UPDATED RUCA CODES—Continued

State/ territory *	Total ZIP Codes	Total ZIP Codes changed rural to urban	Percentage of total ZIP Codes	Total ZIP Codes changed urban to rural	Percentage of total ZIP Codes	Total ZIP Codes not changed	Percentage of total ZIP Codes not changed
IN	1,000	33	3.30	20	2.00	947	94.70
KY	1,030	30	2.91	5	0.49	995	96.60
LA	739	69	9.34	1	0.14	669	90.53
MA	751	8	1.07	9	1.20	734	97.74
MD	630	69	10.95	0	0.00	561	89.05
ME	505	5	0.99	12	2.38	488	96.63
MH	2	0	0.00	0	0.00	2	100.00
MI	1,185	22	1.86	21	1.77	1,142	96.37
MN	1,043	31	2.97	7	0.67	1,005	96.36
MP	3	0	0.00	0	0.00	3	100.00
MS	541	14	2.59	1	0.18	526	97.23
MT	411	0	0.00	3	0.73	408	99.27
NC	1,102	87	7.89	10	0.91	1,005	91.20
ND	419	2	0.48	0	0.00	417	99.52
NE	632	7	1.11	6	0.95	619	97.94
NH	292	0	0.00	2	0.68	290	99.32
NJ	748	1	0.13	2	0.27	745	99.60
NM	438	4	0.91	2	0.46	432	98.63
NV	257	1	0.39	2	0.78	254	98.83
NY	2,246	84	3.74	42	1.87	2,120	94.39
OH	1,487	23	1.55	54	3.63	1,410	94.82
OK	791	5	0.63	7	0.88	779	98.48
OR	496	26	5.24	9	1.81	461	92.94
PA	2,244	129	5.75	38	1.69	2,077	92.56
PR	177	21	11.86	0	0.00	156	88.14
PW	2	0	0.00	0	0.00	2	100.00
RI	91	2	2.20	1	1.10	88	96.70
SC	544	47	8.64	2	0.37	495	90.99
SD	418	0	0.00	1	0.24	417	99.76
TN	814	52	6.39	12	1.47	750	92.14
TX	2,726	64	2.35	32	1.17	2,630	96.48
UT	360	2	0.56	0	0.00	358	99.44
VA	1,277	98	7.67	19	1.49	1,160	90.84
VI	16	0	0.00	0	0.00	16	100.00
VT	309	3	0.97	0	0.00	306	99.03
WA	744	17	2.28	6	0.81	721	96.91
WI	919	19	2.07	5	0.54	895	97.39
WV	711	11	1.55	7	0.98	693	97.47
WM	342	2	0.58	3	0.88	337	98.54
WV	936	149	15.92	3	0.32	784	83.76
WY	198	0	0.00	1	0.51	197	99.49
Totals	42,927	1,600	3.73	451	1.05	40,876	95.22

* ZIP code analysis includes U.S. States and Territories (FM—Federated States of Micronesia, GU—Guam, MH—Marshall Islands, MP—Northern Mariana Islands, PW—Palau, AS—American Samoa; VI—Virgin Islands; PR—Puerto Rico). Missouri is divided into east and west regions due to work distribution of the Medicare Administrative Contractors (MACs): EM—East Missouri, WM—West Missouri. Johnson and Wyandotte counties in Kansas were changed as of January 2010 to East Kansas (EK) and the rest of the state is West Kansas (WK).

For more detail on the impact of these changes, in addition to Table 23, the following files are available through the Internet on the Ambulance Fee Schedule Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html>, Downloads, CY 2016 Final Rule; ZIP Codes By State Changed From Urban To Rural; ZIP Codes By State Changed From Rural To Urban; List of ZIP Codes With RUCA Code Designations; and Complete List of ZIP Codes.

We stated in the CY 2015 PFS final rule with comment period (79 FR 67750) and in the CY 2016 PFS proposed rule (80 FR 41792) that we

believe the most current OMB statistical area delineations, coupled with the updated RUCA codes, more accurately reflect the contemporary urban and rural nature of areas across the country, and thus we believe the use of the most current OMB delineations and RUCA codes under the ambulance fee schedule will enhance the accuracy of ambulance fee schedule payments. As we discussed in the CY 2015 PFS final rule with comment period (79 FR 67750), we considered, as alternatives, whether it would be appropriate to delay the implementation of the revised OMB delineations and the updated RUCA codes, or to phase in the implementation of the new geographic

delineations over a transition period for those ZIP codes losing rural status. We determined that it would not be appropriate to implement a delay or a transition period for the revised geographic delineations for the reasons set forth in the CY 2015 PFS final rule. Similarly, we considered whether a delay in implementation or a transition period would be appropriate for CY 2016 and subsequent CYs. We stated in the CY 2016 PFS proposed rule (80 FR 41792) that we continue to believe it is important to use the most current OMB delineations and RUCA codes available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality

of population shifts. Because we believe the revised OMB delineations and updated RUCA codes more accurately identify urban and rural areas and enhance the accuracy of the Medicare ambulance fee schedule, we stated that we do not believe a delay in implementation or a transition period would be appropriate for CY 2016 and subsequent CYs. Areas that have lost their rural status and become urban have become urban because of recent population shifts. We believe it is important to base payment on the most accurate and up-to-date geographic area delineations available. Furthermore, we stated in the proposed rule that a delay in implementation of the revised OMB delineations and the updated RUCA codes would be a disadvantage to the ambulance providers or suppliers experiencing payment increases based on these updated and more accurate OMB delineations and RUCA codes. Thus, we did not propose a delay in implementation or a transition period for the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs.

We invited public comments on our proposals to continue implementation of the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13-01) and the most recent modifications of the RUCA codes as discussed above for CY 2016 and subsequent CYs for purposes of payment under the ambulance fee schedule. In addition, we invited public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes.

We received several comments from ambulance providers and suppliers and associations representing ambulance providers and suppliers on our proposals to continue implementation of the revised OMB delineations and the most recent modifications of the RUCA codes as discussed above for CY 2016 and subsequent CYs. The following is a summary of those comments along with our responses.

Comment: A commenter supported our proposal to continue implementation of the new OMB delineations for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes.

Response: We appreciate the commenter's support of our proposal.

Comment: Several commenters agreed with CMS that it is appropriate to adjust the geographic area designations periodically so that the ambulance fee schedule reflects population shifts.

These commenters remain concerned, however, because they contend that the modifications finalized last year have led to some rural ZIP codes being designated as urban. Several commenters urged CMS to refine the modified geographic area designations to restore rural status to those ZIP codes the commenters contended were improperly classified as urban last year. Specifically, commenters urged CMS to adopt HRSA's rural designations of 132 census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. According to the commenters, the discrepancy between CMS and HRSA in the application of RUCA codes appears to result from the fact that HRSA designates rural areas for its programs by focusing on the Census tract, while CMS focuses on a U.S. Department of Agriculture (USDA) ZIP code list. The commenters stated that it is important for these 132 Census tract areas to be taken into account for making geographic designations. The commenters suggested that CMS adopt a methodology to adjust the RUCA code status for the 132 census tracts recognized by HRSA as rural to RUCA code status 4 before cross walking the ZIP codes. According to the commenters, when the analysis is re-run, the resulting ZIP codes would be appropriately designated as rural. The commenters stated that by recognizing the 132 census tracts as rural, CMS's policy would align with HRSA's policy and address the concerns raised by ambulance providers and suppliers. According to the commenters, this approach would avoid the concerns that CMS has raised about splitting ZIP codes.

Response: We appreciate the commenters' support for adjusting the geographic area designations periodically to reflect population shifts. As discussed in this section and in the CY 2016 PFS proposed rule (80 FR 41788 through 41792), we believe that the most current OMB delineations, coupled with the updated RUCA codes, more accurately reflect the urban and rural nature of areas across the country, and thus we believe the use of the most current OMB delineations and RUCA codes under the ambulance fee schedule enhances the accuracy of ambulance fee schedule payments. Further, as discussed previously, we believe that our methodology of designating rural geographic areas by using OMB's delineations, and by using RUCA codes of 4 and above to identify rural census tracts within MSAs, is appropriate for

ambulance fee schedule payment purposes.

We have concerns with the methodology proposed by the commenters to identify as rural certain census tracts with RUCA codes of 2 and 3. The 132 census tracts recognized as rural by HRSA have RUCA code designations of 2 or 3, indicating that the census tracts are predominantly urban. To assign these entire census tracts a RUCA code of 4 before cross walking the ZIP codes could result in inappropriate classifications of urban areas as rural. Payment under the ambulance fee schedule is based on ZIP codes (§ 414.610(e)). We would require a list of ZIP codes assigned to the 132 census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile to appropriately identify these areas as rural. As we previously discussed, we do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. We do not believe it would be prudent at this time to implement the commenters' suggested methodology absent the data and methodology to precisely identify the ZIP codes for the census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. We will consider further evaluating for CY 2017 these additional census tracts that HRSA has designated as rural and the feasibility of identifying the ZIP codes that are assigned to those areas.

Comment: Several commenters requested that CMS issue an Advanced Notice of Proposed Rulemaking (ANPRM) prior to the CY 2017 rulemaking cycle to seek input from all interested stakeholders about whether a new urban-rural data set should be used or other policy modifications should be adopted to apply the RUCA designations. According to the commenters, the data to determine the levels for RUCAs are no longer collected through the long-form census, which had a high response rate. The commenters contend that the RUCA data are now based on a response rate in the single digits which is not high enough to accurately identify urban-rural areas when it comes to access to vital ambulance services. The commenters stated that an ANPRM would allow CMS to hear from all interested parties at an early stage in the process and provide CMS with the information it needs to fully evaluate the current policy and to identify options for addressing the issues that have been raised by commenters with

RUCA being used as the data set for identifying rural census tracts within urban areas.

Response: The updated RUCA code definitions are based on data from the 2010 decennial census and the 2006–2010 American Community Survey (ACS). According to the United States Census Bureau’s Web site, <http://www.census.gov/programs-surveys/acs/guidance/training-presentations/acs-basics.html>, ACS is a nationwide survey that provides characteristics of the population and housing throughout the country, similar to the long-form questionnaire used in Census 2000. The ACS produces estimates of these characteristics for small areas and small population groups throughout the country.

According to the Census Bureau’s Web site, the content collected by the ACS can be grouped into four main types of characteristics—social, economic, demographic, and housing. For example, economic characteristics include such topics as health insurance coverage, income, benefits, employment status, occupation, industry, commuting to work, and place of work. This is the same information that was collected by the 2010 Census.

The ACS is a continuous survey, in which, each month, a sample of housing unit addresses receives a questionnaire. For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. About 3.5 million addresses are surveyed each year. The ACS collects data from the 50 states, the District of Columbia, and Puerto Rico. The survey had the following response rates at the state level for 2006–2010: 91.1 percent to 99.0 percent in 2006, 91.7 percent to 99.3 percent in 2007, 91.4 percent to 99.4 percent in 2008, 94.9 percent to 99.4 percent in 2009, and 95.3 percent to 99.0 percent in 2010. The ACS collects survey information continuously and then aggregates the results over a specific period of time—1 year, 3 years, or 5 years. The ACS period estimates describe the average characteristics of the population or housing over a specified period of time. For smaller geographic areas, such as the census tracts, 5 year estimates are used. As mentioned in this section, the most recent update of the RUCA codes was developed using data collected from the 2006, 2007, 2008, 2009, and 2010 ACS. According to the Census Bureau, the estimates that they published based on the ACS had a 90 percent confidence interval.

According to the USDA’s Web site, <http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx>, the RUCA codes were based on a special tabulation for the Department of Transportation, Census Transportation Planning Products, Part 3, Worker Home-to-Work Flow Tables (http://www.fhwa.dot.gov/planning/census_issues/ctpp/data_products/2006-2010_table_list/sheet04.cfm). According to the USDA, as with all survey data, ACS estimates are not exact because they are based on a sample. Nevertheless, we believe that the ACS provides the most recent comprehensive source of data on the population and is robust enough for use for purposes of determining the rural status of census tracts throughout the country.

We do not believe it is necessary to issue an ANPRM prior to the CY 2017 rulemaking cycle. In the CY 2016 PFS proposed rule and in past rules, we have discussed the implementation of the OMB delineations and the RUCA codes for purposes of payment under the ambulance fee schedule, and we believe that the public has had ample opportunity to provide comments and suggestions about other methodologies for designating geographic areas or other policy modifications that should be adopted to apply the RUCA code designations. We note that the public did not provide any suggestions for any alternative data sources for designating rural geographic areas.

We note that we utilize the ACS data in other Medicare payment systems as well. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49501), we finalized our proposal that the out-migration adjustments be based on commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. (See also the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24471)). Furthermore, the physician fee schedule uses the 2008–2010 ACS data for calculating the office rent component of the PE of the geographic practice cost index (78 FR 74390).

After consideration of the public comments received and for the reasons discussed in this section and in the CY 2016 PFS proposed rule, we are finalizing without modification our proposal to continue implementation of the revised OMB delineations as set forth in OMB’s February 28, 2013 bulletin (No. 13–01) and the most recent modifications of the RUCA codes, as discussed in this section, for CY 2016 and subsequent CYs for purposes of payment under the ambulance fee

schedule. As we proposed, using the updated RUCA code definitions, we will continue to designate any census tracts falling at or above RUCA code 4.0 as rural areas. In addition, as discussed in this section, none of the current super rural areas will lose their super rural status upon implementation of the revised OMB delineations and the updated RUCA codes.

4. Proposed Changes to the Ambulance Staffing Requirements

Under section 1861(s)(7) of the Act, Medicare Part B covers ambulance services when the use of other methods of transportation is contraindicated by the individual’s medical condition, but only to the extent provided in regulations. Section 410.41(b)(1) requires that a vehicle furnishing ambulance services at the Basic Life Support (BLS) level must be staffed by at least two people, one of whom must meet the following requirements: (1) Be certified as an emergency medical technician by the state or local authority where the services are furnished; and (2) be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

Section 410.41(b)(2) states that, for vehicles furnishing ambulance services at the Advanced Life Support (ALS) level, ambulance providers and suppliers must meet the staffing requirements for vehicles furnishing services at the BLS level, and, additionally, that one of the two staff members must be certified as a paramedic or an emergency medical technician, by the state or local authority where the services are being furnished, to perform one or more ALS services. These staffing requirements are further explained in the Medicare Benefit Policy Manual (Pub. No. 100–02), Chapter 10 (see sections 10.1.2 and 30.1.1)

In its July 24, 2014 Management Implication Report, 13–0006, entitled “Medicare Requirements for Ambulance Crew Certification,” the Office of Inspector General (OIG) discussed its investigation of ambulance suppliers in a state that requires a higher level of training than Medicare requires for ambulance staff. In some instances, OIG found that second crew members: (1) Possessed a lower level of training than required by state law, or (2) had purchased or falsified documentation to establish their credentials. The OIG expressed its concern that our current regulations and manual provisions do not set forth licensure or certification requirements for the second crew member. The OIG was informed by federal prosecutors that prosecuting

individuals who had purchased or falsified documentation to establish their credentials would be difficult because Medicare had no requirements regarding the second ambulance staff member and the ambulance transports complied with the relevant Medicare regulations and manual provisions for ambulance staffing.

As we stated in the CY 2016 PFS proposed rule (80 FR 41792), the OIG recommended that Medicare revise its regulations and manual provisions related to ambulance staffing to parallel the standard used for vehicle requirements at § 410.41(a), which requires that ambulances be equipped in ways that comply with state and local laws. Specifically, the OIG recommended that our regulation and manual provisions addressing ambulance vehicle staffing should indicate that, for Medicare to cover ambulance services furnished to a Medicare beneficiary, the ambulance crew must meet the requirements currently set forth in § 410.41(b) or the state and local requirements, whichever are more stringent. Currently, § 410.41(b) does not require that ambulance vehicle staff comply with all applicable state and local laws. In the CY 2016 PFS proposed rule, we stated that we agree with OIG's concerns and believe that requiring ambulance staff to also comply with state and local requirements would enhance the quality and safety of ambulance services furnished to Medicare beneficiaries.

Accordingly, in the CY 2016 PFS proposed rule (80 FR 41792), we proposed to revise § 410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished, and the current Medicare requirements under § 410.41(b). We believe that this would, in effect, require both of the required ambulance vehicle staff to also satisfy any applicable state and local requirements that may be more stringent than those currently set forth at § 410.41(b), consistent with OIG's recommendation. In addition, we proposed to revise the definition of Basic Life Support (BLS) in § 414.605 to include the proposed revised staffing requirements discussed above for § 410.41(b) (80 FR 41793). We stated that these revisions to § 410.41(b) and § 414.605 would account for differences in individual state or local staffing and licensure requirements, better accommodating state or local laws enacted to ensure beneficiaries' health and safety. Likewise, these revisions would strengthen the federal

government's ability to prosecute violations associated with such requirements and recover inappropriately or fraudulently received funds from ambulance companies found to be operating in violation of state or local laws. Furthermore, we stated in the proposed rule that we believe these proposals would enhance the quality and safety of ambulance services provided to Medicare beneficiaries.

In addition, we proposed to revise § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605 to clarify that, for BLS vehicles, at least one of the staff members must be certified, at a minimum, as an emergency medical technician—basic (EMT-Basic), which we believe would more clearly state our current policy (80 FR 41793). Currently, these regulations require that, for BLS vehicles, one staff member be certified as an EMT (§ 410.41(b)) or EMT-Basic (§ 414.605). These revisions to the regulations do not change our current policy, but clarify that one of the BLS vehicle staff members must be certified at the minimum level of EMT-Basic, but may also be certified at a higher level, for example, EMT-intermediate or EMT paramedic.

Finally, we proposed to revise the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions (80 FR 41793). This sentence has been included in the definition of BLS since the ambulance fee schedule was finalized in 2002 (67 FR 9100, Feb. 27, 2002). Because state laws may change over the course of time, we are concerned that this sentence may not accurately reflect the status of the relevant state laws over time. Therefore, we proposed to delete the last sentence of this definition. Furthermore, we do not believe that the examples set forth in this sentence are necessary to convey the definition of BLS for Medicare coverage and payment purposes.

We invited public comments on our proposals to revise the ambulance vehicle staffing requirements in § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605, as discussed in this section. We also stated that, if we finalized these proposals, we would revise our manual provisions addressing ambulance vehicle staffing as appropriate, consistent with our finalized policy.

We received approximately 21 comments from ambulance providers and suppliers and associations representing such entities. The following is a summary of the comments we received along with our responses.

Comment: Several commenters supported the proposed changes to the ambulance staffing requirements. Commenters also requested that CMS support efforts to designate ambulance services as providers under the Medicare program (rather than having some designated as suppliers).

Response: We appreciate the commenters' support of our proposals. Comments requesting us to support efforts to designate ambulance services as providers are outside the scope of this final rule with comment period.

Comment: One commenter requested additional clarification on whether the proposed revision would require both ambulance medical technicians to be certified by the state as EMTs. This same commenter requested clarification on whether both technicians would need to be legally authorized to operate lifesaving and life-sustaining equipment on board the vehicle.

Two commenters opposed the proposed changes to the ambulance staffing requirements, expressing concern that the proposed changes would require both crew members to be certified as EMTs, a change they believed would negatively impact ambulance services in rural communities. One of these commenters stated that such a change would (1) not increase the level of care provided to the patient being transported, and (2) make it more difficult for volunteer Emergency Medical Services (EMS) providers to be properly reimbursed for their work. The commenters also stated that this requirement would limit access in rural communities, and that it would be difficult for volunteer EMS staff to meet such requirements.

Response: We believe that these commenters misinterpreted our proposal. We did not propose to require that both ambulance crew members be certified as EMTs or that both ambulance crew members be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. The only change we proposed to our current policy was to require both ambulance vehicle staff to meet the requirements of state and local laws where the services are being furnished. Thus, our proposed policy would require that both ambulance vehicle staff be certified as EMTs only when this is required by the state or local laws where the services are being furnished. As we stated in the CY 2016 PFS proposed rule (80 FR 41942), because we expect that ambulance providers and suppliers already comply with their state and local laws, we expect that this requirement would have a minimal

impact on ambulance providers and suppliers.

Comment: Several commenters supported the proposed revision to the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions.

Response: We appreciate the commenters' support for our proposed revision to the definition of Basic Life Support (BLS) in § 414.605.

After consideration of the public comments received, and for the reasons discussed in this section, we are finalizing without modification our proposals to revise (1) § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605, as discussed in this section, to require that all Medicare-covered ambulance transports be staffed by at least two people who meet both the requirements of state and local laws where the services are being furnished, and the current Medicare requirements, (2) § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605 to clarify that for BLS vehicles, one of the staff members must be certified at a minimum as an EMT-Basic, and (3) the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions. We will also revise our manual provisions addressing ambulance vehicle staffing, as appropriate, to be consistent with these finalized policies.

B. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. Primary Care and Care Coordination

Over the last several years, we have been increasing our focus on primary care, and have explored ways in which care coordination can improve health outcomes and reduce expenditures.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794, and 42917 through 42920), and the CY 2012 PFS final rule (76 FR 73063 through 73064), we discussed how primary care services have evolved to focus on preventing and managing chronic disease, and how refinements for payment for post-discharge care management services could improve care management for a beneficiary's transition from the hospital to the community setting. We acknowledged that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved in primary care, and may not reflect all the services

and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay. We initiated a public discussion on primary care and care coordination services, and stated that we would consider payment enhancements in future rulemaking as part of a multiple year strategy exploring the best means to encourage primary care and care coordination services.

In the CY 2013 PFS proposed rule (77 FR 44774 through 44775), we noted several initiatives and programs designed to improve payment for, and encourage long-term investment in, care management services. These include the Medicare Shared Savings Program; testing of the Pioneer Accountable Care Organization (ACO) model and the Advance Payment ACO model; the Primary Care Incentive Payment (PCIP) Program; the patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration; the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration; the Comprehensive Primary Care (CPC) initiative; and the HHS Strategic Framework on Multiple Chronic Conditions. We also noted that we were monitoring the progress of the AMA Chronic Care Coordination Workgroup in developing codes to describe care transition and care coordination activities, and proposed refinement of the PFS payment for post discharge care management services.

In the CY 2013 PFS final rule (77 FR 68978 through 68994), we finalized policies for payment of Transitional Care Management (TCM) services, effective January 1, 2013. We adopted two CPT codes (99495 and 99496) to report physician or qualifying nonphysician practitioner care management services for a patient following a discharge from an inpatient hospital or SNF, an outpatient hospital stay for observation or partial hospitalization services, or partial hospitalization in a community mental health center. As a condition for receiving TCM payment, a face-to-face visit was required.

In the CY 2014 PFS proposed rule (78 FR 43337 through 43343), we proposed to establish separate payment under the PFS for chronic care management (CCM) services and proposed a scope of services and requirements for billing and supervision. In the CY 2014 PFS final rule (78 FR 74414 through 74427), we finalized policies to establish separate

payment under the PFS for CCM services furnished to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline. In the CY 2015 PFS final rule (79 FR 67715 through 67730), additional billing requirements were finalized, including the requirement to furnish CCM services using a certified electronic health record or other electronic technology. Payment for CCM services was effective beginning on January 1, 2015, for physicians billing under the PFS.

b. RHC and FQHC Payment Methodologies

A RHC or FQHC visit must be a face-to-face encounter between the patient and a RHC or FQHC practitioner (physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker, and under certain conditions, an RN or LPN furnishing care to a homebound RHC or FQHC patient) during which time one or more RHC or FQHC services are furnished. A TCM service can also be a RHC or FQHC visit. A Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be a FQHC visit.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary medical and mental health services, and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B MAC calculates the AIR for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for those RHCs that have an exception to the payment limit. Services furnished incident to a RHC professional service are included in the per-visit payment and are not billed separately.

FQHCs have also been paid under the AIR methodology; however, on October 1, 2014, FQHCs began to transition to a FQHC PPS system in which they are paid based on the lesser of a national encounter-based rate or their total adjusted charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC

(vi) Qualified PLEs are required to re-apply. The application must be received by CMS by January 1 of the 5th year after the PLE's most recent approval date.

(d) *Endorsement.* Qualified PLEs may endorse the AUC set or individual criteria of other qualified PLEs, under agreement by the respective parties, in order to enhance an AUC set.

(e) *Identifying priority clinical areas.* (1) CMS identifies priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, the volume and variability of use of particular imaging services, and strength of evidence supporting particular imaging services. We will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.

(3) The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.

(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals (section 1834(q)(5) of the Act).

(f) *Identification of non-evidence-based AUC or other non-adherence to requirements for qualified PLEs.* (1) CMS will accept public comment to facilitate identification of AUC sets, subsets or individual criterion that are not evidence-based, giving priority to AUC associated with priority clinical areas and to AUC that conflict with one another. CMS may also independently identify AUC of concern.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

(3) If a qualified PLE is found non-adherent to the requirements in paragraph (c) of this section, CMS may terminate its qualified status or may consider this information during re-qualification.

■ 36. Section 414.605 is amended by revising the definition of “Basic life support (BLS)” to read as follows:

§ 414.605 Definitions.

* * * * *

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local

authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from State to State.

* * * * *

§ 414.610 [Amended]

■ 37. In § 414.610, amend paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) by removing the date “March 31, 2015” and adding in its place the date “December 31, 2017”.

■ 38. Section 414.904 is amended by revising paragraph (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(j) *Biosimilar biological products.* Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in § 414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in § 414.902).

■ 39. Section 414.1205 is amended by adding the definition of “Certified registered nurse anesthetist (CRNA)” and “Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS)” in alphabetical order to read as follows:

§ 414.1205 Definitions.

* * * * *

Certified registered nurse anesthetist (CRNA) has the same meaning given this term under section 1861(bb)(2) of the Act.

* * * * *

Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) have the same meanings given these terms under section 1861(aa)(5) of the Act.

* * * * *

■ 40. Section 414.1210 is amended by—

■ a. Revising paragraph (a)(4), (b)(2)(i)(B), (C), and (D), (b)(3), (b)(4), and (c).

■ b. Adding paragraphs (b)(2)(i)(E) and (F).

The revisions and additions read as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) * * *

(4) For the CY 2018 payment adjustment period, to nonphysician

eligible professionals who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 2 or more eligible professionals and to physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(b) * * *

(2) * * *

(i) * * *

(B) The quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under § 425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score.

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to –4% for groups of physicians with 10 or more eligible professionals and equal to –2% for groups of physicians with two to nine eligible professionals and for physician solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group of physician or physician solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment