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42 CFR Parts 403, 405, 410, et al.
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule

impact of allowing payment for secondary interpretation of images under other circumstances. Upon reviewing the comments received, we will consider whether any further action is appropriate, for instance, proposing under a future rulemaking to allow for payment of subsequent interpretations of advanced diagnostic images in lieu of duplicative studies.

J. Conditions Regarding Permissible Practice Types for Therapists in Private Practice

Section 1861(p) of the Act defines outpatient therapy services to include physical therapy, occupational therapy, and speech-language pathology services furnished by qualified occupational therapists, physical therapists, and speech-language pathologists in their offices and in the homes of beneficiaries. The regulations at §§ 410.59(c), 410.60(c), and 410.62(c) set forth special provisions for services furnished by therapists in private practice, including basic qualifications necessary to qualify as a supplier of occupational therapy (OT), physical therapy (PT), and speech-language pathology (SLP), respectively. As part of these basic qualifications, the current regulatory language includes descriptions of the various practice types for therapists' private practices. Based on our recent review of these three sections of our regulations, we are concerned that the language is not as clear as it could be—especially with regard to the relevance of whether a practice is incorporated. The regulations appear to make distinctions between unincorporated and incorporated practices, and some practice types are listed twice. Accordingly, we are proposing changes to the regulatory language to remove unnecessary distinctions and redundancies within the regulations for OT, PT, and SLP. We note that these proposed changes are for clarification only, and do not reflect any proposed change in our current policy.

To consistently specify the permissible practice types (a solo practice, partnership, or group practice; or as an employee of one of these) for suppliers of outpatient therapy services in private practice (for occupational therapists, physical therapists and speech-language pathologists), we propose to replace the regulatory text at § 410.59(c)(1)(ii)(A) through (E), § 410.60(c)(1)(ii)(A) though (E), and § 410.62(c)(1)(ii)(A) through (E).

K. Payments for Physicians and Practitioners Managing Patients on Home Dialysis

In the CY 2005 PFS final rule with comment period (69 FR 66357 through 66359), we established criteria for furnishing outpatient per diem ESRD-related services in partial month scenarios. We specified that use of per diem ESRD-related services is intended to accommodate unusual circumstances when the outpatient ESRD-related services would not be paid for under the monthly capitation payment (MCP), and that use of the per diem services are limited to the circumstances listed below.

- Transient patients—Patients traveling away from home (less than full month);
- Home dialysis patients (less than full month);
- Partial month where there were one or more face-to-face visits without the comprehensive visit and either the patient was hospitalized before a complete assessment was furnished, dialysis stopped due to death, or the patient received a kidney transplant.
- Patients who have a permanent change in their MCP physician during the month.

Additionally, we provided billing guidelines for partial month scenarios in the Medicare claims processing manual, publication 100–04, chapter 8, section 140.2.1. For center-based patients, we specified that if the MCP physician or practitioner furnishes a complete assessment of the ESRD beneficiary, the MCP physician or practitioner should bill for the full MCP service that reflects the number of visits furnished during the month. However, we did not extend this policy to home dialysis (less than a full month) because the home dialysis MCP service did not include a specific frequency of required patient visits. In other words, unlike the ESRD MCP service for center-based patients, a visit was not required for the home dialysis MCP service as a condition of payment.

In the CY 2011 PFS final rule with comment period (75 FR 73295 through 73296), we changed our policy for the home dialysis MCP service to require the MCP physician or practitioner to furnish at least one face-to-face patient visit per month as a condition of payment. However, we inadvertently did not modify our billing guidelines for home dialysis (less than a full month) to be consistent with partial month scenarios for center-based dialysis patients. Stakeholders have recently brought this inconsistency to our attention. After reviewing this issue, we are proposing to allow the MCP physician or practitioner to bill for the age appropriate home dialysis MCP service (as described by HCPCS codes 90963 through 90966) for the home dialysis (less than a full month) scenario if the MCP physician or practitioner furnishes a complete monthly assessment of the ESRD beneficiary and at least one face-to-face patient visit. For example, if a home dialysis patient was hospitalized during the month and at least one face-to-face outpatient visit and complete monthly assessment was furnished, the MCP physician or practitioner should bill for the full home dialysis MCP service. We believe that this proposed change to home dialysis (less than a full month) provides consistency with our policy for partial month scenarios pertaining to patients dialyzing in a dialysis center. If this proposal is adopted, we would modify the Medicare Claims Processing Manual to reflect the revised billing guidelines for home dialysis in the less than a full month scenario.

III. Other Provisions of the Proposed Regulations

A. Ambulance Extender Provisions

1. 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) of the Act have been extended several times. Recently, section 1104(a) of the Pathway for SGR Reform Act of 2013, enacted on December 26, 2013, as Division B (Medicare and Other Health Provisions) of Pub L. 113–67, amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above through March 31, 2014. Subsequently, section 104(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons again

through March 31, 2015. Thus, these payment add-ons also apply to covered ground ambulance transports furnished before April 1, 2015. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to these statutory requirements. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule (78 FR 74438 through 74439)).

These statutory requirements are 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.

2. 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 on the CMS-supplied ZIP code File.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Recently, section 1104(b) of the Pathway for SGR Reform Act of 2013, enacted on December 26, 2013, as Division B (Medicare and Other Health Provisions) of Public Law 113–67, amended section 1834(l)(12)(A) of the Act to extend this rural bonus through March 31, 2014. Subsequently, section 104(b) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted on April 1, 2014) amended section 1834(l)(12)(A) of the Act to extend this rural bonus again through March 31, 2015. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service before April 1, 2015 where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to these statutory requirements. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule (78 FR 74439 through 74440)).

These statutory provisions are self-implementing. Together, these statutory provisions require a 15-month extension of this rural bonus (which was previously established by the Secretary) through March 31, 2015, and do not require any substantive exercise of discretion on the part of the Secretary.

B. Proposed Changes in Geographic Area Delineations for Ambulance Payment

1. Background

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)

a. 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.

b. 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. Provisions of the Proposed Rule

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 urban and rural differences. This promotes consistency across the Medicare program, and it provides for use of consistent geographic standards for Medicare payment purposes.

The current geographic areas used under the ambulance fee schedule are based on OMB standards published on

December 27, 2000 (65 FR 82228 through 82238) and 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 (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, ''[t]his 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 on June 28, 2010, in the **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).

While the revisions OMB published on February 28, 2013 are not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2007, the February 28, 2013 OMB bulletin does contain a number of significant changes. For example, if we adopt the revised OMB delineations, there would be new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. Because the bulletin was not issued until February 28, 2013, with supporting data not available until later, and because the changes made by the bulletin and their ramifications needed to be extensively reviewed and verified, we were unable to undertake such a lengthy process before publication of the CY 2014 PFS proposed rule, and thus, did not implement the changes to the OMB delineations under the ambulance fee schedule for CY 2014. We have reviewed our findings and impacts relating to the new OMB delineations, and find no compelling reason to further delay implementation. We believe it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts.

Additionally, in the FY 2015 IPPS proposed rule (79 FR 28055), we also proposed to adopt OMB's revised delineations to identify urban areas and rural areas for purposes of the IPPS wage index. For the reasons discussed above, we believe it would be 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, we are proposing to implement the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 beginning in CY 2015 to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We 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), 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), would be recognized as rural areas.

In addition to the OMB's statistical area delineations, the current geographic areas used in the ambulance fee schedule also are based on the most recent version of the Goldsmith Modification. 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. These rural census tracts are considered rural areas under the ambulance fee schedule (see § 414.605). In the CY 2007 PFS final rule (71 FR 69714 through 69716), we adopted the most recent (at that time) version of the Goldsmith Modification, designated as Rural-Urban Commuting Area (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 (71 FR 69714 through 69716). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, 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 2006–10 American Community Survey. We are proposing to adopt the most recent modifications of the RUCA codes beginning in CY 2015, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the ambulance fee schedule. If we adopt the most recent RUCA codes, many counties that are designated as urban at the county level based on population would have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

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 (71 FR 69715), we would 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 (71 FR 69715), 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: *ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf* for additional information. Consistent with the HRSA guidelines discussed above, we are proposing, beginning in CY 2015, to designate as rural areas (1) those census tracts that fall at or above RUCA level 4.0, and (2) those census tracts that fall within RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. As discussed in the CY 2007 PFS final rule (71 FR 69715), we continue to believe that HRSA's guidelines accurately identify rural census tracts throughout the country, and thus would be appropriate to apply for ambulance payment purposes. We invite comments on this proposal.

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, and 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, 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.

Currently, section 1834(l)(12) of the Act (as amended by section 104(b) of the PAMA) specifies that, for services furnished during the period July 1, 2004 through March 31, 2015, 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). 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.

The adoption of the new OMB delineations and the updated RUCA codes would affect whether or not transports would be eligible for other 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)). Furthermore, under section 1834(l)(13) of the Act (as amended by section 104(a) of the PAMA), for ground ambulance transports furnished through March 31, 2015, 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)).

If we adopt OMB's revised delineations and the updated RUCA codes, 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 are currently within urban areas) may experience increases in payment for such transports because they may be eligible for the rural adjustment factors discussed above, while 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 are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed above.

The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. Based on the latest United States Postal Service (USPS) ZIP code file, there are a total of 42,914 ZIP codes in the U.S. The geographic designations for approximately 99.48 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes. There are a similar number of ZIP codes that would change from rural to urban (122, or 0.28 percent) and from urban to rural (100, or 0.23 percent). In general, it is expected that ambulance providers and suppliers in 100 ZIP codes within 11 states may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. The state of Ohio would have the most ZIP codes changing from urban to rural with a total of 40, or 2.69 percent. Ambulance providers and suppliers in 122 ZIP codes within 22 states may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. The state of West Virginia would have the most ZIP codes changing from rural to urban (17, or 1.82 percent), while Connecticut would have the greatest percentage of ZIP codes changing from rural to urban (15 ZIP codes, or 3.37 percent). Our findings are illustrated in Table 17.

TABLE 17—ZIP CODES ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State	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	0	0.00	0	0.00	854	100.00
AR	725	0	0.00	3	0.41	722	99.59
AS	1	0	0.00	0	0.00	1	100.00
AZ	569	0	0.00	0	0.00	569	100.00
CA	2723	0	0.00	0	0.00	2723	100.00
CO	677	0	0.00	0	0.00	677	100.00
CT	445	15	3.37	0	0.00	430	96.63
DC	301	0	0.00	0	0.00	301	100.00
DE	99	1	1.01	0	0.00	98	98.99
EK	63	0	0.00	0	0.00	63	100.00
EM	856	0	0.00	3	0.35	853	99.65
FL	1513	5	0.33	0	0.00	1508	99.67
FM	4	0	0.00	0	0.00	4	100.00
GA	1032	4	0.39	0	0.00	1028	99.61
GU	21	0	0.00	0	0.00	21	100.00
HI	143	0	0.00	0	0.00	143	100.00
IA	1080	5	0.46	0	0.00	1075	99.54
ID	335	0	0.00	0	0.00	335	100.00
IL	1628	0	0.00	0	0.00	1628	100.00
IN	1000	1	0.10	14	1.40	985	98.50
KY	1030	0	0.00	0	0.00	1030	100.00
LA	739	2	0.27	0	0.00	737	99.73
MA	751	0	0.00	4	0.53	747	99.47
MD	630	9	1.43	0	0.00	621	98.57
ME	505	0	0.00	0	0.00	505	100.00
MH	2	0	0.00	0	0.00	2	100.00
MI	1185	4	0.34	8	0.68	1173	98.99
MN	1043	1	0.10	0	0.00	1042	99.90
MP	3	0	0.00	0	0.00	3	100.00
MS	541	0	0.00	0	0.00	541	100.00
MT	411	0	0.00	0	0.00	411	100.00
NC	1101	12	1.09	5	0.45	1084	98.46
ND	418	0	0.00	0	0.00	418	100.00
NE	632	0	0.00	0	0.00	632	100.00
NH	292	0	0.00	0	0.00	292	100.00
NJ	747	0	0.00	0	0.00	747	100.00
NM	438	0	0.00	0	0.00	438	100.00
NV	257	0	0.00	0	0.00	257	100.00
NY	2246	4	0.18	0	0.00	2242	99.82
OH	1487	6	0.40	40	2.69	1441	96.91
OK	791	0	0.00	0	0.00	791	100.00
OR	494	6	1.21	0	0.00	488	98.79
PA	2244	8	0.36	0	0.00	2236	99.64
PR	177	0	0.00	0	0.00	177	100.00
PW	2	0	0.00	0	0.00	2	100.00
RI	91	0	0.00	0	0.00	91	100.00
SC	543	7	1.29	0	0.00	536	98.71
SD	418	0	0.00	0	0.00	418	100.00
TN	814	2	0.25	0	0.00	812	99.75
TX	2726	0	0.00	1	0.04	2725	99.96
UT	359	0	0.00	0	0.00	359	100.00
VA	1277	8	0.63	17	1.33	1252	98.04
VI	16	0	0.00	0	0.00	16	100.00
VT	309	0	0.00	0	0.00	309	100.00
WA	744	2	0.27	0	0.00	742	99.73
WI	919	3	0.33	0	0.00	916	99.67
WK	711	0	0.00	2	0.28	709	99.72
WM	342	0	0.00	0	0.00	342	100.00
WV	936	17	1.82	3	0.32	916	97.86
WY	198	0	0.00	0	0.00	198	100.00
Totals	42914	122	0.28	100	0.23	42692	99.48

We believe that 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 that use of the most current OMB delineations and RUCA codes under the ambulance fee schedule would enhance

the accuracy of ambulance fee schedule payments. We invite comments on our proposal to implement the new OMB delineations and the updated RUCA codes as discussed above beginning in CY 2015, for purposes of payment under the Medicare ambulance fee schedule.

C. Clinical Laboratory Fee Schedule

In the CY 2014 PFS final rule with comment period (78 FR 74440–74445, 74820), we finalized a process under which we would reexamine the payment amounts for test codes on the Clinical Laboratory Fee Schedule (CLFS) for possible payment revision based on technological changes beginning with the CY 2015 proposed rule, and we codified this process at § 414.511. After we finalized this process, Congress enacted the PAMA. Section 216 of the PAMA creates new section 1834A of the Act, which requires us to implement a new Medicare payment system for clinical diagnostic laboratory tests based on private payor rates. Section 216 of the PAMA also rescinds the statutory authority in section 1833(h)(2)(A)(i) of the Act for adjustments based on technological changes for tests furnished on or after April 1, 2014 (PAMA's enactment date). As a result of these provisions, we are not proposing any revisions to payment amounts for test codes on the CLFS based on technological changes and are proposing to remove § 414.511. Instead, we will establish through rulemaking the parameters for the collection of private payor rate information and other requirements to implement section 216 of the PAMA.

D. Removal of Employment Requirements for Services Furnished ''Incident to'' Rural Health Clinics (RHC) and Federally Qualified Health Center (FQHC) Visits

1. Background

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) furnish physicians' services; services and supplies incident to the services of physicians; nurse practitioner (NP), physician assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services; and services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs. They may also furnish diabetes self-management training and medical nutrition therapy (DSMT/MNT), transitional care management services, and in some cases, visiting nurse services furnished by a registered professional nurse or a licensed practical nurse. (For additional information on requirements for furnishing services in RHCs and FQHCs, see Chapter 13 of the CMS Benefit Policy Manual.)

In the May 2, 2014 final rule with comment period (79 FR 25436) entitled ''Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral,'' we removed the regulatory requirements that NPs, PAs, CNMs, CSWs, and CPs furnishing services in a RHC must be employees of the RHC. RHCs are now allowed to contract with NPs, PAs, CNMs, CSWs, and CPs, as long as at least one NP or PA is employed by the RHC, as required under section 1861(aa)(2)(iii) of the Act.

Services furnished in RHCs and FQHCs by nurses, medical assistants, and other auxiliary personnel are considered ''incident to'' a RHC or FQHC visit furnished by a RHC or FQHC practitioner. The regulations at § 405.2413(a)(6), § 405.2415(a)(6), and § 405.2452(a)(6) state that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC. Since there is no separate benefit under Medicare law that specifically authorizes payment to nurses, medical assistants, and other auxiliary personnel for their professional services, they cannot bill the program directly and receive payment for their services, and can only be remunerated when furnishing services to Medicare patients in an ''incident to'' capacity.

2. Provisions of Proposed Rule

To provide RHCs and FQHCs with as much flexibility as possible to meet their staffing needs, we are proposing to revise § 405.2413(a)(5), § 405.2415(a)(5) and § 405.2452(a)(5) and delete § 405.2413(a)(6), § 405.2415(a)(6) and § 405.2452(a)(6) to remove the requirement that services furnished incident to an RHC or FQHC visit must be furnished by an employee of the RHC or FQHC to allow nurses, medical assistants, and other auxiliary personnel to furnish incident to services under contract in RHCs and FQHCs. We believe that removing the requirements will provide RHCs and FQHCs with additional flexibility without adversely impacting the quality or continuity of care.

E. Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models

1. Background and Statutory Authority

Section 3021 of the Affordable Care Act amended the Social Security Act to include a new section 1115A, which established the Center for Medicare and Medicaid Innovation (Innovation Center). Section 1115A tasks the Innovation Center with testing innovative payment and service delivery models that could reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XX of the Act. The Secretary is also required to conduct an evaluation of each model tested.

Evaluations will typically include quantitative and qualitative methods to assess the impact of the model on quality of care and health care expenditures. To comply with the statutory requirement to evaluate all models conducted under section 1115A of the Act, we will conduct rigorous quantitative analyses of the impact of the model test on health care expenditures, as well as an assessment of measures of the quality of care furnished under the model test. Evaluations will also include qualitative analyses to capture the qualitative differences between model participants, and to form the context within which to interpret the quantitative findings. Through the qualitative analyses, we will assess the experiences and perceptions of model participants, providers, and individuals affected by the model.

In the evaluations we use advanced statistical methods to measure effectiveness. Our methods are intended to provide results that meet a high standard of evidence, even when randomization is not feasible. To successfully carry out evaluations of Innovation Center models, we must be able to determine specifically which individuals are receiving services from or are the subject of the intervention being tested by the entity participating in the model test. Identification of such individuals is necessary for a variety of purposes, including the construction of control groups against which model performance can be compared. In addition, to determine whether the observed impacts are due to the model being tested and not due to differences between the intervention and comparison groups, our evaluations will have to account for potential confounding factors at the individual level, which will require the ability to identify every individual associated

report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional's patients. Of these measures, report on at least 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, or efficiency/appropriate use.

(ii) [Reserved]

* * * * *

(m) * * *

(1) To request an informal review for reporting periods that occur prior to 2014, an eligible professional or group practice must submit a request to CMS within 90 days of the release of the feedback reports. To request an informal review for reporting periods that occur in 2014 and subsequent years, an eligible professional or group practice must submit a request to CMS within 30 days of the release of the feedback reports. The request must be submitted in writing and summarize the concern(s) and reasons for requesting an informal review and may also include information to assist in the review.

* * * * *

(3) If, during the informal review process, CMS finds errors in data that was submitted using a third-party vendor using either the qualified registry, EHR data submission vendor, or QCDR reporting mechanisms, CMS may allow for the resubmission of data to correct these errors on an ad-hoc basis.

(i) CMS will not allow resubmission of data submitted via claims, direct EHR, and the GPRO Web interface reporting mechanisms.

(ii) CMS will only allow resubmission of data that was already previously submitted to CMS.

(iii) CMS will only accept data that was previously submitted for the reporting periods for which the corresponding informal review period applies.

* * * * *

§ 414.511 [Removed]

■ 25. Section 414.511 is removed.

■ 26. Section 414.610 is amended by revising paragraphs (c)(1)(ii) introductory text and (c)(5)(ii) to read as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through March 31, 2015, ambulance services originating in:

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through March 31, 2015, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

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■ 27. Section 414.1200 is amended by revising paragraphs (a) and (b)(5) to read as follows:

§ 414.1200 Basis and scope.

(a) *Basis.* This subpart implements section 1848(p) of the Act by establishing a payment modifier that provides for differential payment starting in 2015 to a group of physicians and starting in 2017 to a group and a solo practitioner under the Medicare Physician Fee Schedule based on the quality of care furnished compared to cost during a performance period.

(b) * * *

(5) Additional measures for groups and solo practitioners.

* * * * *

■ 28. Section 414.1205 is amended by—

■ a. Revising the definitions of ''Group of physicians'' and ''Value-based payment modifier''.

■ b. Adding the definition of ''Solo practitioner'' in alphabetical order.

The addition and revisions read as follows:

§ 414.1205 Definitions.

* * * * *

Group of physicians (Group) means a single Taxpayer Identification Number (TIN) with 2 or more eligible professionals, as identified by their individual National Provider Identifier (NPI), who have reassigned their Medicare billing rights to the TIN.

* * * * *

Solo practitioner means a single TIN with 1 eligible professional as identified by an individual NPI billing under the TIN.

* * * * *

Value-based payment modifier means the percentage as determined under § 414.1270 by which amounts paid to a group or solo practitioner under the Medicare Physician Fee Schedule established under section 1848 of the Act are adjusted based upon a comparison of the quality of care furnished to cost as determined by this subpart.

■ 29. Section 414.1210 is amended by—

■ a. Adding paragraphs (a)(3) and (b)(2), (3), and (4).

■ b. Revising paragraph (c).

The additions and revision reads as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) * * *

(3) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, to physicians and eligible professionals in groups with 2 or more eligible professionals and to physicians and eligible professionals who are solo practitioners based on the performance period described at § 414.1215(c).

(b) * * *

(2) For the CY 2017 payment adjustment period and each subsequent payment adjustment period, the value-based payment modifier is applicable to physicians and eligible professionals in groups with 2 or more eligible professionals and to physicians and eligible professionals who are solo practitioners that participate in the Shared Savings Program. The value-based payment modifier for groups and solo practitioners that participate in the Shared Savings Program during the payment adjustment period is determined based on paragraphs (b)(2)(i) through (iv) of this section. For groups and solo practitioners that participate in the Shared Savings Program during the performance period, but do not participate in the Shared Savings Program during the payment adjustment period, the quality composite is classified as ''average'' under § 414.1275(b)(1) and the cost composite score is calculated under § 414.1260(b) based on performance on the cost measures identified under § 414.1235 during the performance period.

(i) The cost composite is classified as ''average'' under § 414.1275(b)(2) for the payment adjustment period.

(ii) The quality composite score is calculated under § 414.1260(a) using quality data from the ACO in which the groups and solo practitioners participate during the payment adjustment period, as collected under § 425.500 of this chapter for the performance period.

(iii) If the ACO did not exist during the performance period, then the quality composite for the groups and solo