

rural and urban status and allow all interested parties to provide comments on the proposal. In addition to delaying implementation, the commenter suggested implementing a 4-year transition that would phase-in the payment reduction over a specified period for those ZIP codes losing rural status.

Other commenters requested that the implementation of the geographic adjustments outlined in the proposed rule be delayed until such time as the data is available to complete a full and accurate analysis of the ZIP codes affected and the financial impact to industry. Absent such a delay, the commenters stated that the final rule must clarify, in a complete and transparent manner, the accuracy of the analysis used in the proposed rule.

*Response:* We believe that ambulance providers and suppliers had sufficient notice of and opportunity to comment on the proposed adoption of the revised OMB delineations and the updated RUCA codes under the ambulance fee schedule, and thus we do not believe a delay in implementation is warranted. In the proposed rule, we proposed to adopt the revised OMB delineations as set forth in OMB Bulletin No. 13-01 and the updated RUCA codes for purposes of payment under the ambulance fee schedule consistent with the policy we implemented in CY 2007 (see the CY 2007 PFS final rule (71 FR 69713 through 69716)). We explained in the proposed rule that the adoption of the revised OMB delineations and updated RUCA codes would affect the urban/rural designation of certain areas, and thus would affect whether transports in certain areas would be eligible for rural adjustments under the ambulance fee schedule. In addition, OMB Bulletin No. 13-01 was available on February 28, 2013, and contained additional information regarding the changes in OMB geographic area delineations. As discussed above, the ZIP code analysis set forth in the proposed rule reflected the impact of the revised OMB delineations. The 2010 RUCA codes and definitions were available on December 31, 2013 on the U.S. Department of Agriculture's Economic Research Service's Web site, which provided ambulance providers and suppliers with additional information regarding changes to the level of rurality in census tracts. Furthermore, section 1834(l) requires that we use the most recent modification of the Goldsmith Modification to determine rural census tracts for purposes of certain rural additions, and our established policy, as set forth in § 414.605, is that rural areas include rural census tracts as

determined under the most recent version of the Goldsmith modification.

As discussed above and in the CY 2015 PFS proposed rule, 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. We believe that 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 do not believe a delay in implementation or a transition period would be appropriate. Areas that lose 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 believe a delay would disadvantage the ambulance providers or suppliers experiencing payment increases based on these updated and more accurate OMB delineations and RUCA codes.

Finally, given the relatively small percentage of ZIP codes affected by the revised OMB delineations and updated RUCA codes (a total of 3,425 ZIP codes changing their urban/rural status out of 42,918 ZIP codes, or 7.98 percent), we do not believe that a delay is warranted. As commenters requested, we have included in Table 47 our updated analysis of the impact of adopting the revised OMB delineations and the updated RUCA codes.

*Comment:* One commenter recommended that if any ZIP codes would lose their super rural status as a result of the proposed adoption of the revised OMB delineations and the updated RUCA codes, then CMS should grandfather the current super rural ZIP codes. Another commenter stated that the ambulance providers must have verification from CMS that the super rural ZIP codes will not be affected by the changes described in the proposed rule in advance of their implementation in the final rule.

*Response:* As we stated previously, the adoption of the OMB's revised delineations and the updated RUCA codes will have no negative impact on

ambulance transports in super rural areas, as none of the current super rural areas will lose their status upon implementation of the revised OMB delineations and the updated RUCA codes. Current areas designated as super rural areas will continue to be eligible for the super rural bonus.

After consideration of the public comments received, and for the reasons discussed above, we are finalizing our proposals to adopt, 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 RUCA codes for purposes of payment under the ambulance fee schedule. As we proposed, using the updated RUCA codes definitions, we will continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas. However, as discussed above, we are not finalizing our proposal to designate as rural those census tracts that fall within RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. Finally, as discussed above, 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.

### C. Clinical Laboratory Fee Schedule

In the CY 2014 PFS final rule with comment period (78 FR 74440 through 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, the 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 did not propose any revisions to payment amounts for test codes on the CLFS based on technological changes, and we proposed to remove § 414.511.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to remove § 414.511. In addition, 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 coverage requirements for services furnished in RHCs and FQHCs, see Chapter 13 of the CMS Benefit Policy Manual.)

In the May 2, 2014 final rule with comment period 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” (79 FR 25436), 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 clause (iii) in the first sentence of the flush material following subparagraph (K) of section 1861(aa)(2) 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. Sections 405.2413(a)(6), 405.2415(a)(6), and 405.2452(a)(6) currently 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.

To provide RHCs and FQHCs with as much flexibility as possible to meet their staffing needs, we proposed 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, in order 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.

We received 23 comments on our proposal. The following is a summary of the comments received.

*Comment:* Most commenters were strongly in favor of removing these employment requirements. Several commenters stated that this flexibility will assist RHCs and FQHCs in increasing access to care, enable them to recruit highly qualified health professionals, and fill temporary staffing voids without adversely impacting the quality of care. Some commenters expressed concerns about maintaining professional standards, and others were concerned about the potential loss of benefits for contracted staff.

A few commenters stated that they support removal of the employment requirement, provided that RHC and FQHC auxiliary personnel are held to the same high professional standards for the quality of care, regardless of whether they are working under contract or as employees. Commenters also added that all members of a physician-led health care team should be enabled to perform medical interventions that they are capable of performing according to their education, training, licensure, and experience.

*Response:* The proposal to remove the requirement that auxiliary workers in RHCs and FQHCs be employees of the RHC or FQHC does not change either their professional standards of care or their scope of practice. Nurses, medical assistants, and other auxiliary personnel are expected to maintain their professional standards of care and furnish services in adherence to their scope of practice, regardless of whether they are employed or contracted by the RHC or FQHC.

*Comment:* Some commenters stated that although they understand the need for greater staffing flexibility, they were concerned about the potential loss of benefit packages to individuals that are contracted and not employed. The commenters questioned whether the issue was investigated or vetted, and how RHCs and FQHCs would compensate for this loss of compensation for individuals providing incident to services under contract rather than as an employee.

*Response:* We appreciate the concern that these commenters raised regarding the potential loss of benefit packages for contracted individuals; however, we do not regulate employment agreements or benefit packages for individuals working at RHCs and FQHCs.

After consideration of the public comments, we are finalizing this provision as proposed.

*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 XXI 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