DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, 421, 423, 425, 486, and 495

[CMS-1590-FC]

RIN 0938-AR11

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013

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, payments for Part B drugs, 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. It also implements provisions of the Affordable Care Act by establishing a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items. In addition, it implements statutory changes regarding the termination of non-random prepayment review. This final rule with comment period also includes a discussion in the Supplementary Information regarding various programs . (See the Table of Contents for a listing of the specific issues addressed in this final rule with comment period.)

DATES: Effective date: The provisions of this final rule with comment period are effective on January 1, 2013 with the exception of provisions in §410.38 which are effective on July 1, 2013. The incorporation by reference of certain publications listed in the rule was approved by the Director of the Federal Register on May 16, 2012.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR—insert date 60 days after the date of filing for

However, because this new code was added through an NCD effective as of October 14, 2011, public commenters, including the AMA RUC, were not able to comment for consideration for CY 2012. We note that since this code was valued in CY 2012 based upon CPT code 97803 and AMA RUC had provided recommendation on this code previously, the AMA RUC was involved, albeit indirectly, in setting this rate. In addition, there was opportunity for the AMA RUC to provide comment on this code in the response to the solicitation for comment on the CY 2013 proposed rule.

After the consideration of the public comments we received, we are finalizing the proposed work RVU of 0.45 and a time of 15 minutes for HCPCS G0447 code. For malpractice expense, we are finalizing our proposal to crosswalk HCPCS code G0447 to CPT code 97803. We are also finalizing the direct PE inputs as proposed. The direct PE inputs associated with this code are included in the CY 2013 direct PE input database, available on the CMS website under the downloads for the CY 2013 PFS final rule with comment period at http://www.cms.gov/PhysicianFeeSched/. Additionally, we note that the PE RVUs included in Addendum B reflect the values that result from the finalization of this policy.

K. Certified Registered Nurse Anesthetists Scope of Benefit

The benefit category for services furnished by a certified registered nurse anesthetist (CRNA) was added in section 1861(s)(11) of the Act by section 9320 of the Omnibus Budget Reconciliation Act (OBRA) of 1986. Since this benefit was implemented on January 1, 1989, CRNAs have been eligible to bill Medicare directly for services within this benefit category. Section 1861(bb)(2) of the Act defines a CRNA as "a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists."

Section 410.69(b) defines a CRNA as a registered nurse who: (1) is licensed as a registered professional nurse by the State in which the nurse practices; (2) meets any licensure requirements the State imposes with respect to nonphysician anesthetists; (3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and (4) meets one of the following criteria: (i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or (ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

Section 1861(bb)(1) of the Act defines services of a CRNA as "anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished." CRNAs are paid at the same rate as physicians for furnishing such services to Medicare beneficiaries. Payment for services furnished by CRNAs only differs from physicians in that payment to CRNAs is made only on an assignment-related basis (§414.60) and supervision requirements apply in certain circumstances.

At the time that the Medicare benefit for CRNA services was established, anesthesia practice, for anesthesiologists and CRNAs, largely occurred in the surgical setting and services other than anesthesia (medical and surgical) were furnished in the immediate pre- and post-surgery timeframe. The scope of "anesthesia services and related care" as delineated in section 1861(bb)(1) of the Act reflected that practice. As anesthesiologists and CRNAs have moved into other practice settings, questions have arisen regarding what services are encompassed under the benefit category's characterization of "anesthesia and related care." As an example, some

CRNAs now offer chronic pain management services that are separate and distinct from a surgical procedure. We recently received additional information about upcoming changes to CRNA curricula to include specific training regarding chronic pain management services. Such changes in CRNA practice have prompted questions as to whether these services fall within the scope of section 1861(bb)(1) of the Act.

As we noted in the CY 2013 proposed rule (77 FR 44788), Medicare Administrative Contractors (MACs) have reached different conclusions as to whether the statutory benefit category description of "anesthesia services and related care" encompasses the chronic pain management services furnished by CRNAs. The scope of the benefit category determines the scope of services for which a physician, practitioner, or supplier may receive Medicare payment. In order for the specific services to be paid by Medicare, the services must be reasonable and necessary for treatment of the patient's illness or injury.

To address what is included in the benefit category for CRNAs in the CY 2013 proposed rule, we assessed our current regulations and subregulatory guidance, and determined that the existing guidance does not specifically address whether chronic pain management is included in the CRNA benefit. In the Internet Only Manual (Pub 100-04, Ch 12, Sec 140.4.3), we discuss the medical or surgical services that fall under the "related care" language stating: "These may include the insertion of Swan Ganz catheters, central venous pressure lines, pain management, emergency intubation, and the pre-anesthetic examination and evaluation of a patient who does not undergo surgery." Some have interpreted the reference to "pain management" in this language as authorizing direct payment to CRNAs for chronic pain management services, while others have taken the view that the services highlighted in the manual language are services furnished in the perioperative setting and refer only to acute pain management associated with the surgical procedure.

After assessing in the proposed rule (see 77 FR 44788) the information available to us, we concluded that chronic pain management was an evolving field, and we recognized that certain states have determined that the scope of practice for a CRNA should include chronic pain management to meet health care needs of their residents and ensure their health and safety. We also found that several states, including California, Colorado, Missouri, Nevada, South Carolina, and Virginia, were debating whether to include pain management in the CRNA scope of practice. After determining that the scope of practice for CRNAs was evolving and that there was not a clear answer on pain management specifically, we proposed to revise our regulations at §410.69(b) to define the statutory benefit for CRNA services with deference to state scope of practice laws. Specifically, we proposed to add the following language: "Anesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished." We explained that this proposed definition would set a Medicare standard for the services that can be furnished and billed by CRNAs while allowing appropriate flexibility to meet the unique needs of each state. The proposal also dovetailed with the language in section 1861(bb)(1) of the Act requiring the state's legal authorization to furnish CRNA services as a key component of the CRNA benefit category. Finally, we stated that the proposed benefit category definition was also consistent with our policy to recognize state scope of practice as defining the services that can be furnished and billed by other NPPs.

The following is a summary of the comments we received regarding the proposal to revise our regulations at §410.69(b) to define the statutory description of CRNA services. We received a significant volume of comments from specialty groups, individual physicians, and practitioners, including CRNAs and Student Registered Nurse Anesthetists (SRNAs), educational program directors, and patients, who strongly supported defining the CRNA benefit broadly. There were also many commenters who strongly opposed this proposal, including

specialty groups, individual physicians and practitioners, patients, educational program directors, and a patient advocacy group.

Comment: Among those supporting the concept of our proposal, we received several comments suggesting alternative regulatory definitions of the statutory benefit category phrase, "anesthesia and related care." Many commenters said that CMS should allow CRNAs to practice to the full extent of state law. Some commenters provided alternative definitions for anesthesia and related care. These included "medical and surgical services that are related to anesthesia or that a CRNA is legally authorized to perform by the State in which the services are furnished," "medical and surgical services that are related to anesthesia, including chronic pain management services unless specifically prohibited or outside the scope of the CRNA's license to practice," "medical services, surgical services, and chronic and acute pain management services that a CRNA is legally authorized to perform by the State in which the services are furnished," "medical and surgical services a CRNA is legally authorized to perform by the state in which services are furnished and which are done to provide surgical or obstetrical anesthesia or alleviate post-operative or chronic pain," and "medical and surgical services that are related to anesthesia, including chronic pain management, unless a CRNA is legally prohibited to perform by the State in which the services are furnished." One commenter made the point that Medicare should use a definition that included coverage of advanced practice registered nurse services that are within the scope of practice under applicable state law, just as physicians' services are now covered.

Other commenters referenced preamble text in our 1992 final rule, which states "we describe related care services as… pain management services, and other services not directly connected with the anesthesia service or associated with the surgical service" and noted that historically, related care services have been recognized as a different class of anesthesia services, which may or may not be related to anesthesia. One commenter requested that we define

“related care” separately from anesthesia, as "medical and surgical services not directly related to anesthesia, including but not limited to the insertion of arterial lines, central venous pressure lines, and Swan Ganz catheters, acute and chronic pain management and emergency intubation, and that a CRNA is legally authorized to perform by the state in which the services are furnished."

Some commenters pointed to Medicare policies allowing other advanced practice nurses such as nurse practitioners or clinical nurse specialists to furnish and bill for physicians’ services as support for recognizing a similar interpretation of the scope of CRNA practice. Commenters stated that CRNAs should be able to practice to the full extent of state law. Commenters cited the Institute of Medicine report [The Future of Nursing: Leading Change, Advancing Health, 11/17/10] that stated that nurses should be able to practice to the full extent of their education and training.

Our proposal to define related care as “related to anesthesia” resulted in various views as to whether this would include pain management and other services. Some stated that it restricted the benefit category, but others believed that it expanded it. The commenters further stated that there are no chronic, long-term, anesthesia related services that occur outside the operating room or recovery room where the practice of anesthesia is appropriate. Others stated that chronic pain management services are outside the scope of perioperative related care defined in the Act, and that chronic pain is not related to anesthesia.

Response: After reviewing comments regarding our proposed definition of “anesthesia and related care,” we believe that the proposed regulation language stating that “Anesthesia and related care includes medical and surgical services that are related to anesthesia and that a CRNA is legally authorized to perform by the state in which the services are furnished” would not accomplish our goals. It would require updating as health care evolves and as CRNA practice changes. It also would continue Medicare’s differentiation between CRNAs and other NPPs

because the Medicare benefit for other NPPs relies more heavily on the NPPs' authority under state law. In addition, we agree with commenters that the primary responsibility for establishing the scope of services CRNAs are sufficiently trained and, thus, should be authorized to furnish, resides with the states. We agree with commenters that, as CRNA training and practice evolve, the state scope of practice laws for CRNAs serve as a reasonable proxy for what constitutes "anesthesia and related care." Therefore, we are revising §410.69(b) to define the statutory benefit category for CRNAs, which is specified as "anesthesia and related care," as "those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished." By this action, we are defining the Medicare benefit category for CRNAs as including any services the CRNA is permitted to furnish under their state scope of practice. In addition, this action results in CRNAs being treated similarly to other advanced practice nurses for Medicare purposes. This policy is consistent with the Institute of Medicine's recommendation that Medicare cover services provided by advanced practice nurses to the full extent of their state scope of practice. CMS will continue to monitor state scope of practice laws for CRNAs to ensure that they do not expand beyond the appropriate bounds of "anesthesia and related care" for purposes of the Medicare program.

Comment: Some commenters suggested that the proposal expands the scope of practice of CRNAs into the practice of medicine, and that the proposal undermines medical education, the practice of medicine, and the pain medicine specialty by equating nurses with physicians. Commenters further stated that such proposals, which lead to privileging and reimbursement for nonphysician practitioners that are identical to that of physicians, decrease the incentives to complete the rigorous training involved in medical school. Others stated that the proposal would interfere with the authority of states to regulate scope of practice.

Response: We acknowledge the concerns of the physician community; however, the intent of the proposal is not to undermine medical education, the practice of medicine, or the pain

medicine specialty, but to establish parity between the scope of the Medicare benefit category for CRNAs and the CRNA authority to practice under state law. This proposal does not address payment rates for anesthesiologists or CRNAs. The statutory provisions that establish payment rates for CRNAs at the same rate as anesthesiologists are relatively longstanding. Our proposal in no way is intended to interfere with the authority of individual states; rather, it largely defers to individual states to determine the scope of practice for CRNAs. We believe that using state scope of practice law as a proxy for services encompassed in the statutory benefit language "anesthesia and related care" is preferable to choosing among individual interpretations of whether particular services fall within the scope of "anesthesia and related care." Moreover, we believe states are in an ideal position to gauge the status of, and respond to changes in, CRNA training and practice over time that might warrant changes in the definition of the scope of "anesthesia services and related care" for purposes of the Medicare program. As such, we believe it is appropriate to look to state scope of practice law as a proxy for the scope of the CRNA benefit.

Comment: Many commenters addressed the extent to which the standards for nurse anesthesia curricula and the content of nurse anesthesia educational programs do or do not prepare CRNAs to practice outside the perioperative setting, and specifically, to furnish chronic pain services. We received detailed comments regarding the necessary components of chronic pain services and conflicting information about whether CRNAs are trained or licensed to furnish such services. We received thorough descriptions of the skills required to furnish chronic pain services and the necessity of medical education to prepare one to furnish such services. Commenters also provided information about the inherent dangers involved in chronic pain services, the manner in which technical skills in chronic pain procedures are obtained, and the ways in which chronic pain services are or are not similar to other procedures performed by CRNAs in the perioperative setting and for labor epidurals. We received many comments from

the physician community with concerns about the possibility of the furnishing of procedures that are not indicated due to lack of medical knowledge required to screen out patients who are not appropriate candidates for procedures.

Some commenters pointed to the long period of time during which CRNAs have furnished chronic pain services with no documented differences in patient outcomes, while others expressed concern about negative outcomes observed from inadequately trained providers. Descriptions were also provided regarding lawsuits at the state level that have debated whether CRNAs are qualified to furnish chronic pain services, the importance of medical regulation in protecting patients who may not be able to differentiate between different types of providers, and the role of the medical education process in ensuring competency of physicians. Other commenters opined that it is the responsibility of the individual provider to assure his or her competency for any and all procedures furnished.

Response: We acknowledge the varying perspectives about the education and training of CRNAs to furnish chronic pain management services as well as differences of opinion regarding the safety of chronic pain management services furnished by CRNAs. We are unable, at this time, to assess the appropriateness of the CRNA training relating to specific procedures. We are also unaware of any data regarding the safety of chronic pain management services when furnished by different types of professionals. However, we expect that states take into account all appropriate practitioner training and certifications, as well as the safety of their citizens, when making decisions about the scope of services CRNAs are authorized to furnish and providing licenses to individual practitioners in their jurisdictions.

We note that we did not address the services that CRNAs are trained and qualified to furnish in our proposal or in this final rule with comment period. Our proposal and this final rule merely define what services are included in the scope of the Medicare benefit established in section 1861(bb)(1) of the Act. The definition that we are adopting uses the state scope of

practice as a proxy for what the term “anesthesia and related care” in section 1861(bb)(1) of the Act means and thus leaves decisions about what services constitute anesthesia and related care to be resolved by the state. This appropriately recognizes the actions of state bodies formed specifically to address the issue of what constitutes the scope of practice for a CRNA. We believe that determining whether or not CRNAs are adequately trained and can safely furnish chronic pain management is an appropriate decision for state bodies. This proposal is consistent with the Institute of Medicine’s report on advanced practice nursing, which recommends that Medicare should “include coverage of advanced practice registered nurse services that are within the scope of practice under applicable state law, just as physicians’ services are now covered."

We agree with commenters that it also is the responsibility of individual practitioners (physicians and CRNAs) to ensure that they are adequately trained and qualified to furnish any and all procedures that they furnish.

Comment: We received comments about the cost of CRNA services relative to those furnished by anesthesiologists. Commenters stated that chronic pain management services are less costly than surgical interventions, and that the services of CRNAs are more cost-effective for the Medicare program. Others stated that allowing CRNAs to furnish these services could increase spending due to the provision of inappropriate services and the complications that could result from procedures furnished by CRNAs who are not adequately trained.

Response: We do not have sufficient evidence to determine that chronic pain management interventions reduce the need for surgical interventions, or that there would be increased provision of inappropriate services and complications under a definition of the Medicare benefit category that defines “anesthesia and related care” as services a CRNA is authorized to furnish in his or her state. Spending for services under Medicare is not a factor in determining whether the statutory benefit encompasses particular services. However, we would note that CRNAs are generally paid at the same rate as anesthesiologists so there are no direct

cost savings when services are furnished by CRNAs.

Comment: We received comments regarding special concerns about access in rural areas. Commenters stated that CRNAs help patients avoid traveling long distances and long waits for appointments by having local providers available. Furthermore, commenters noted that as the population ages, the demand for chronic pain management services will increase. Commenters stated that decreased access to chronic pain management services (which would result if CRNAs are not permitted to furnish and bill for these services) would result in more institutionalization, reduced quality of life, longer wait times, and increased costs. Others stated that chronic pain management services are not emergent care services; that chronic pain management is a specialty that should be furnished by those with a high degree of sub-specialty training, and that pain physicians can be spread out over large areas since only a small minority of patients need procedural care. Some commenters cited a shortage of pain management physicians qualified to treat chronic pain, others stated that there is no shortage of such providers, while still others stated that the proposal may increase access, but at the expense of having unqualified providers. Finally, some commenters stated that procedures furnished improperly pose a greater danger than a lack of available services.

Response: While assuring access for beneficiaries in rural areas is a priority for Medicare, we do not have sufficient data to evaluate the presence or degree of problems of access to chronic pain management services in rural areas. We also do not have evidence that CRNAs have furnished chronic pain management services in quantities sufficient to improve any access problems in rural areas. We further lack sufficient data to determine whether beneficiaries who lack access to a CRNA care are more likely to suffer the negative outcomes cited by commenters. This lack of information does not deter us taking action to define the statutory benefit as it is not necessary to conclude that beneficiaries will suffer negative consequences to prompt us to act. Rather we are issuing this regulation based upon the factors we described

above.

Comment: We received comments regarding those services included in the definition of anesthesia and related care, as well as services "related to anesthesia." Some commenters stated that chronic pain management services are not directly "related to anesthesia" but still constitute "related care". Other commenters stated that CMS has already acknowledged in early preamble language that CRNAs may furnish services not directly related to anesthesia. Still other commenters stated that chronic pain services are not related to anesthesia in any way. One commenter suggested that CMS has already differentiated between anesthesia related acute pain and interventional chronic pain based on the creation of different specialty codes for anesthesia and chronic pain. One commenter requested that CMS make a regulatory change to allow CRNAs to order diagnostic tests in order to effectively provide chronic pain management services.

Response: We believe that the statutory intent was to include services not directly related to the peri-anesthetic setting in the CRNA benefit category. We believe that relying on state scope of practice to define the services encompassed in anesthesia and related care is preferable to choosing among conflicting definitions of "anesthesia and related care" or listing the specific services that fall within that benefit category. Rather, we believe states are in a better position to gauge the status of, and respond to changes in, CRNA training and practice over time that might warrant changes in the definition of the scope of "anesthesia services and related care" for purposes of the Medicare program. As such, we believe it is appropriate to look to state scope of practice law as a proxy for the scope of the CRNA benefit.

Comment: Several commenters expressed concern with the wording of our proposal; specifically, that the term "related to anesthesia" was unclear and subject to interpretation. States do not typically define services "related to anesthesia" in their state scope of practice acts.

Response: We agree with commenters that the wording of the proposal was unclear. In

response to these and other commenter concerns, we are adopting a modification of our proposal to rely on state scope of practice to define the services encompassed in "anesthesia and related care" under section 1861(bb)(1) of the Act.

Comment: One commenter requested that we provide clarification for the payment of CRNA services furnished; specifically, which medical and/or surgical CRNA services are eligible for cost-based reimbursement (for CRNA pass-through payments or Method II billing for Critical Access Hospitals).

Response: We will be modifying the Internet Only Manual to reflect the change we are making in this final rule with comment period. The request for the list of services that are eligible for cost-based reimbursement is beyond the scope of this rule, as it pertains to hospital billing. We anticipate this matter will be addressed separately in a forthcoming transmittal.

Comment: Commenters requested that CMS instruct Medicare contractors to review prior denials of claims for CRNA services prior to any final rule determination of the scope of the CRNA Medicare benefit category.

Response: This definition of the Medicare benefit for CRNAs will be effective for services furnished on or after January 1, 2013. It does not apply to services furnished prior to this point so we will not be instructing contractors to review prior denials of claims.

After consideration of all comments, we are finalizing our proposal with modification to revise our regulations at §410.69(b) to define "Anesthesia and related care" under the statutory benefit for CRNA services as follows: "Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished." We will continue to monitor the state scope of practice laws for CRNAs in order to insure that the use of state scope of practice as a proxy to define "anesthesia services and related care" is consistent with the goals and needs of Medicare program.

L. Ordering of Portable X-Ray Services

D. Effect of Proposed Changes to Medicare Telehealth Services Under the PFS

As discussed in section III.E.3 of this final rule with comment period, we are finalizing our proposal to add several new codes to the list of Medicare telehealth services. While we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the additions.

E. Effect of Proposed Definition of Certified Registered Nurse Anesthetists' (CRNA) Services

As discussed in section III.K.1. of this final rule with comment period, we clarified that "anesthesia and related care", with respect to the statutory benefit category for CRNAs under Section 1861(bb)(2) of the Social Security Act, means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the service is furnished.

.Our final rule clarification recognizes local variation in state scope of practice, which does not diverge significantly from current practice. Therefore, we estimate no significant budgetary impact from this proposed change.

F. Effects of Proposed Change to Ordering Requirements for Portable X-Ray Services Under the PFS

As discussed in section III.K.2. of this final rule with comment period, we are finalizing our proposal to revise our current regulation that limits ordering of portable x-ray services to only a doctor of medicine or a doctor of osteopathy to allow other physicians and nonphysician practitioners (acting within the scope of state law and their Medicare benefit) to order portable x-ray services. We estimated no significant impact on PFS expenditures from the additions.

G. Geographic Practice Cost Indices (GPCIs)

As discussed in section III.E. of this final rule with comment period, we are required to

§410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

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(a) * * *

(1) * * *

(viii) Persons diagnosed with diabetes mellitus.

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12. Section 410.69 is amended in paragraph (b) by adding the definition of "Anesthesia and related care" in alphabetical order to read as follows:

§410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

* * * * *

(b) * * *

Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.

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13. Section 410.78 is amended by revising the introductory text of paragraph (b) to read as follows:

§410.78 Telehealth services.

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(b) General rule. Medicare Part B pays for office or other outpatient visits, subsequent hospital care services (with the limitation of one telehealth visit every 3 days by the patient's admitting physician or practitioner), subsequent nursing facility care services (not including the Federally-mandated periodic visits under §483.40(c) of this chapter and with the limitation of one telehealth visit every 30 days by the patient's admitting physician or nonphysician