**2016 Physician Fee Schedule Proposed Rule**

**Excerpts for Quality Measures Task Force Review**

The proposed rule is currently on display and can be accessed at: <https://www.federalregister.gov/articles/2015/07/15/2015-16875/medicare-programs-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>

Note that key proposals and questions for comment are highlighted in the below text excerpts.

Key Sections of the Rule for Task Force Review

* **Appropriate Use Criteria for Advanced Diagnostic Imaging Services (pages 352 – 369 pdf display version)**

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. This proposed rule outlines the initial component of the new Medicare AUC program and our plan for implementing the remaining components.

1. Background

In general, AUC are a set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context.

We believe the goal of this statutory AUC program is to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging.

Professional medical societies, health systems, and academic institutions have been designing and implementing AUC for decades. Experience and published studies alike show that results are best when AUC are built on an evidence base that considers patient health outcomes, weighing the benefits and harms of alternative care options, and integrated into broader care management and continuous quality improvement (QI) programs. Successful QI programs in turn have provider-led multidisciplinary teams collectively identify key clinical processes and then develop bottom-up, evidence-based AUC or guidelines that are embedded into clinical workflows, and become the organizing principle of care delivery (Aspen 2013). Feedback loops, an essential component, compare provider performance and patient health outcomes to individual, regional and national benchmarks.

 There is also consensus that AUC programs built on evidence-based medicine and applied in a QI context are the best method to identify appropriate care and eliminate inappropriate care, and are preferable to across-the-board payment reductions that do not differentiate interventions that add value from those that cause harm or add no value.
2. Previous AUC Experience

The first CMS experience with AUC, the Medicare Imaging Demonstration (MID), was required by section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Designed as an alternative to prior authorization, the MID’s purpose was to examine whether provider exposure to appropriateness guidelines would reduce inappropriate utilization of advanced imaging services. In the 2-year demonstration which began in October 2011, nearly

4,000 physicians, grouped into one of five conveners across geographically and organizationally diverse practice settings, ordered a total of nearly 50,000 imaging studies1.

In addition to the outcomes of the MID (http://www.rand.org/content/dam/rand/pubs/research\_reports/RR700/RR706/RAND\_RR706.pd

f), we considered others’ experiences and results from implementation of imaging AUC and other evidence-based clinical guidelines at healthcare organizations such as Brigham &

Women’s, Intermountain Healthcare, Kaiser, Massachusetts General Hospital, and Mayo, and in states such as Minnesota. From these experiences, and analyses of them by medical societies and others, general agreement on at least two key points has emerged. First, AUC, and the clinical decision support (CDS) mechanisms through which providers access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery.

Second, the ideal AUC is an evidence-based guide that starts with a patient’s specific clinical condition or presentation (symptoms) and assists the provider in the overall patient workup, treatment and follow-up. Imaging would appear as key nodes within the clinical management decision tree. The end goal of using AUC is to improve patient health outcomes. In reality, however, many providers may encounter AUC through a CDS mechanism for the first time at the point of image ordering. The CDS would ideally bring the provider back to that specific clinical condition and work-up scenario to ensure and simultaneously document the appropriateness of the imaging test.

However, there are different views about how best to roll out AUC into clinical practice.

One opinion is that it is best to start with as comprehensive a library of individual AUC as possible to avoid the frustration, experienced and voiced by many practitioners participating in the MID, of spending time navigating the CDS tool only to find that, about 40 percent of the time, no AUC for their patient’s specific clinical condition existed. The other opinion is that, based on decades of experience rolling out AUC in the context of robust QI programs, it is best to focus on a few priority clinical areas (for example, low back pain) at a time, to ensure that providers fully understand the AUC they are using, including when they do not apply to a particular patient. This same group also believes, based on experience with the MID, that too many low-evidence alerts or rules simply create “alert fatigue.” They envision that, rather than navigating through a CDS to find relevant AUC, providers would simply enter the patient’s condition and a message would pop up stating whether AUC existed for that condition.

We believe there is merit to both approaches, and it has been suggested to us that the best approach may depend on the particular care setting. The second, “focused” approach may work better for a large health system that produces and uses its own AUC. The first, “comprehensive” approach may in turn work better for a smaller practice with broad image ordering patterns and fewer resources that wants to simply adopt and start using from day one a complete AUC system developed elsewhere. We believe a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee competing sets of AUC developed by different provider led entities, and competing CDS mechanisms, from which providers may choose.

3. Statutory Authority

Section 218(b) of the PAMA amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, “Recognizing Appropriate Use Criteria for Certain Imaging Services,” which directs us to establish a new program to promote the use of AUC. In section

1834(q)(1)(B) of the Act, AUC are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual.

4. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section

1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section

1834(q)(5)). In this proposed rule, we primarily address the first component under section

1834(q)(2) – the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1).

Section 1834(q)(1) of the Act describes the program and provides definitions of terms.

The program is required to promote the use of AUC for applicable imaging services furnished in an applicable setting by ordering professionals and furnishing professionals. Section 1834(q)(1) of the Act provides definitions for AUC, applicable imaging service, applicable setting, ordering professional, and furnishing professional. An “applicable imaging service” under section 1834(q)(1)(C) of the Act must be an advanced imaging service as defined in section

1834(e)(1)(B) of the Act, which defines “advanced diagnostic imaging services” to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services we may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services.

Section 1834(q)(2)(A) of the Act requires the Secretary to specify applicable AUC for applicable imaging services, through rulemaking and in consultation with physicians, practitioners and other stakeholders, by November 15, 2015. Applicable AUC may be specified only from among AUC developed or endorsed by national professional medical specialty societies or other provider-led entities. Section 1834(q)(2)(B) of the Act identifies certain considerations the Secretary must take into account when specifying applicable AUC including whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. Section 1834(q)(2)(C) of the Act requires the Secretary to review the specified applicable AUC each year to determine whether there is a need to update or revise them, and to make any needed updates or revisions through rulemaking. Section 1834(q)(2)(D) of the Act specifies that, if the Secretary determines that more than one AUC applies for an applicable imaging service, the Secretary shall apply one or more AUC for the service.

The PAMA was enacted into law on April 1, 2014. Implementation of many aspects of the amendments made by section 218(b) requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We believe the PFS rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted. The PFS proposed rule is published in late June or early July each year. For the new Medicare AUC program to have been a part of last year’s proposed rule (CY 2015), we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. Additionally, given the complexity of the program to promote the use of AUC for advanced imaging services established under section 1834(q) of the Act, we believed it was imperative to consult with physicians, practitioners and other stakeholders in advance of developing proposals to implement the program. In the time since the legislation was enacted, we have met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program. Having this open door with stakeholders has greatly informed our proposed policy. In addition, before AUC can be specified as directed by section 1834(q)(2)(A) of the Act, there is first the need to define what AUC are and to specify the process for developing them. To ensure transparency and meet the requirements of the statute, we are proposing to implement section 1834(q)(2) of the Act by first establishing through rulemaking a process for specifying applicable AUC and proposing the requirements for AUC development. Under our proposal, the specification of AUC under section 1834(q)(2)(A) of the Act will flow from this process.

We are also proposing to define the term, “provider-led entity,” which is included in section 1834(q)(1)(B) of the Act so that the public has an opportunity to comment, and entities meeting the definition are aware of the process by which they may become qualified under Medicare to develop or endorse AUC. Under our proposed process, once a provider-led entity is qualified (which includes rigorous AUC development requirements involving evidence evaluation, as provided in section 1834(q)(2)(B) of the Act and proposed in this proposed rule) the AUC that are developed or endorsed by the entity would be considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act.

The second major component of the Medicare AUC program is the identification of qualified CDS mechanisms that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. We envision a CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user.

The ordering professional would input information regarding the clinical presentation of the patient into the CDS tool, which may be a feature of or accessible through an existing system, and the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, multiple CDS mechanisms would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology (IT) systems. This would minimize burden on provider teams and avoid duplicate documentation.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDS mechanisms in consultation with physicians, practitioners, health care technology experts, and other stakeholders. This paragraph authorizes the Secretary to specify mechanisms that could include: CDS modules within certified EHR technology; private sector CDS mechanisms that are independent of certified EHR technology; and a CDS mechanism established by the Secretary.

However, all CDS mechanisms must meet the requirements under section 1834(q)(3)(B) of the Act which specifies that a mechanism must: make available to the ordering professional applicable AUC and the supporting documentation for the applicable imaging service that is ordered; where there is more than one applicable AUC specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDS was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Section 1834(q)(3)(C) of the Act specifies that the

Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDS mechanisms.

We are not including proposals to implement section 1834(q)(3) of the Act in this proposed rule. We need to first establish, through notice and comment rulemaking, the process for specifying applicable AUC. Specified applicable AUC would serve as the inputs to any qualified CDS mechanism, therefore, these must first be identified so that prospective tool developers are able to establish relationships with AUC developers. In addition, we anticipate that in PFS rulemaking for CY 2017, we will provide clarifications, develop definitions and establish the process by which we will specify qualified CDS mechanisms. The requirements for qualified CDS mechanisms set forth in section 1834(q)(3)(B) of the Act will also be vetted through PFS rulemaking for CY 2017 so that mechanism developers have a clear understanding and notice regarding the requirements for their tools. The CY 2017 proposed rule would be published at the end of June or in early July of 2016, be open for a period of public comment, and then the final rule would be published by November 1, 2016. We anticipate that the initial list of specified applicable CDS mechanisms will be published sometime after the CY 2017 PFS final rule. In advance of these actions, we will continue to work with stakeholders to understand how to ensure that appropriate mechanisms are available, particularly with respect to standards for certified health IT, including EHRs, that can enable interoperability of AUC across systems.

The third major component of the AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning

January 1, 2017, the requirement for an ordering professional to consult with a listed qualified

CDS mechanism when ordering an applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional’s consultation with a qualified CDS mechanism. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders the imaging service is usually not the same professional who bills Medicare for the test when furnished. Section

1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under

Medicare Part A, and ordering professionals who obtain a hardship exemption. Section

1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the physician fee schedule, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

We are not including proposals to implement section 1834(q)(4) of the Act in this proposed rule. Again, it is important that we first establish through notice and comment rulemaking the process by which applicable AUC will be specified as well as the CDS mechanisms through which ordering providers would access them. We anticipate including further discussion and adopting policies regarding claims-based reporting requirements in the CY 2017 and CY 2018 rulemaking cycles.

The fourth component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Although, we are not including proposals to implement these sections in this proposed rule, we are proposing to identify outlier ordering professionals from within priority clinical areas that would be established through subsequent rulemaking. In this rule, we propose a process to provide clarity around priority clinical areas.

The concept of priority clinical areas allows CMS to implement an AUC program that combines two approaches to implementation. Under our proposed policy, while potentially large volumes of AUC would become specified across clinical conditions and advanced imaging technologies, we believe this rapid roll out of specified AUC should be balanced with a more focused approach to identifying outlier ordering professionals. We believe this will provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

In future rulemaking, with the benefit of public comments, we will establish priority clinical areas and expand them over time. Also in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals.

5. Proposals for Implementation

We are proposing to amend our regulations to add a new §414.94, “Appropriate Use Criteria for Certain Imaging Services.”

a. Definitions

In §414.94 (b), we are proposing to codify and add language to clarify some of the definitions provided in section 1834(q)(1) of the Act as well as define terms that were not defined in statute but for which a definition would be helpful for program implementation. In this section of the proposed rule, we provide a description of the terms we are proposing to codify to facilitate understanding and encourage public comment on the proposed AUC program.

Due to circumstances unique to imaging, it is important to note that there is an ordering professional (the physician or practitioner that orders that the imaging service be performed) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the radiologic interpretation of the image) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.

This proposed AUC program only applies in applicable settings. An applicable setting would include a physician’s office, a hospital outpatient department (including an emergency department) and an ambulatory surgical center. The inpatient hospital setting, for example, is not an applicable setting. Further, the proposed program only applies to applicable imaging services. These are advanced diagnostic imaging services for which one or more applicable

AUC apply, one or more qualified CDS mechanisms is available, and one of those mechanisms is available free of charge.

We are proposing to clarify the definition for appropriate use criteria, which is defined in statute to include only criteria developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based. To further describe AUC, we are proposing to add the following language to this definition: AUC are a collection of individual appropriate use criteria. Individual criteria are information presented in a manner that links: a specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s).

For the purposes of implementing this program, we are proposing to define new terms in

§414.94(b). A provider-led entity would include national professional medical specialty societies (for example the American College of Radiology and the American Academy of Family Physicians) or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare (for example hospitals and health systems). Applicable

AUC become specified when they are developed, modified or endorsed by a qualified provider led entity. A provider-led entity is not considered qualified until CMS makes a determination via the qualification process discussed in this proposal. We are introducing priority clinical areas to inform ordering professionals and furnishing professionals of the clinical topics, clinical topics and imaging modalities or imaging modalities that may be identified by the agency through annual rulemaking and in consultation with stakeholders which may be used in the identification of outlier ordering professionals.

The proposed definitions in §414.94 are important in understanding our proposals for implementation. Only AUC developed, modified or endorsed by organizations meeting the definition of provider-led entity would be considered specified applicable AUC. As required by the statute, specified applicable AUC, which encompass all AUC developed, modified or endorsed by qualified provider-led entities, must be consulted and such consultation must be reported on the claim for applicable imaging services. To assist in identification of outlier ordering professionals, we propose to focus on priority clinical areas. Priority clinical areas would be associated with a subset of specified AUC.

b. AUC Development by Provider-Led Entities

In §414.94, we are proposing to include regulations to implement the first component of the Medicare AUC program – specification of applicable AUC. We are first proposing a process by which provider-led entities (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for provider-led entities to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we propose to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for the AUC. Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. It is not feasible for us to review every individual criterion. Rather, we propose to establish a qualification process and requirements for qualified provider-led entities in order to ensure that the AUC development or endorsement processes used by a provider-led entity result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B). Therefore, we propose that AUC developed, modified, or endorsed by qualified provider-led entities will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

In order to become and remain a qualified provider-led entity, we propose to require a provider-led entity to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. The first proposed requirement is related to the evidentiary review process for individual criteria. Entities must engage in a systematic literature review of the clinical topic and relevant imaging studies. We would expect the literature review to include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the provider-led entity must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. Consideration of relevant published evidence-based guidelines and consensus statements by professional medical specialty societies must be part of the evidence assessment. Published consensus statements may form part of the evidence base of AUC and would be subject to the evidentiary grading methodology as any other evidence identified as part of a systematic review.

In addition, we propose that the provider-led entity’s AUC development process must be led by at least one multidisciplinary team with autonomous governance that is accountable for developing, modifying, or endorsing AUC. At a minimum, the team must be composed of three members including one with expertise in the clinical topic related to the criterion and one with expertise in imaging studies related to the criterion. We encourage such teams to be larger, and include experts in each of the following domains: statistical analysis (such as biostatics, epidemiology, and applied mathematics); clinical trial design; medical informatics; and quality improvement. A given team member may be the team’s expert in more than one domain. These experts should contribute substantial work to the development of the criterion, not simply review the team’s work.

Another important area to address that provides additional assurance regarding quality and evidence-based AUC development is the disclosure of conflicts of interest. We believe it is appropriate to impose relatively stringent requirements for public transparency and disclosure of potential conflicts of interest for anyone participating with a provider-led entity in the development of AUC. We propose that the provider-led entity must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The provider-led entity must disclose any direct or indirect relationships, as well as ownership or investment interests, among the multidisciplinary team members or immediate family members and organizations that may financially benefit from the AUC that are being considered for development, modification or endorsement.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, we propose that the provider-led entity must maintain on its website each criterion that is part of the AUC that the entity has considered or is considering for development, modification, or endorsement. This public transparency of individual criteria is critical not only to ordering and furnishing professionals, but also to patients and other health care providers who may wish to view all available AUC.

Although evidence should be the foundation for the development, modification and endorsement of AUC, we recognize that not all aspects of a criterion will be evidence-based, and that a criterion does not exist for every clinical scenario. We believe it is important for AUC users to understand which aspects of a criterion are evidence-based and which are consensus-based. Therefore, we propose that key decision points in individual criteria be graded in terms of strength of evidence using a formal, published, and widely recognized methodology. This level of detail must be part of each AUC posted to the entity’s website.

It is critical that as provider-led entities develop large collections of AUC, they have a transparent process for the timely and continual review of each criterion, as there are sometimes rapid changes in the evidence base for certain clinical conditions and imaging studies.

Finally, we propose that a provider-led entity’s process for developing, modifying, or endorsing AUC (which would be inclusive of the requirements being proposed in this rule) must be publicly posted on the entity’s website.

We believe it is important to fit AUC to local circumstances and populations, while also ensuring a rigorous due process for doing so. Under our proposed AUC program, local adaptation of AUC might happen in three ways. First, compatibility with local practice is something that ordering professionals can assess when selecting AUC for consultation. Second, professional medical societies (many of which have state chapters) and large health systems (which incorporate diverse practice settings, both urban and rural) that become qualified provider-led entities can get local feedback at the outset and build alternative options into the design of their AUC. Third, local provider-led entities can themselves become qualified to develop, modify, or endorse AUC.

c. Process for Provider-Led Entities to Become Qualified to Develop, Endorse or Modify AUC

We are proposing that provider-led entities must apply to CMS to become qualified. We are proposing that entities that believe they meet the definition of provider-led submit applications to us that document adherence to each of the qualification requirements. The application must include a statement as to how the entity meets the definition of a provider-led entity. Applications will be accepted each year but must be received by January 1. A list of all applicants that we determine to be qualified provider-led entities will be posted to our website by the following June 30 at which time all AUC developed or endorsed by that provider-led entity will be considered to be specified AUC. All qualified provider-led entities must re-apply every 6 years and their applications must be received by January 1 during the 5th year of their approval.

Note that the application is not a CMS form; rather it is created by the applicant entity.

d. Identifying Priority Clinical Areas

Section 1834(q)(4) of the Act requires that, beginning January 1, 2017, ordering professionals must consult applicable AUC using a qualified CDS mechanism when ordering applicable imaging services for which payment is made under applicable payment systems, and that furnishing professionals must report the results of this consultation on Medicare claims.

Section 1834(q)(5) of the Act further provides for the identification of outlier ordering professionals based on a low adherence to applicable AUC. We are proposing to identify priority clinical areas of AUC that we will use in identifying outlier ordering professionals.

Although there is no consequence to being identified as an outlier ordering professional until

January 2020, it is important to allow ordering and furnishing professionals as much time as possible to use and familiarize themselves with the specified applicable AUC that will eventually become the basis for identifying outlier ordering professionals.

To identify these priority clinical areas, we may consider incidence and prevalence of diseases, as well as the volume, variability of utilization, and strength of evidence for imaging services. We may also consider applicability of the clinical area to a variety of care settings, and to the Medicare population. We are proposing to annually solicit public comment and finalize clinical priority areas through the PFS rulemaking process beginning in CY 2017. To further assist us in developing the list of proposed priority clinical areas, we are proposing to convene the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), a CMS

FACA compliant committee, as needed to examine the evidence surrounding certain clinical areas.

Specified applicable AUC falling within priority clinical areas may factor into the low-adherence calculation when identifying outlier ordering professionals for the prior authorization component of this statute, which is slated to begin in 2020. Future rulemaking will address further details.

e. Identification of Non-Evidence Based AUC

Despite our proposed provider-led entity qualification process that should ensure evidence-based AUC development, we remain concerned that non-evidence based criteria may be developed or endorsed by qualified provider-led entities. Therefore, we are proposing a process by which we would identify and review potentially non-evidence-based criteria that fall within one of our identified priority clinical areas. We are proposing to accept public comment through annual PFS rulemaking so that the public can assist in identifying AUC that potentially are not evidence-based. We foresee this being a standing request for comments in all future rules regarding AUC. We are proposing to use the MEDCAC to further review the evidentiary basis of these identified AUC, as needed. The MEDCAC has extensive experience in reviewing, interpreting, and translating evidence. If through this process, a number of criteria from an AUC library are identified as being insufficiently evidence-based, and the provider-led entity that produced the library does not make a good faith attempt to correct these in a timely fashion, this information could be considered when the provider-led entity applies for re-qualification.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a new Medicare AUC program for advanced imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast.

We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDS mechanism developers. It is for these reasons we are proposing a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

In summary, we are proposing definitions of terms necessary to implement the AUC program. We are particularly seeking comment on the proposed definition of provider-led entity as these are the organizations that have the opportunity to become qualified to develop, modify or endorse specified AUC. We are also proposing an AUC development process which allows some flexibility for provider-led entities but sets standards including an evidence-based development process and transparency. In addition, we are proposing the concept and definition of priority clinical areas and how they may contribute to the identification of outlier ordering professionals. Lastly, we are proposing to develop a process by which non-evidence-based AUC will be identified and discussed in the public domain. We invite the public to submit comments on these proposals.

* **Certification Requirements for Reporting Electronic Clinical Quality Measures (eCQMs)** **in the EHR Incentive Program and PQRS (pages 506-508 pdf display version)**

In the CY 2015 PFS final rule with comment period (79 FR 67906), we finalized our proposal for the Medicare EHR Incentive Program that, beginning in CY 2015, EPs are not required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Although we are not requiring recertification, EPs must still report the most recent version of the electronic specifications for the CQMs if they choose to report CQMs electronically for the Medicare EHR Incentive Program.

In the FY 2016 IPPS proposed rule (80 FR 24611 through 24615), HHS’ Office of the

National Coordinator for Health Information Technology (ONC) proposed a certification criterion for “CQMs – report” at 45 CFR 170.315(c)(3). This proposal would require that health information technology enable users to electronically create a data file for transmission of clinical quality measurement data in accordance with the Quality Reporting Document Architecture (QRDA) Category I (individual patient-level report) and Category III (aggregate report) standards, at a minimum. As part of the “CQMs – report” criterion, ONC also proposed to offer optional certification for EHRs according to the “form and manner” that CMS requires for electronic submission to participate in the EHR Incentive Programs and PQRS. These requirements are published annually as the “CMS QRDA Implementation Guide” and posted on CMS’ website at [http://www.cms.gov/Regulations-and Guidance/Legislation/EHRIncentivePrograms/eCQM\_Library.html](http://www.cms.gov/Regulations-and%20Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html). The latest set of requirements (2015 CMS QRDA Implementation Guide for Eligible Professional Programs and

Hospital Quality Reporting) combines the requirements for EPs, eligible hospitals, and CAHs.

For a complete discussion of these proposals, we refer readers to 80 FR 24611 through 24615.

In the FY 2016 IPPS proposed rule (80 FR 24323 through 24629), we stated that we anticipate proposing to require EPs, eligible hospitals, and CAHs seeking to report CQMs electronically as part of meaningful use under the EHR Incentive Programs for 2016 to adhere to the additional standards and constraints on the QRDA standards for electronic reporting as described in the CMS QRDA Implementation Guide. We stated that we anticipate proposing to revise the definition of “certified electronic health record technology” at §495.4 to require certification to the optional portion of the 2015 Edition CQM reporting criterion (proposed at 45

CFR 170.315(c)(3)) in the CY 2016 Medicare PFS proposed rule later this year.

Accordingly, to allow providers to upgrade to 2015 Edition CEHRT before 2018, we propose to revise the CEHRT definition for 2015 through 2017 to require that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept (CMS’ “form and manner” requirements) if certifying to the 2015

Edition “CQMs – report” certification criterion at §170.315(c)(3). Specifically, this would require technology to be certified to §170.315(c)(3)(i) (the QRDA Category I and III standards) and §170.315(c)(3)(ii) (the optional CMS “form and manner”). We note that the proposed

CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule published on

March 30, 2014 (80 FR 16732 through 16804) allows providers to use 2014 Edition or 2015

Edition certified EHR technology. These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

We also propose to revise the CEHRT definition for 2018 and subsequent years to require that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept. Specifically, this would require technology to be certified to §170.315(c)(3)(i) (the QRDA Category I and III standards) and §170.315(c)(3)(ii) (the optional CMS “form and manner”). These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

We are proposing these amendments at §495.4 to ensure that providers participating in

PQRS and the EHR Incentive Programs under the 2015 Edition possess EHRs that have been certified to report CQMs according to the format that CMS requires for submission. We invite comment on our proposals.

* **Request for Comment Related to Use of Health Information Technology (pages 535 – 537 of pdf display version)**

In the November 2011 final rule, we included a measure related to the use of health information technology under the Care Coordination/Patient Safety domain: the percent of PCPs within an ACO who successfully qualify for an EHR Incentive Program incentive (76 FR

67878). In finalizing this measure, we included eligible professionals that qualified for payments to adopt, implement, or upgrade EHR technology, in addition to those receiving a payment for meeting Meaningful use Requirements. We selected this measure as opposed to other proposed measures in order to focus on EHR adoption among the primary care physicians within an ACO.

Finally, we chose to focus on this measure because it represented a structural measure of EHR program participation that is not duplicative of measures within the EHR Incentive program for which providers may already qualify for incentive payments or face penalties. Although this was the only measure we finalized related to use of health information technology, we chose to double weight this measure for scoring purposes in order to signal the importance of health information technology for ACOs (76 FR 67895).

In the CY 2015 PFS final rule with comment period, we finalized a proposal to change the name and specification of this measure to “Percent of PCPs who Successfully Meet

Meaningful Use Requirements” in order to reflect the transition from incentive payments to downward payment adjustments in 2015 (79 FR 67912). We believe this name will more accurately depict successful use and adoption of EHR technology.

We continue to believe that measures which encourage the effective adoption and use of health information technology among participants in accountable care initiatives are an important way to signal the importance of technology infrastructure in supporting successful ACOs, especially as they mature and assume additional risk. Since the initial EHR quality measure was finalized in 2011, the EHR Incentive Program and Meaningful Use requirements have shifted from an initial focus on technology adoption and data capture to interoperable exchange of data across systems and the use of more advanced health IT functions to support care coordination and quality improvement. A notice of proposed rulemaking for “Stage 3” of the EHR Incentive program, was released in March 2015 (80 FR 16731), along with a related proposed 2015

Edition of ONC certification criteria (80 FR 16804), which aim to support providers’ ability to exchange a common clinical dataset across the continuum of care. In addition, ONC has released a document entitled “Connecting Health and Care for the Nation: A Shared Nationwide

Interoperability Roadmap (available at http://www.healthit.gov/sites/default/files/nationwideinteroperability-

roadmap-draft-version-1.0.pdf) which focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017.

We believe that the widespread inclusion of these capabilities within health IT systems, and their adoption and effective use by providers, will greatly enhance ACOs’ ability to coordinate care for beneficiaries with practitioners both within and outside their ACO and more effectively manage the total cost of care for attributed patients. While we are not proposing any changes to the current measure “Percent of PCPs who Successfully Meet Meaningful Use

Requirements” (ACO-11) at this time, we are seeking comment on how this measure might evolve in the future to ensure we are incentivizing and rewarding providers for continuing to adopt and use more advanced health IT functionality as described above, and broadening the set of providers across the care continuum that have adopted these tools. We welcome comments on the following questions:

* Although the current measure focuses only on primary care physicians, should this measure be expanded in the future to include all eligible professionals, including specialists?
* How could the current measure be updated to reward providers who have achieved higher levels of health IT adoption?
* Should we substitute or add another measure that would focus specifically on the use of health information technology, rather than meeting overall Meaningful Use requirements, for instance, the transitions of care measure required for the EHR Incentives Program?
* What other measures of IT-enabled processes would be most relevant to participants within ACOs? How could we seek to minimize the administrative burden on providers in collecting these measures?