G. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

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 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 services. 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 are integrated into broader care management and continuous quality improvement (QI) programs. Successful QI programs in turn have provider-led multidisciplinary teams that 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 studies[4].

In addition to the outcomes of the MID (http://www.rand.org/content/dam/rand/pubs/research_reports/RR700/RR706/RAND_RR706.pdf), 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

4 Timbie J, Hussey P, Burgette L, et al. Medicare Imaging Demonstration Final Evaluation: Report to Congress. 2014 The Rand Corporation

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. A second 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 a number of sets of AUC developed by different provider-led entities, and an array of CDS mechanisms, from which providers may choose.

3. Statutory Authority

Section 218(b) of the PAMA amended Title XVIII of the Act by adding a new section 1834(q) 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 the proposed rule, we primarily addressed 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) of the PAMA requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We believe the PFS calendar year rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing of the PFS rulemaking process, 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 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 proposed 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 also proposed to define the term, "provider-led entity," which is included in section 1834(q)(1)(B) of the Act so that the public had 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 (PLE) 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 the CY 2016 PFS 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 did not include proposals to implement section 1834(q)(3) of the Act in the CY 2016 PFS proposed rule. We needed 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 intend 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. If we were to follow a similar process for CDS as we have for specifying AUC, the initial list of CDS mechanisms would be available in the summer of 2017. 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 PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

We did not include proposals to implement section 1834(q)(4) of the Act in the CY 2016 PFS 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. Therefore, we do not intend to require that ordering professionals meet this requirement by January 1, 2017.

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 did not include proposals to implement these sections in the CY 2016 PFS proposed rule, we proposed to identify outlier ordering professionals from within priority clinical areas. Prior clinical areas will be identified through subsequent rulemaking.

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 (as some eligible PLEs have large libraries 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 the CY 2017 PFS rulemaking process, with the benefit of public comments, we will begin to identify 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 proposed to amend our regulations to add a new §414.94, "Appropriate Use Criteria for Certain Imaging Services."

a. Definitions

In §414.94 (b), we proposed 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 we provide a description of the terms we proposed to codify to facilitate understanding and encourage public comment on the 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 furnished) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the interpretation of the imaging study) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.

This AUC program only applies in applicable settings as defined in section 1834(q)(1)(D)

of the Act. An applicable setting would include a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any provider-led outpatient setting determined appropriate by the Secretary. The inpatient hospital setting, for example, is not an applicable setting. Further, the program only applies to applicable imaging services as defined in section 1834(q)(1)(C) of the Act. 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 proposed to clarify the definition for appropriate use criteria, which is defined in section 1834(q)(2)(B) of the Act to include only criteria developed or endorsed by national professional medical specialty societies or other PLEs, 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 proposed 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 proposed to define new terms in §414.94(b). A PLE 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 or modified by a qualified PLE, or when a qualified PLE endorses AUC developed by another qualified PLE. A PLE is not considered qualified until CMS makes a determination via the qualification process finalized in this CY 2016 PFS final rule with comment period. We introduced priority clinical areas to

inform ordering professionals and furnishing professionals of the clinical topics alone, clinical topics and imaging modalities combined or imaging modalities alone 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 definitions in §414.94 are important in understanding implementation of the program. Only AUC developed, modified or endorsed by organizations meeting the definition of PLE would be considered specified applicable AUC. As required by the statute, specified applicable AUC 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 proposed 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 proposed to include regulations to implement the first component of the Medicare AUC program – specification of applicable AUC. We first proposed a process by which PLEs (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for PLEs to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we proposed to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for specifying 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 of an AUC. Rather, we proposed to establish a qualification process and requirements for qualified PLEs to ensure that the AUC development or endorsement processes used by a PLE result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B).

Therefore, we proposed that AUC developed, modified, or endorsed by qualified PLEs will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

To become and remain a qualified PLE, we proposed to require a PLE 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 PLE 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 proposed that the PLE'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 PLE in the development of AUC. We proposed that the PLE must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The PLE 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. In addition, the information must be made available to the public, if requested, in a timely manner.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, we proposed that the PLE 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 recognized 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 proposed 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 PLEs 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 proposed that a PLE'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 AUC program, local adaptation of AUC will 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 PLEs can get local feedback at the outset and build alternative options into the design of their AUC. Third, local PLEs 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 proposed that PLEs must apply to CMS to become qualified. We proposed that entities that believed they met 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 PLE. Applications will be accepted each year but must be received by January 1. A list of all applicants that we determine to be qualified PLEs will be posted to our website by the following June 30 at which time all AUC developed or endorsed by that PLE will be considered to be specified AUC. We proposed all qualified PLEs 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 provide information about the CDS mechanism consultation to the furnishing professional, 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 proposed 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 proposed 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 proposed 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 PLE qualification process that should ensure evidence-based AUC development, we remain concerned that non-evidence-based criteria may be developed or endorsed by qualified PLEs. Therefore, we proposed 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 proposed 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 proposed 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 PLE 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 PLE 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 proposed 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 proposed definitions of terms necessary to implement the AUC program. We were particularly seeking comment on the proposed definition of PLE as these are the organizations that have the opportunity to become qualified to develop, modify, or endorse specified AUC. We also proposed an AUC development process which allows some flexibility for PLEs but sets standards including an evidence-based development process and transparency. In addition, we proposed the concept and definition of priority clinical areas and how they may contribute to the identification of outlier ordering professionals. Lastly, we proposed to develop a process by which non-evidence-based AUC will be identified and discussed in the public domain. We invited the public to submit comments on these proposals.

The following is a summary of the comments we received regarding our proposals.

Comment: There was disagreement among commenters regarding the proposed definition of PLE. Numerous commenters supported finalization of the proposed definition for PLE. One commenter noted that national professional medical specialty societies were specified in PAMA as an example of a PLE and therefore the definition should encompass such societies. Another commenter requested the agency provide a definition of national professional medical specialty societies. Some commenters requested the definition ensure that provider groups, physicians, and alliances of provider organizations are included. Some commenters requested that the definition of PLE be expanded to include radiology benefit management (RBM) or similar companies, health plans and manufacturers. These commenters stated that providers, physicians and other practitioners are integrally involved if not in control of their AUC development processes. They stated that by including these entities in the definition of PLE, there would be more AUC available in the market (which they believe would yield healthy competition). They also indicated that these entities can move more quickly to update AUCs. Commenters in support of RBMs stated that national professional medical specialty societies had

potential conflicts of interest when developing AUC for use by their own medical specialty as some specialties are paid by performing imaging services. Commenters in support of national professional medical specialty societies state that RBMs had potential conflicts of interest and were incentivized to control costs. Commenters also expressed conflicting opinions regarding the intent of the term "provider-led entities" as used in section 218(b) of the PAMA.

Response: We agree with the commenter that national professional medical societies were identified in the statute as an example of the entities that should fall within the definition of PLE. The proposed definition of PLE explicitly included national professional medical specialty societies, as well as organizations comprised primarily of providers and actively engaged in the practice and delivery of health care. The way that national professional medical societies and other similar organizations are structured, many would not have been considered "actively engaged in the practice and delivery of healthcare" under the proposed definition. This is because national professional medical specialty societies and other similar entities do not, as an organization, deliver care to patients. Therefore, we are modifying the proposed definition of PLE to finalize a definition that focuses on the practitioners and providers that comprise an organization and not on whether the organization, as an entity, delivers care. This approach subsumes national professional medical specialty societies whose members are actively engaged in delivering care in the community and eliminates the need to establish a separate definition for national professional medical specialty societies as they are now an example of a PLE. This will also include alliances and collaboratives of hospitals and hospital system.

Some commenters suggested that physicians and other practitioners are involved in the AUC development process and, therefore, should be considered PLEs. However, we believe the AUC development process typically would be embedded within a larger organization, and the organization as a whole may not be primarily comprised of practitioners. We continue to believe that the statute is intended to focus on the structure of the entire organization, and to require that

it be "provider-led." We believe that the PLE definition must apply to the organization as a whole, as processes that are embedded within the organization are not the same as a separately identifiable entity. We do not believe the modified definition of PLE that we are finalizing will limit the AUC market or the participation of third parties (such as RBMs) in the AUC development process. There may be opportunity for third parties to collaborate with PLEs to develop AUC.

Comment: Some commenters expressed concerns that the process to become a qualified PLE is more restrictive than section 218(b) of the PAMA requires and could prohibit some organizations with evidence-based AUC from participating in the program, which could limit physician and practitioner choice for AUC consultation.

Response: Section 1834(q)(2)(A) of the Act, as added by section 218(b) of the PAMA, requires that we specify AUC for applicable imaging services only from among AUC developed or endorsed by national professional medical specialty societies or other PLEs. Section 1834(q)(2)(B) of the Act requires that, in specifying these AUC, we must take into account whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on published studies that are reviewable by stakeholders. We believe the process we proposed to identify qualified PLEs is essential to ensuring that we take into account the factors described in the statute.

Comment: Regarding our proposal to require that, in order to be considered a qualified PLE, the PLE's AUC development process be led by a multidisciplinary team with specific characteristics, some commenters requested that the multidisciplinary team should include more than the minimum three members we had proposed, with some commenters suggesting upwards of 15 members. Other commenters suggested the requirements for the team should not restrict the participation of any qualified participants; in other words, expertise should not be dictated entirely by CMS and teams should have the option to add whomever they determine appropriate.

Still other commenters suggested that CMS should require representation on the multidisciplinary team from primary care, industry, patient advocates and insurers and experts on the imaging study and clinical topic.

Response: We agree that the multidisciplinary team would benefit from additional representation and, more specifically, from representation by primary care practitioners, because a large proportion of imaging orders will be made by primary care practitioners. In response to these comments, we are modifying our proposal to instead require that the multidisciplinary team must have at least seven members including a primary care practitioner. We are also modifying the requirements to clearly state that the required expertise in the clinical topic and imaging service related to the AUC that are being developed must be provided by practicing physicians. These modifications to the multidisciplinary team requirements align with many of the commenters' support for more representation from practitioners in the field.

We agree with the commenters' suggestions that the team should be required to include more members, and that the types of experts required on the team should also be expanded. In addition to primary care, we are also modifying our proposal to require that experts in clinical trial design and statistical analysis be required members of the team. While we do not agree that involvement from industry or patient advocates should be required on the team, we do believe that teams could benefit from dialogue with such stakeholders. In response to the commenters that expressed concern about CMS restricting team participation, we encourage teams to be inclusive and seek members with any other relevant expertise.

Comment: Some commenters expressed concerns regarding the burden associated with the evidence review process we proposed to require for qualified PLEs in the AUC development process. Commenters indicated that the evidence review process that we proposed to require would be expensive, as commissioned systematic reviews are costly, and the process would require a significant amount of time which would be burdensome especially for smaller

organizations. Some commenters suggested replacing "systematic" with "thorough" in describing the evidence review process to avoid unintentionally requiring a commissioned systematic review, and to account for specific methods included in systematic reviews that may not be applicable to all advanced diagnostic imaging studies. One commenter recommended that the cost of systematic reviews and the costs associated with AUC development should be at least partially mitigated by government organizations like CMS, and tax incentives or grant money should be available to medical specialty societies to help offset the costs.

Response: While we understand the commenters' concerns about the cost and time necessary to comply with the proposed evidence review requirement for developing AUC, we believe that this is a fundamental to ensuring that AUC are evidence-based to the extent feasible as required by section 1834(q)(1)(B) of the Act. We also believe the proposed evidence review process is essential to ensuring that the AUC that are developed can serve their purpose, as indicated in section 1834(q)(1)(B) of the Act, to assist ordering professionals in making the most appropriate treatment decision for specific clinical conditions for individual patients. However, we believe some commenters might have misinterpreted the reference in the proposed rule to a "systematic" review. To clarify, we did not intend to require that the evidence review process must be accomplished by commissioning external systematic evidence reviews or technology assessments. We expect PLEs to undertake evidence reviews of sufficient depth and quality to ensure that all relevant evidence-based publications on trials, studies and consensus statements are identified, considered and evaluated; and that such reviews are reproducible. In response to the commenter that requested financial support in the development of AUC, we note that section 218(b) of the PAMA included no provisions authorizing funding tax incentives, grants, or other financial assistance to PLEs developing AUC.

Comment: Commenters requested clarification on the requirements for modifying and endorsing AUC. Some commenters suggested that qualified PLEs that modify or endorse AUC

should be required to go through the same process required for initial AUC development while other commenters recommended different requirements for modification or endorsement of AUC. Other commenters stated that modification of AUC should not be permitted, and that evidence-based AUC should not be changed to fit local scenarios.

Response: We believe the same process and requirements should apply to the AUC development process for all qualified PLEs, and that modification of AUC should be accomplished using the same process and requirements that apply to the development of AUC. This will ensure that there is documented evidence for the modification. In the proposed rule, we did not intend to differentiate between the process and requirements for AUC development, modification, and endorsement by qualified PLEs. We are clarifying in this rule that this is because a PLE must be qualified to endorse another qualified PLE's AUC. Both entities would have followed the process to become qualified and both entities would be listed on the CMS website as such. Endorsement is not intended to be duplicative. In other words it is not necessary for the endorsing qualified PLE to duplicate the extensive evidence review process performed by the qualified PLE that developed the AUC set or individual criterion.

Regarding local adaption, we believe it is important to fit AUC to local circumstances, while also ensuring application of a rigorous process in doing so. However, only AUC modified by qualified PLEs can become specified applicable AUC.

Comment: Some commenters recommended that CMS identify specific evidence grading methodologies that AUC developers are required to use, for example the GRADE, AHRQ and USPSTF grading systems.

Response: We believe that evidence grading is an essential component of the AUC development process and that AUC developers should have flexibility when working within the requirements we have set forth. In addition, one grading system may be more appropriate for AUC development for a certain clinical condition while another grading system may be best for

another condition. Therefore, we will not require the use of specific grading mechanisms.

Comment: Some commenters requested clarification regarding the meaning of "autonomous governance" specific to the multidisciplinary team.

Response: In proposing that, in order to be a qualified PLE, the PLE's AUC development process must be led by at least one multidisciplinary team with autonomous governance, we intended to highlight the need for the multidisciplinary team to be independent in its work from influence and oversight by components of the PLE not involved or associated with the multidisciplinary team.

Comment: Some commenters requested the inclusion of a requirement for public comment and/or stakeholder feedback on AUC developed, modified or endorsed by qualified PLEs.

Response: We recognize that some AUC development processes could invite public comment. While we believe this would be appropriate, we do not believe we should establish this as a requirement for the development of AUC by a qualified PLE. We do however believe that public transparency of the resulting AUC and the corresponding evidence base is critical to this program. In order to be a qualified PLE, the PLE must post AUC on their website in the public domain that allows all developed AUC to be reviewed by all stakeholders.

Comment: Some commenters requested further clarification regarding the requirement for AUC to be reviewed and updated. Many had concerns that some PLEs would not update AUC on a frequent enough basis to capture changes in the medical literature. One commenter agreed with requiring regular reviews and updating, and another commenter suggested that review be continuous and should occur on a cycle shorter than 1 year.

Response: We agree that AUC should be reviewed and updated frequently and have included a requirement for qualified PLEs to go through this process at least annually. We believe that qualified PLEs that produce quality AUC should have a process in place to evaluate

the state of the medical literature on an annual basis. These annual reviews will not always result in changes to the AUC, rather, it will ensure that the AUC reflect the current body of evidence.

Comment: Some commenters recommended including processes approved by the National Guidelines Clearinghouse (NGC) as examples of a rigorous evidence-based process, and that we grant provisional approval as qualified to PLEs that have met the NGC inclusion criteria and whose AUC are posted to the NGC.

Response: While the NGC serves as an important repository for clinical practice guidelines, we believe that the CMS application process for qualified PLE status is not overly burdensome as a stand-alone process. We believe our application process is appropriate to assure key aspects of AUC development. We also recognize that PLEs that have their AUC posted to the NGC may find that they are at an advantage in the application process to become a qualified PLE because they have already prepared a package with some similar information.

Comment: One commenter stressed the importance of allowing expert opinion in the AUC development process, especially when relevant studies are limited or lacking in available literature. The commenter also noted the importance of transparency and disclosure of conflict of interest for experts.

Response: The process of AUC development allows for the opportunity for expert opinion, especially as we expect the multidisciplinary team to be populated with such experts. In addition, in the literature review we would expect published consensus papers and similar documents to be identified and be part of the evidentiary review. AUC developers may choose to put their draft AUC into the public domain for comment and receive expert opinion in that manner.

Comment: One commenter recommended that CMS should initiate the AUC development process and use public comment, qualified PLEs and multidisciplinary committees to develop AUC.

Response: Section 1834(q)(7) of the Act clarifies that section 1834(q) of the Act does not authorize the Secretary to develop or initiate the development of clinical practice guidelines or AUC. Additionally, under section 1834(q)(1)(B) of the Act, AUC are defined as criteria only developed or endorsed by national professional medical specialty societies or other PLEs. As such, we do not believe it would be appropriate for us to develop or initiate the development of AUC for purposes of the program under section 1834(q) of the Act.

Comment: One commenter recommended that CMS create a concise list of AUC development requirements or create a template for entities to use for their application and post the list or template to the CMS website.

Response: At least for the first round of applications for qualified PLEs, we will not be making available templates or applications. CMS might consider developing such templates or applications in the future if we find it would be useful, efficient or necessary.

Comment: Some commenters expressed their confusion with the AUC terminology used in the proposed rule. One commenter recommended, for the sake of clarity, using the terms "AUC", "AUC set" and "required AUC" in the final rule and to revise the definition of AUC accordingly.

Response: We understand that there might have been some confusion, and we have revised the terminology used in this final rule with comment period to provide greater clarity. In general, when we refer to AUC we mean a set or library of AUC, and when we use the term "individual criterion" we are referring to a single appropriate use criterion.

Comment: Some commenters opposed our proposal to specify applicable AUC by first identifying qualified PLEs, and recommended instead that we specify a small group of AUC in order to meet the timeline specified under section 218(b) of the PAMA, and then expanding the list of AUC over time. Other commenters requested that we adopt a phased approach with a focus on AUC for a limited number of clinical conditions that would be used first in larger

hospitals and health systems with gradual expansion to smaller practices.

Response: We believe some of these concerns will be addressed by clarifying our expected timeline which allows additional time for all impacted providers and practitioners to prepare for the AUC consultation program specified under section 1834(q) of the Act. There will be a delay in not only specifying applicable AUC and identifying qualifying CDS mechanisms, but these delays will necessarily result in a delay of the date when ordering practitioners will be expected to report on the Medicare claim form information on their consultation with CDS mechanisms.

Specified AUC must first exist prior to being loaded into CDS mechanisms, and qualified CDS mechanisms must exist prior to consultation by ordering professionals.

We fully anticipate that we will be able to finalize rules and requirements around the CDS mechanism and approve mechanisms through rulemaking in 2017. This timeline will significantly impact when we would expect practitioners to begin using those CDS mechanisms to consult AUC and report on those consultations. We do not anticipate that the consultation and reporting requirements will be in place by the January 1, 2017 deadline established in section 218(b) of the PAMA. Again, we are not in a position to predict the exact timing of this deliverable; however, we do not anticipate that it will take place, conservatively, until CDS mechanisms are established through rulemaking. We do not agree that the requirement to consult with specified AUC should be limited to certain topics or program areas as we believe such consultation will help to improve appropriate utilization across-the-board. We believe that section 218(b) of the PAMA can be rolled out in a stepwise manner to allow adequate time for all providers and practitioners to prepare.

Comment: Some commenters recommended that priority clinical areas be established prior to AUC development and physicians and other practitioners be required to consult AUC only within these areas. Commenters stated priority clinical areas should focus on areas with

AUC for which there are consistently available appropriateness ratings and improved practices resulting from AUC consultation. Other commenters recommended placing limitations on specified AUC, for example limiting the number specified for each clinical condition and limiting specified AUC to those developed by national professional associations.

Response: We do not agree that we should limit the areas in which AUC may be specified. We believe it is more advantageous to specify libraries of AUC because this program is intended to assist ordering professionals in making the most appropriate treatment decisions for a specific clinical condition for an individual with reference to ordering practices for all advanced diagnostic imaging services. However, we believe that the identification of priority clinical areas will allow for physicians and other practitioners to focus their efforts on clinical areas for which there is strong evidence and which may have high impact on patients and society. Our goal is to tie outlier calculations to these high impact clinical areas.

Comment: One commenter requested that we include a process by which AUC developed by national professional medical specialty societies that do not seek to be qualified PLEs can be considered specified applicable AUC and, thereby, incorporated into CDS mechanisms (for example, PLEs with small, specific AUC libraries).

Response: We do not believe it would be appropriate either to allow AUC to be specified that do not meet the development criteria we have established, or to presume that AUC developed by a national professional medical specialty society would meet the requirements of this rule or to develop a separate process for specifying individual appropriate use criterion other than through the PLE qualification process. The requirements for the AUC developed process logically apply whether the PLE is producing only a few subspecialty criteria or hundreds of criteria to covering a large portion of all advanced diagnostic imaging services.

Comment: Some commenters suggested that CMS ensure that PLEs provide all specified AUC to any developers of CDS mechanisms and do so in a similar manner in order to allow

ordering professionals to choose any AUC and any CDS mechanism, and to promote innovation. Other commenters recommended requiring standardization of AUC for the purposes of CDS mechanism integration.

Response: While we are not able to respond fully to these comments in this rule, we believe comments regarding standardization of AUC and CDS mechanisms for purposes of interoperability are very important, and we intend to further consider these comments and address this issue through rulemaking next year.

Comment: One commenter requested that CMS ensure that AUC developers do not use the process to restrict the scope of practice and limit a CRNA's ability to provide comprehensive pain management care.

Response: We are not aware of AUC developed with the goal of limiting the scope of practice for any practitioners. However, should this become a concern, especially to the extent that the limitations might not be evidence-based, then we would take measures to review these AUC, possibly including a review by the MEDCAC of their evidentiary basis.

Comment: One commenter recommended that qualified PLEs that develop AUC for a priority clinical area should be required to produce AUC that reasonably encompass the entire scope of that priority clinical area, so as to ensure that ordering professionals cannot use only a very small number of criteria with the goal of participating in the program as little as possible.

Response: We agree that for a qualified PLE to identify their AUC as addressing a priority clinical area, the AUC must address the area comprehensively; and we are revising our regulations to include language that addresses this concern.

Comment: Some commenters requested clarification about the AUC consultation process. For example, commenters questioned whether ordering professionals are expected to consult all AUC developed by qualified PLEs or just the AUC incorporated into the CDS mechanism they use. Some commenters supported the former approach. Other commenters

recommended that ordering professionals would only be required to consult and report on AUC included in priority clinical areas.

Response: Additional details regarding how this new program will be operationalized and what will appear on the Medicare claim form will be forthcoming in future rulemaking. However, section 218(b) of the PAMA does not expressly limit consultation to only a subset (priority clinical area) of AUC; rather, it is clear that AUC must be consulted for all advanced imaging services. Section 218(b) of the PAMA also recognizes the possibility that ordering practitioners could consult CDS and find no corresponding AUC. We anticipate that more details regarding consultation with CDS mechanisms and claims-based reporting will be released through rulemaking in CY 2017.

Comment: Some commenters expressed concern regarding conflicting AUC and conflicts between AUC and other policies (such as national coverage determinations). Some commenters requested clarification as to a reconciliation process for conflicting AUC and other commenters suggested that specialty societies work together to publish information regarding conflicting AUC.

Response: While we believe that qualified PLEs will be using an evidence-based AUC development process that will reduce the likelihood and frequency of conflicting AUC, we agree that conflicting AUC may be of concern. Conflicting AUC are now highlighted in our rule as an example of situations in which it might be appropriate for CMS and the MEDCAC to review the evidence base. Dramatically conflicting AUC may be a signal that one of them is not evidence-based. The MEDCAC could review the underlying evidence and the committee could discuss whether that evidence supports the conclusions of the AUC thereby exposing any non-evidence-based AUC.

Comment: Some commenters recommended including a mechanism to suspend or remove qualification for PLEs before the periodic requalification process in the event that the

PLE has non-evidence-based AUC and does not take steps to remediate or remove those criteria. Concerns from commenters included that a qualified PLE might fail to follow the process, but continue to have their AUC specified and used by ordering practitioners. Further, there was concern by commenters that non-evidence-based AUC would continue to be used by ordering practitioners for an extended period of time since requalification only occurs every 5 years.

Response: We agree with this comment and have added language to enable us to take steps to remove the qualified status of qualified PLEs that have non-evidence-based AUC within their AUC libraries and do not take prompt measures to resolve or remove the criteria. In addition to this scenario of non-evidence-based AUC, it is important that we have the ability to remove the qualified status from a PLE that fails to meet any of the other requirements set forth in our regulations under §414.94(c) relating to AUC development processes and transparency.

Comment: One commenter suggested that CMS accept applications to become a qualified PLE until March of 2016 rather than requiring them to be submitted by January 1, 2016. Other commenters request a further extension of the deadline, or postponement altogether of the PLE application process.

Response: We are finalizing the proposed deadline of January 1, 2016 for PLEs to apply to become qualified PLEs because we believe it is important that we avoid further delay of AUC specification and program implementation. We note that PLEs will have an annual opportunity to apply to become qualified.

Comment: Some commenters disagreed with our proposal to require qualified PLEs to reapply for qualification every 6 years, and were instead in favor of a shorter time frame for review.

Response: We carefully reviewed the timeline for reapplication and have determined that an application submitted by January of the 5^{th} year of approval will receive a determination prior to the start of the qualified PLE's 6^{th} year. Therefore, the cycle of approval for qualified PLEs is

every 5 years. This is different than what was proposed as we had originally proposed a cycle that was every 6 years. As finalized, a PLE that becomes qualified for the first 5-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021. A determination would be made by June 2021 and, if approved, the second 5-year cycle would begin in July 2021. For example:

Year 1 = July 2016 to June 2017

Year 2 = July 2017 to June 2018

Year 3 = July 2018 to June 2019

Year 4 = July 2019 to June 2020

Year 5 = July 2020 to June 2021 (reapplication is due by January 1, 2021)

We believe the reapplication timeline is appropriate and allows for PLEs, CDS mechanism developers and ordering practitioners to enter into longer term agreements without the constant concern that the PLE will lose its qualified status. We will assess whether a qualified PLE consistently has developed evidence-based AUC and met our other requirements at the time of requalification. We note, however, that if it appears that qualified PLEs are not maintaining compliance with our requirements for AUC development, we could reevaluate the requalification timeline in future rulemaking.

Comment: One commenter recommended listing all qualified PLEs on the CMS website.

Response: We agree with this comment and will list all qualified PLEs on the CMS website.

Comment: One commenter recommended a limit to the number of PLEs that can be qualified.

Response: We do not, at this time, believe it is necessary to limit the number of PLEs that can be qualified. If a PLE becomes qualified and is developing evidence-based AUC we believe they should have the opportunity for their AUC to become specified.

Comment: We received numerous comments regarding how to identify priority clinical areas. Some commenters recommended that CMS initially focus on a small number of high volume services. One commenter recommended limiting the priority clinical areas to only those with a strong evidence base rather than areas reliant on consensus opinions. Another commenter recommended including areas where a large gap exists between currently available AUC and studies that are ordered in the Medicare program (for example muscular-skeletal conditions, abdominal conditions). One commenter recommended that the priority clinical areas should clearly define cohorts of patients with common disease processes or symptom complexes. One commenter recommended that qualified PLEs identify the priority clinical areas or that CMS should accept proposals from qualified PLEs when identifying these areas. One commenter suggested that CMS consider imaging studies that have had high utilization rates over the past 10 years, conditions for which AUC have been most recently adopted where significant inappropriate use may still exist, and simple, common conditions.

Response: We appreciate these recommendations and believe that the proposals that we are finalizing will allow for consideration of varying elements in identifying priority clinical areas. We expect to propose the first priority clinical areas in next year's PFS rule based on stakeholder consultation, and hope to receive further, more specific public comments at that time.

Comment: Some commenters suggested that CMS identify a substantial number of priority clinical areas to ensure enough data are available to calculate outlier ordering professionals with statistical significance. One commenter recommended that, for the purpose of outlier identification, these areas should include those where there is wide clinical variance in appropriate ordering patterns.

Response: We appreciate these suggestions and will consider them when identifying proposed priority clinical areas.

Comment: Many comments strongly supported the proposed transparency requirements for qualified PLEs. Commenters supported the public posting of AUC, references to the information considered in developing AUC and AUC development, and the review and updating processes to qualified PLE websites. One commenter recommended posting all AUC development information to a website hosted by CMS. Another commenter requested clarification about acceptance of alternate means of making the information public (for example, hard copies upon request, electronically upon request, but not posted in full to the website).

Response: We agree that the transparency requirements are important and essential to this program. Public posting of the AUC and other required information to each PLE's website is required; and it will not suffice to make the information available in other, less accessible and transparent ways. It is our goal that the information be easily accessible and reviewable by all stakeholders. We do not anticipate posting this information on a CMS website as each qualified PLE retains responsibility for public posting of the required information.

Comment: Most commenters supported our proposed policies on transparency and conflicts of interest for multidisciplinary team members. Some commenters recommended further strengthening these requirements to incorporate references to AUC-related activities or relationships specific to commercial, non-commercial, intellectual, institutional, patient/public arenas. Other commenters recommended requiring the exclusion of team members with any significant conflicts of interest. Some commenters recommended that we impose transparency requirements for individuals and organizations at the commercial level specific to CDS mechanism sales/marketing, licensing relationships and advisory board memberships. One commenter requested clarification regarding conflict of interest requirements for entities that endorse AUC.

Response: We agree that transparency and disclosure of conflicts of interest is essential for multidisciplinary team members, and we are clarifying in this final rule with comment period

that these requirements apply to the team and to any other party involved in developing AUC including the qualified PLE itself. We disagree with the commenter's suggestion to categorically exclude through our regulations team members for whom there is a conflict of interest as those individuals may also have the greatest knowledge base for particular issues. Some conflicts may be unavoidable, and we believe transparency and disclosure will go far toward promoting objectivity. We believe that qualified PLEs should use their judgment to establish thresholds where certain conflicts would result in recusal or removal of an individual from the multidisciplinary team. We are aware that there are a number of existing templates, thresholds, and mechanisms that might reasonably apply to address conflicts of interest. We might address this issue further, and standardization of the treatment of conflicts could evolve through our annual rulemaking process. At this time we believe it is appropriate for conflicts to be disclosed and for the PLE to have a reasonable process in place to identify and address them. The final rule with comment period also provides for the information to be documented and available to the public upon request for a period of 5 years.

Comment: One commenter requested that transparency requirements specific to AUC and AUC development processes be balanced with "intellectual property protection for evidence-based content produced by commercial entities…" which could involve a process by which interested parties request access to criteria while intellectual property is protected. One commenter stated that CMS should not require public release of evidence-based content published under copyright protection.

Response: We support and have received strong support for the required public disclosure of these processes and resulting content. Transparency is essential to ensure all patients and stakeholders can review and understand how and why AUC are developed, and to which types of patients they do and do not apply. Making this information public is particularly important for ordering professionals when they are selecting the qualified PLEs and CDS

mechanisms that best address their practice needs. CDS mechanism developers and qualified PLEs may need to enter into agreements for AUC to be loaded into the mechanisms and used by ordering professionals.

Comment: One commenter recommended that we adopt a requirement for AUC developers to disclose any participating medical specialty societies that do not endorse the AUC being developed and the rationale for their not endorsing.

Response: PLEs may choose to list which medical specialties societies agree with their AUC and which ones do not. However, we do not believe it would be appropriate for us to require this disclosure or explanation. By having AUC in the public domain, any organization may respond to the AUC and state their agreement or disagreement in any format they determine is appropriate.

Comment: Many commenters expressed significant concerns regarding the implementation timeline set forth in section 218(b) of the PAMA. Commenters questioned whether it is feasible or reasonable to meet the January 1, 2017 deadline to require consultation by ordering professionals with CDS mechanisms given that we do not anticipate finalizing requirements for CDS mechanisms until rulemaking for the CY 2017 PFS and CDS mechanism developers and ordering professionals will need 12-18 months to incorporate the requirements into clinical practice.

Response: We understand these concerns and agree that the timeline set forth in section 218(b) of the PAMA is difficult to meet. As such, we will delay implementation of certain AUC program components including the requirement for consultation with CDS mechanisms. Consultation with a CDS mechanism will not be required on January 1, 2017 because we do not expect to have approved CDS mechanisms by that date. Although we will develop our plans through further rulemaking, at this time, we do not expect to have approved CDS mechanisms until approximately summer of 2017. In that event, consultations with CDS mechanisms could

not take place on January 1, 2017.

Comment: Some commenters supported maintaining the timeline set forth in the PAMA for AUC program implementation. One commenter stated that their organization was able to comply with the timeline. Some commenters also recommended using subregulatory guidance and requests for information (RFIs) outside of rulemaking to meet the timeline set forth in the PAMA.

Response: We appreciate the willingness and enthusiasm of these stakeholders in moving quickly forward in AUC program implementation; however, we believe that it is important to take a stepwise approach to implementation and to establish the components of this program as proposed through notice and comment rulemaking. This approach will ensure that we fully comply with requirements set forth in PAMA for stakeholder consultation, and that we develop a sound implementation plan. We will continue to engage with stakeholders to inform development of future AUC program components and we will consider using an RFI to help inform the next rulemaking cycle.

Comment: Many commenters encouraged CMS to engage in continued stakeholder interactions and dialogue for all aspects of the AUC program. Commenters particularly advocated for continued stakeholder involvement as we develop CDS mechanism requirements during the CY 2017 rulemaking cycle. Some commenters recommended more engagement with professional societies representing ordering physicians and one commenter suggested representation of ordering and primary care physicians if a MEDCAC is convened.

Response: We will continue to have an open-door policy and engage all stakeholders to develop and refine the AUC program. Not only is stakeholder consultation a requirement of PAMA, but we have found these interactions to be highly informative and critical in building this program.

Comment: Many commenters offered suggestions regarding the CDS component of the

AUC program. Commenters identified specific areas of importance for CMS to focus on such as interoperability of CDS mechanisms and electronic health records (EHRs) and the relationship between AUC developers and CDS mechanisms. Commenters also cautioned against a roll out of this component that would not allow sufficient time for CDS mechanisms to comply with the requirements yet to be established in rulemaking or the incorporation of AUC consultation through approved CDS mechanisms into clinical practice. Commenters further requested that CMS address the CDS mechanisms as soon as possible, potentially via avenues outside of the rulemaking process, to account for the short implementation timeline specified in section 218(b) of the PAMA. Commenters provided important and thoughtful recommendations and feedback regarding the CDS component of this program.

Response: We understand the interest in, and concerns expressed about the need for more information and details regarding the CDS mechanism requirements and incorporation into clinical practice; however, as discussed in our proposal, we anticipate that details regarding CDS mechanisms will be the focus of rulemaking during 2016 for the CY 2017 PFS. We appreciate these comments and will use them to inform development of future proposals. We will also continue to consult and interact with stakeholders. We note again that we do not expect that the AUC consultation through approved CDS mechanisms could be required on January 1, 2017.

Comment: Some commenters expressed concern regarding the burden placed on furnishing professionals in reporting on ordering professionals' compliance with AUC consultation. One commenter recommended that the furnishing professional should only be required to report on the claim whether or not the ordering professional consulted AUC.

Response: Under section 1834(q)(4)(B) of the Act, the furnishing professional is required by statute to include information on the claim (for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system) that identifies what qualified CDS mechanism was consulted by the ordering professional, whether the service

ordered would or would not adhere to that AUC, or was not applicable to the service, and the NPI of the ordering professional.

Comment: Some commenters requested clarification about allowing variations in AUC based on local populations and circumstances and cautioned that allowing exceptions to specified AUC could work against the goal of the AUC program. Many commenters supported flexibility in allowing variations based on local populations and circumstances, but some commenters suggested that processes for variations should still meet the AUC program requirements and should be rare.

Response: We believe that allowing for variations in AUC based on local circumstances is important to ensure that AUC consultation can be incorporated into clinical practice throughout the country. We agree that local variations should still meet the program requirements to ensure that the evidence to support modification is evaluated and graded and only performed by qualified PLEs.

Comment: Some commenters noted that section 218(b) of the PAMA allows for an exception to the requirement to consult AUC in the case of certain emergency services, but our proposal states that AUC applies to various settings including the Emergency Department. Commenters stated that this ambiguity could cause a delay in the delivery of emergency services to patients and requested clarification on the application of the AUC program in emergency departments and exceptions for certain emergency services.

Response: We understand the confusion and will take these comments into account as we further develop our policies on exceptions in the case of certain emergency services. We anticipate addressing this issue in rulemaking for the CY 2017 PFS.

Comment: One commenter requested clarification on whether mobile, free-standing high tech radiology units are subject to this program.

Response: Whether the equipment is mobile or fixed, the requirement to consult AUC is

based on whether the service at issue is an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system. Applicable imaging services include, in general, advanced diagnostic imaging services for which AUC are publicly available without charge. Applicable settings include a physician's office, hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. Applicable payment systems include the PFS, the hospital outpatient prospective payment system, and the ambulatory surgical center payment system. Although we anticipate developing further details regarding these specifications through future rulemaking, we believe the statutory specifications are fairly clear as to the services for which ordering professionals will be required to consult, and report on their consultation of, AUC. We believe the commenter can make a good preliminary assessment as to whether its services fall within these specifications.

Comment: One commenter stated that the proposed AUC program will have unintended consequences on ordering professionals and creates a burden for these practices without the promise of improved care. This commenter stated that some professional societies were not consulted in development of section 218(b) of the PAMA.

Response: AUC consultation by all advanced diagnostic imaging ordering professionals is a requirement under section 218(b) of the PAMA. We are developing this program with extensive stakeholder consultation and input to ensure that the program is implemented in a manner that does not create excessive burden for ordering professionals; yet we recognize that there unavoidably will be some underlying burden for ordering professionals in consulting AUC and reporting on that consultation.

Comment: Some commenters recommended that physicians and hospitals already involved in payment reform models be exempt from reporting requirements for ordering

professionals under this program.

Response: Section 218(b) of the PAMA does not include a provision for exceptions for participants in payment reform models. We will consider whether there is authority within the context of such models to consider developing exceptions for model participants.

Comment: Some commenters requested clarification regarding the use of non-evidence-based AUC, particularly when evidence-based AUC are available. Commenters suggested that non-evidence-based AUC may be more prevalent in the everyday practice of medicine.

Response: Section 218(b) of the PAMA requires that, to the extent feasible, AUC must be evidence-based; and we are including that requirement in the AUC development process. However, the process allows for the spectrum of the hierarchy of evidence to be used as part of the systematic review. AUC based on lower levels of evidence will be apparent as each appropriate use criterion posted to the PLE website would include the level of evidence for each of the decision node.

Comment: Some commenters expressed support for our proposal to identify non-evidence-based AUC through annual rulemaking and encourage public and stakeholder input in the process. One commenter suggested requiring all non-evidence-based AUC to be reviewed by the MEDCAC. One commenter recommended that CMS define and implement an additional auditing process that could be used to identify abuses and systematic failures.

Response: We are finalizing this proposal with additional language stating that conflicting AUC will be incorporated into the process for addressing non-evidence-based AUC. The MEDCAC may be convened to review these AUC. If a non-evidence-based appropriate use criterion is identified by the MEDCAC and the qualified PLE fails to revise the criterion to reflect the evidence then we may take action regarding the qualified PLE's status. In other words, we may determine that qualification should be reconsidered outside the 5 year reapplication process. We have not created additional auditing processes beyond those that we

already possess. We could consider this in future rulemaking if the agency and MEDCAC become overwhelmed by the volume of non-evidence-based AUC.

Comment: One commenter requested incorporation of a process for hardship exemptions to consider factors that might prevent or delay institutions from meeting the requirements of the AUC program.

Response: We will address the significant hardship exemption (section 1834(q)(4)(C)(iii) of the Act) in future rulemaking, and anticipate doing so in rulemaking for the CY 2017 PFS.

Comment: Some commenters recommended that ordering professionals who follow AUC that are developed by internationally-accepted methodologies should not have to complete prior authorizations related to that treatment. One commenter cautioned against including new care improvements in the identification of outliers as clinical practice will continue to change. One commenter requested that the CMS definition for outliers and mechanisms used to identify and penalize outliers must have the necessary flexibility to account for differences in volume of advanced imaging studies due to the composition of a physician's practice.

Response: We will address outlier identification and the prior authorization component of this program in future rulemaking.

Comment: Many commenters expressed concerns about the absence of claims processing instructions and reporting requirements for AUC consultation in our proposal, and the short time frame between publication of the CY 2017 PFS and the PAMA deadline for consultation with CDS mechanisms. Some of these commenters included suggestions for these instructions and reporting requirements.

Response: As discussed in the proposal, we anticipate addressing claims reporting requirements during the CY 2017 PFS rulemaking process. The deadline for consulting CDS mechanisms and reporting such consultations on Medicare claims will be delayed for a year consistent with our proposals in the proposed rule.

Comment: Some commenters believed that our proposal addressed problems encountered in the MID. One commenter specifically noted that the proposal accomplished this by: (a) expanding on the AUC definition to identify AUC as link between presenting clinical conditions and appropriate imaging services, not just based on imaging service; (b) correctly stressing the importance of integration of the CDS into clinical workflow; and (c) recognizing the importance of flexibility in implementing best practices given local circumstances. Other commenters stated that the proposal ignored some recommendations from the MID, specifically the recommendation to include guidelines from entities other than national specialty societies as the MID noted that societies "have a vested interest in advising that imaging be ordered."

Response: We have attempted to balance the findings of the MID with the statutory requirements by specifying libraries of AUC as opposed to individual criteria, and we hope that our transparency and conflict of interest requirements will address concerns that commenters had regarding conflict of interest of AUC developers. We also believe that lessons learned in the MID will benefit CDS mechanism development, and we encourage additional comments in that regard in the future.

Comment: One commenter requested confirmation that the AUC program will only be applicable to Medicare FFS, and not Medicare Advantage.

Response: This program is applicable only to services for which payment is made under the PFS, the hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

Comment: One commenter suggested that AUC should fit under the Merit-Based Incentive Payment System and should not be a stand-alone program.

Response: We do not believe, at this time, that it would be feasible for this program to be incorporated under other quality or value-based programs. However, we could explore whether there are opportunities for consolidation in the future.

In response to comments, we are making some changes to our proposals as well as finalizing most aspects of the policies as they were proposed in the CY 2016 PFS proposed rule.

We are finalizing the majority of definitions as they were proposed. However, based on public comments, we are changing the definitions of AUC, PLE and priority clinical area.

We proposed to define AUC as criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria must be evidence-based. 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). We are revising the last two sentences of the definition in response to public comments that expressed confusion regarding the AUC terminology used in our proposal. We have also revised related language throughout the final regulation accordingly.

We proposed to define PLE as a national professional medical specialty society, or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare. We are revising the definition of PLE to refer to organizations comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. The definition of PLE will retain the direct reference to national professional medical specialty societies, and other organizations like them are now subsumed within the definition.

This definition of PLE will include health care collaboratives and other similar organizations such as the National Comprehensive Cancer Network and the High Value Healthcare Collaborative. While this is not a dramatic change from the proposed rule, the focus is now on the role of the members that comprise the organization and not the function of the

organization itself. This definition aligns with the statute in that national professional medical specialty societies are given as an example of a PLE. Under the proposed definition, these societies were expressly specified as PLEs. It is not the function of the society to deliver care but rather their members are actively engaged in practicing medicine in the field. This final definition appropriately encompasses these organizations and others that are comprised of providers or practitioners who care for patients.

We are also modifying our proposed definition of priority clinical area. We proposed to define priority clinical area as clinical topics, clinical topics and imaging modalities, or imaging modalities identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the determination of outlier ordering professionals. We are changing the language to better describe the breadth of clinical areas that may be the focus of priority clinical areas. The finalized definition better reflects that priority clinical areas may identify clinical conditions, diseases or symptom complexes and their associated advanced diagnostic imaging services. This definition will allow the priority clinical areas to better align with the variety of clinical situations for which a patient may present to the ordering practitioner.

In response to the comments we received regarding the role of endorsement of AUC, we are adding a new §414.94(d) to the regulations. This new section clearly describes the role of endorsement. We note that only a qualified PLE may provide endorsement of AUC. Further, qualified PLEs may only endorse the AUC of other qualified PLEs. Independently, each organization must have been qualified, and therefore, we do not envision participation by CMS in the endorsement relationship. The primary function of endorsement is for qualified PLEs to combine their AUC to create a larger, more clinically encompassing library. For example, one qualified PLE may focus on developing AUC related to neuroimaging, another may focus on developing AUC related to abdominal imaging. The endorsement relationship gives recognition to this type of collaboration.

While we are finalizing the requirements for developing or modifying AUC as proposed (with the exception of grammatical, non-substantive changes for regulatory consistency) in §414.94(c)(1), we provide clarification in this final rule with comment period around what is expected regarding a systematic literature review as public commenters did not indicate a consistent understanding of this concept. To clarify, the evidence review requirement does not mean that PLEs must commission external systematic evidence reviews or technology assessments. We expect many organizations will undertake their own systematic evidence review to ensure all relevant evidence-based information is considered and evaluated. The literature review must be systematic, reproducible and encompass all relevant literature related to the specific imaging study. Ideally, the review would include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the PLE must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. We do not require that a particular methodology be used as there may be certain methodologies better suited to some evidentiary assessments than others.

For consistency with regulatory structure, we have revised the proposed language throughout §414.94(c) to more clearly represent the responsibility of the PLEs seeking qualification in demonstrating adherence to AUC development requirements under this section.

Based on public comments, we are changing the requirements for the multidisciplinary team that must be used in the AUC development process. We proposed at least one multidisciplinary team with autonomous governance, decision making and accountability for developing, modifying or endorsing AUC. At a minimum the team must be comprised of three members including one with expertise in the clinical topic related to the criterion and one with expertise in the imaging modality related to the criterion. While we proposed to require a smaller team, we are finalizing §414.94(c)(1)(ii) to state that a qualified PLE must utilize at least one multidisciplinary team with autonomous governance, decision making and accountability for

developing or modifying AUC. At a minimum the team must be comprised of seven members including at least one practicing physician with expertise in the clinical topic related to the appropriate use criterion being developed or modified, at least one practicing physician with expertise in the imaging studies related to the appropriate use criterion, at least one primary care physician or practitioner (as defined in sections 1833(u)(6), 1833(x)(2)(A)(i)(I), and 1833(x)(2)(A)(i)(II) of the Act), one expert in statistical analysis and one expert in clinical trial design. A given team member may be the team's expert in more than one domain. A team comprised in this manner and at this size better encompasses the expertise and the dedication needed to develop quality AUC. We encourage such teams to be larger where appropriate, and to include experts in medical informatics and quality improvement. These experts should contribute substantial work to the development of the criteria, not simply review the team's work. Teams may also consider involving other stakeholders.

Based on public comments in support of frequent review of AUC, we are adding language to §414(c)(1)(vii) to require at least annual review by qualified PLEs of their AUC.

In addition, since new §414.94(d) has been added to clarify the role of qualified PLE endorsement, the term endorsement has been removed from §414(c)(1)(ii) as it relates to the multidisciplinary team. Since only qualified PLEs can provide endorsement, these qualified PLEs have already demonstrated they meet the requirements of §414.94(c)(1)(ii).

We have added language to the conflict of interest disclosure requirement in §414.94(c)(1)(iii) to make clear that the conflict of interest processes and disclosures would apply not only to members of the multidisciplinary team but also the PLE and any entity that participated in the development of AUC.

In addition, and in response to comments, we have included that the conflict of interest process put in place by the PLE must also include processes to recuse or exclude members of the multidisciplinary team where appropriate. This language was not included in the proposed

language of §414.94(c)(1)(iii). We are finalizing conflict of interest language in §414.94(c)(1)(iii) and §414.94(c)(1)(iii)(A) and §414.94(c)(1)(iii)(B).

We are finalizing language to clarify that CMS will perform a review of each PLE's application for qualification. We have added "for review" to §414.94(c)(2)(i) to make it clear that PLEs must submit an application to CMS for review that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section.

We proposed the requalification timeline in §414.94(c)(2)(v). We revised the language and finalized two sections to clarify the requirements related to qualified PLE reapplication.

In the proposed rule we stated that PLEs, on their website, must identify when they have AUC that address a priority clinical area. Section 414.94(c)(1)(iv) included that, if relevant to a CMS identified priority clinical area, such a statement must be included. We have expanded this requirement and created §414.94(c)(1)(v) to include this requirement. This ensures that the AUC are broad enough in scope that an ordering professional could use those AUC to satisfy the priority clinical area.

Section 414.94(f)(3) has been added to clearly specify that CMS will consider information related to a PLE's failure to correct non-evidence-based AUC to determine whether CMS should terminate the PLE's qualified status, and that the information would be used during the PLE's re-qualification review.

To broaden the scope of which potentially non-evidence-based AUC may be reviewed by the MEDCAC, we have revised the language so as not to be limited to reviewing AUC that correspond to priority clinical areas. We proposed §414.94(e)(1) to state that CMS will accept public comment to facilitate identification of individual or groupings of AUC that fall within a priority clinical area and are not evidence-based. CMS may also independently identify AUC of concern. We have added language to §414.94(f)(1) that gives priority to AUC that correspond to priority clinical areas but does not limit review to such. In this section, we have also identified

that conflicting AUC may receive priority in MEDCAC review.

We thank the public for their comments and believe the changes based on these comments have improved the requirements and process that we will follow to specify AUC under this program for advanced diagnostic imaging services. Following the publication of this final rule with comment period, we will post information on our website for this program accessible at www.cms.gov/Medicare/Quality-Initiatives/Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program.