biologicals that are paid under section 1847A of the Act and set forth in 42 CFR part 414 subpart J Until we have collected sufficient sales data as reported by manufacturers, payment limits will be determined in accordance with the provisions in section 1847A(c)(4) of the Act If no manufacturer data is collected prices will be determined by local contractors using any available pricing information including provider invoices As with newly approved drugs and biologicals (including biosimilars), Medicare part B payment would be available once the product is approved by the FDA Payment for biosimilars (and other drugs and biologicals that are paid under part B) may be made before a HCPCS code has been released provided that the claim is reasonable and necessary, and meets applicable coverage and claims submission criteria

We would also like to clarify how wholesale acquisition cost (WAC) data may be used by CMS for Medicare payment of biosimilars in accordance with the provisions in section 1847A(c)(4) of the Act Section 1847A(c)(4) of the Act authorizes the use of a WAC-based payment amount in cases where the ASP during the first quarter of sales is not sufficiently available from the manufacturer to compute an ASP-based payment amount Once the wholesale acquisition cost (WAC) data is available from the pharmaceutical pricing compendia and when WAC-based payment amounts are utilized by CMS to determine the national payment limit for a biosimilar product, the payment limit will be 106 percent of the WAC of the biosimilar product, the reference biological product will not be factored into the WAC-based payment limit determination This approach is consistent with partial quarter pricing that was discussed in rulemaking in the CY 2011 PFS final rule with comment period (75 FR 73465 and 73466) and with statutory language at section 1847A(c)(4) of the Act Once ASP information is available for a biosimilar product, and when partial quarter pricing requirements no longer apply, the Medicare payment limit for a biosimilar product will be determined based on ASP data

F Productivity Adjustment for the Ambulance, Clinical Laboratory, and DMEPOS Fee Schedules

Section 3401 of the Affordable Care Act requires that the update factor under certain payment systems be annually adjusted by changes in economy-wide productivity The year that the productivity adjustment is effective varies by payment system Specifically, section 3401 of the Affordable Care Act requires that in CY 2011 (and in subsequent years) update factors under the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS) and the DMEPOS fee schedule be adjusted by changes in economy-wide productivity Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to add clause (xi)(II), which sets forth the definition of this productivity adjustment The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) Historical published data on the measure of MFP is available on the Bureau of Labor Statistics (BLS) Web site at *http //www bls gov/mfp*

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth The projection of the components of MFP are currently produced by IHS Global Insight, Inc (IGI) a nationally recognized economic forecasting firm with which we contract to forecast the components of MFP To generate a forecast of MFP IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U S macroeconomic models In the CY 2011 and CY 2012 PFS final rules with comment period (75 FR 73394 through 73396, 76 FR 73300 through 73301), we set forth the current methodology to generate a forecast of MFP We identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series Beginning with CY 2016, for the AFS, CLFS and DMEPOS fee schedule, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with CY 2016 A complete description of the MFP projection methodology is available on our Web site at *http //www cms gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and Reports/MedicareProgram RatesStats/MarketBasketResearch html* Although we discuss the IGI changes to the MFP proxy series in this proposed rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking

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 proposed rule outlines the initial component of the new Medicare AUC program and our plan for implementing the remaining components

1 Background

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

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

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

2 Previous AUC Experience

The first CMS experience with AUC, the Medicare Imaging Demonstration (MID), was required by section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) Designed as an alternative to prior authorization, the MID's purpose was to examine whether provider exposure to appropriateness guidelines would reduce inappropriate utilization of advanced imaging services In the 2-year demonstration which began in October 2011, nearly 4,000 physicians, grouped into one of five conveners across geographically and organizationally diverse practice settings, ordered a total of nearly 50,000 imaging studies [1]

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 decision tree The end goal of using AUC is to improve patient health outcomes In reality, however, many providers may encounter AUC through a CDS mechanism for the first time at the point of image ordering The CDS would ideally bring the provider back to that specific clinical condition and work-up scenario to ensure and simultaneously document the appropriateness of the imaging test

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

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

3 Statutory Authority

Section 218(b) of the PAMA amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, "Recognizing Appropriate Use Criteria for Certain Imaging Services," which directs us to establish a new program to promote the use of AUC In section 1834(q)(1)(B) of the Act, AUC are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual

4 Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2)), (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)), (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)), and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)) In this proposed rule, we primarily address the first component under section 1834(q)(2)—the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1)

Section 1834(q)(1) of the Act describes the program and provides definitions of terms The program is required to promote the use of AUC for applicable imaging services furnished in an applicable setting by ordering professionals and furnishing professionals Section 1834(q)(1) of the Act provides definitions for AUC, applicable imaging service, applicable setting, ordering professional, and furnishing professional An "applicable imaging service" under section 1834(q)(1)(C) of the Act must be an advanced imaging service as defined in section 1834(e)(1)(B) of the Act, which defines "advanced diagnostic imaging services" to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography), and other diagnostic imaging services we may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services

Section 1834(q)(2)(A) of the Act requires the Secretary to specify applicable AUC for applicable imaging services, through rulemaking and in consultation with physicians, practitioners and other stakeholders, by November 15, 2015 Applicable AUC may be specified only from among AUC developed or endorsed by national professional medical specialty societies or other provider-led entities Section 1834(q)(2)(B) of the Act identifies certain considerations the Secretary must take into account when specifying applicable AUC including whether the AUC have stakeholder consensus, are scientifically valid and evidence-based,

[1] Timbie J Hussey P Burgette L et al Medicare Imaging Demonstration Final Evaluation Report to Congress 2014 The Rand Corporation

and are based on studies that are published and reviewable by stakeholders Section 1834(q)(2)(C) of the Act requires the Secretary to review the specified applicable AUC each year to determine whether there is a need to update or revise them and to make any needed updates or revisions through rulemaking Section 1834(q)(2)(D) of the Act specifies that, if the Secretary determines that more than one AUC applies for an applicable imaging service, the Secretary shall apply one or more AUC for the service

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

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

The second major component of the Medicare AUC program is the identification of qualified CDS mechanisms that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act We envision a CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user The ordering professional would input information regarding the clinical presentation of the patient into the CDS tool, which may be a feature of or accessible through an existing system and the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services Ideally, multiple CDS mechanisms would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology (IT) systems This would minimize burden on provider teams and avoid duplicate documentation

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

However, all CDS mechanisms must meet the requirements under section 1834(q)(3)(B) of the Act which specifies that a mechanism must Make available to the ordering professional applicable AUC and the supporting documentation for the applicable imaging service that is ordered, where there is more than one applicable AUC specified for an applicable imaging service, indicate the criteria it uses for the service, determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC, generate and provide to the ordering professional documentation to demonstrate that the qualified CDS was consulted by the ordering professional, be updated on a timely basis to reflect revisions to the specification of applicable AUC, meet applicable privacy and security standards, and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional) Section 1834(q)(3)(C) of the Act specifies that the Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDS mechanisms

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

The third major component of the AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a listed qualified CDS mechanism when ordering an applicable imaging service that would be furnished in an

applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDS mechanism. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders the imaging service is usually not the same professional who bills Medicare for the test when furnished. Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain a hardship exemption. Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the physician fee schedule, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

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

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

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

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

5. Proposals for Implementation

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

a. Definitions

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

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

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

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

For the purposes of implementing this program, we are proposing to define new terms in § 414.94(b). A provider-led entity would include national professional medical specialty societies (for example the American College of Radiology and the American Academy of Family Physicians) or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare (for example hospitals and health systems). Applicable AUC become specified when they are developed, modified or endorsed by a qualified provider-led entity. A provider-led entity is not considered qualified until CMS makes a determination via the qualification process discussed in this proposal. We are introducing priority clinical areas to inform ordering professionals and furnishing professionals of the clinical topics, clinical topics and imaging modalities or imaging modalities that may be identified by the agency through annual rulemaking and in consultation with stakeholders which may be used in the identification of outlier ordering professionals.

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

b AUC Development by Provider-Led Entities

In § 414 94, we are proposing to include regulations to implement the first component of the Medicare AUC program—specification of applicable AUC We are first proposing a process by which provider-led entities (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC The cornerstone of this process is for provider-led entities to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC It is through this demonstration that we propose to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for the AUC Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based and are based on studies that are published and reviewable by stakeholders It is not feasible for us to review every individual criterion Rather, we propose to establish a qualification process and requirements for qualified provider-led entities in order to ensure that the AUC development or endorsement processes used by a provider-led entity result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B) Therefore, we propose that AUC developed, modified, or endorsed by qualified provider-led entities will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services

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

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

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

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

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

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

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

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

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

We are proposing that provider-led entities must apply to CMS to become qualified We are proposing that entities that believe they meet the definition of provider-led submit applications to us that document adherence to each of the qualification requirements The application must include a statement as to how the entity meets the definition of a provider-led entity Applications will be accepted each year but must be received by January 1 A list of all applicants that we determine to be

CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the qualified registry If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor* For a group practice of 25 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is patient data Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures a group practice would be required to report on at least 1 measure for which there is Medicare patient data

(vii) *Via a certified survey vendor in addition to the GPRO web interface* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor In addition, the group practice must report on all measures included in the GPRO web interface, AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group s sample for each module or preventive care measure If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries A group practice will be required to report on at least 1 measure for which there is Medicare patient data

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 25 or more eligible professionals who elect to use the GPRO web interface must administer the CAHPS for PQRS survey

(k) *Satisfactory participation requirements for the payment adjustments for individual eligible professionals and group practices* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination or group practice must meet the criteria for satisfactory participation as specified in paragraph (k)(3) for such year, by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section

* * * * *

(2) *Reporting mechanism* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry

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(5) *Satisfactory participation criteria for individual eligible professionals and group practices for the 2018 PQRS payment adjustment* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a QCDR for the 2018 PQRS payment adjustment must report information on quality measures identified by the QCDR in the following manner

(i) For the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional s patients Of these measures, report on at least 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, or efficiency/appropriate use

(ii) [Reserved]

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■ 34 Section 414 94 is added to Subpart B to read as follows

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

(a) *Basis and scope* This section implements the following provisions of the Act

(1) Section 1834(q)—Recognizing Appropriate Use Criteria for Certain Imaging Services

(2) Section 1834(q)(1)—Program Established

(3) Section 1834(q)(2)—Establishment of Applicable Appropriate Use Criteria

(b) *Definitions* As used in this section unless otherwise indicated—

Advanced diagnostic imaging service means an imaging service as defined in section 1834(e)(1)(B) of the Act

Applicable imaging service means an advanced diagnostic imaging service (as defined in section 1834(e)(1)(B) of the Act for which the Secretary determines—

(i) One or more applicable appropriate use criteria apply,

(ii) There are one or more qualified clinical decision support mechanisms listed, and

(iii) One or more of such mechanisms is available free of charge

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department) an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary

Appropriate use criteria (AUC) means criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual To the extent feasible, such criteria must be evidence-based AUC are a collection of individual appropriate use criteria Individual criteria is 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)

Furnishing professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who furnishes an applicable imaging service

Ordering professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who orders an applicable imaging service

Priority clinical areas means 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.

Provider-led entity means 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.

Specified applicable appropriate use criteria means AUC developed, modified or endorsed by a qualified provider-led entity.

(c) *Qualified provider-led entities.* Provider-led entities (PLEs) must follow appropriate, evidence-based processes for the development of AUC and demonstrate adherence to the requirements below to be qualified by CMS. AUC developed, modified or endorsed by qualified PLEs are specified applicable AUC. Qualified PLEs may develop AUC, modify AUC developed by another entity, or provide endorsement to AUC developed by other entities.

(1) *Requirements for developing, modifying or endorsing AUC.* All of the following requirements must be met:

(i) An evidentiary review process that includes:

(A) A systematic literature review of the clinical topic and relevant imaging studies; and

(B) An assessment of the evidence using a formal, published and widely recognized methodology for grading evidence. Consideration of relevant published consensus statements by professional medical specialty societies must be part of the evidence assessment.

(ii) 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.

(iii) A publicly transparent process for identifying potential conflicts of interest of members on the multidisciplinary team. The following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the AUC publication of the related recommendation:

(A) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC. This may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.

(B) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.

(iv) Individual criteria must be published on the provider-led entity's Web site and include an identifying title, authors, and key references used to establish the evidence. If relevant to a CMS identified priority clinical area, such a statement must be included.

(v) Key points in individual criteria must be identified as evidence-based or consensus-based, and graded in terms of strength of evidence using a formal, published and widely recognized methodology.

(vi) The provider-led entity must have a transparent process for the timely and continual updating of each criterion.

(vii) The provider-led entity's process for developing, modifying or endorsing AUC is publicly posted on the entity's Web site.

(2) *Process to identify qualifying provider-led entities.* Provider-led entities must meet all of the following criteria:

(i) Provider-led entities must submit an application to CMS that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section;

(ii) Applications will be accepted by CMS only from provider-led entities that meet the definition in paragraph (b) of this section;

(iii) Applications must be received by CMS annually by January 1;

(iv) All approved provider-led entities from each year of submissions will be posted to the CMS Web site by June 30; and

(v) Qualified provider-led entities are required to re-apply every 6 years. The application must be submitted by January 1 during the 5th year of their approval.

(d) *Identifying priority clinical areas.* (1) CMS must identify priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, volume variability of utilization, and strength of evidence for imaging services. We will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.

(3) The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.

(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals (section 1834(q)(5) of the Act).

(e) *Identification of non-evidence based AUC.* (1) 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.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

■ 35. Section 414.605 is amended by revising the definition of "Basic life support (BLS)" to read as follows:

§ 414.605 Definitions.

* * * * *

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from State to State.

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§ 414.610 [Amended]

■ 36. In § 414.610, amend paragraphs (c)(1)(ii) introductory text and (c)(5)(ii), by removing the date "March 31, 2015" and adding in its place the date "December 31, 2017".

■ 37. Section 414.904 is amended by revising paragraph (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(j) *Biosimilar biological products.* Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in § 414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4)