

C. 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) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The CY 2016 PFS final rule with comment period addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In that rule we established evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs are expected to be posted on the CMS website by the end of June 2016 at which time their AUC libraries will be considered to be specified AUC for purposes of section 1834(q)(2)(A) of the Act.

This rule proposes requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of priority clinical areas; and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

1. Background

AUC 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). For purposes of this program, AUC are a set or library of individual appropriate use criteria. Each individual criterion is an evidence-based guideline for a particular clinical scenario. Each scenario in turn starts with a patient's presenting symptoms and/or condition. 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 clinical presentation.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians would access the AUC during the patient workup. While CDSMs can be standalone applications that require direct entry of patient information, they may be more effective when they automatically incorporate information such as specific patient characteristics, laboratory results, and lists of co-morbid diseases from Electronic Health Records (EHRs) and other sources. Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

Consistent with definitions of CDSM by the Agency for Healthcare Research and Quality (AHRQ) (<http://www.ahrq.gov/professionals/prevention-chronic-care/decision/clinical/index.html>), and the Office of the National Coordinator for Health Information Technology (ONC) (<https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds>), within Health IT applications, a CDSM is a functionality that provides persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

2. Previous CDSM Experience

In the CY 2016 PFS final rule with comment period, we included a discussion of the Medicare Imaging Demonstration (MID), which was required by section 135(b) of the MIPPA, in addition to independent experiences of implementing AUC by several healthcare systems and academic medical centers. Two key aspects of that discussion remain relevant to the CDSM component of this program. First, AUC, and the CDSMs through which clinicians access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery. For instance, a CDSM external to a provider's primary user interface could utilize an application program interface (API), a set of protocols and tools specifying how software components should interact, to pull relevant information into the

decision support application. By adhering to common interoperability standards, such as the national standards advanced through certified health IT (see 2015 edition of criteria available in the **Federal Register** (80 FR 62601) and described in the Interoperability Standards Advisory at <https://www.healthit.gov/standards-advisory>), CDSMs could both ensure integration of patient-specific data from EHRs, and allow clinicians to optimize the time spent using the tool.

Second, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (symptoms) and assists the clinician in the overall patient workup, treatment, and follow-up. Imaging would appear as key nodes within the clinical management decision tree.

Other options outside of certified EHR technology exist to access AUC through CDSMs. Stand-alone, internet-based CDSMs are available and, although they will not interact with EHR data, can nonetheless search for and present AUC relevant to a patient's presenting symptoms or condition.

In communicating an appropriateness rating to the ordering practitioner, some CDSMs provide a scale with numeric ratings, some output a red, yellow, or green light while others provide a dichotomous yes or no. At this time, we do not believe there is one correct approach to communicating the level of appropriateness to the ordering professional. However, section 1834(q)(4)(B) of the Act requires that information be reported on the claim form as to whether the service would or would not adhere to the specified AUC consulted through a particular CDSM, or whether the AUC was not applicable to the service. We are requesting feedback from commenters regarding how appropriateness ratings provided by CDSMs could be interpreted and recorded for the purposes of this program.

There are different views about the comprehensiveness of AUC that should be accessible within CDSMs. Some stakeholders believe that the CDSM should contain as comprehensive a collection of AUC as possible, incorporating individual criteria from across all specified AUC libraries. The intent would be for ordering professionals to avoid the frustration, experienced and voiced by many clinicians

participating in the MID, of spending time navigating the CDSM only to find that no criterion for their patient's specific clinical condition exists.

Other stakeholders believe, based on decades of experience rolling out AUC in the context of robust quality improvement programs that it is best to start with a CDSM that contains AUC for a few clinical areas where impact is large and evidence is strong. This would ensure that quality AUC are developed, and that clinicians and entire care teams could fully understand the AUC they are using, including when they do not apply to a particular patient.

As we stated in the CY 2016 PFS final rule with comment period, 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 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 PLEs, and an array of CDSMs from which clinicians may choose.

3. Priority Clinical Areas

We established in the CY 2016 PFS final rule with comment period that we would identify priority clinical areas through rulemaking, and that these may be used in the determination of outlier ordering professionals (a future phase of the Medicare AUC program). The concept of priority clinical areas allows us to implement an AUC program that combines the focused and comprehensive approaches to implementation discussed above. Although potentially large volumes of AUC (as some PLEs have large libraries of AUC) would become specified across clinical conditions and advanced imaging technologies, we believe this rapid and comprehensive roll out of specified AUC should be

balanced with a more focused approach when 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.

As we describe earlier, CDSMs are the access point for ordering professionals to consult AUC. We believe the combination of the comprehensive and focused approaches should be applied to CDSM requirements as we consider a minimum floor of AUC that must be made available to ordering professionals through qualified CDSMs. AUC that reasonably address the entire clinical scope of priority clinical areas could establish a minimum floor of AUC to be included in qualified CDSMs, and the number of priority clinical areas could be expanded through annual rulemaking and in consultation with physicians and other stakeholders. This allows priority clinical areas to roll out judiciously, and build over time.

4. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, “Recognizing Appropriate Use Criteria for Certain Imaging Services,” which directs the Secretary to establish a new program to promote the use of AUC. Section 1834(q)(3)(A) of the Act requires the Secretary to specify qualified CDSMs that could be used by ordering professionals to consult with specified applicable AUC for applicable imaging services.

5. 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) identification of 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)). As we will discuss later in this preamble, we did not identify mechanisms for consultation by April 1, 2016 and will not have specified or published the list of qualified CDSMs by January 1, 2017; therefore, ordering professionals will not be required to consult CDSMs, and furnishing professionals will not be able to report information on the consultation, by this date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component under section 1834(q)(2) of the Act – the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term PLE and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by CMS, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined the term PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network. Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

A timeline and process was established for PLEs to apply to become qualified with the first list

of qualified PLEs expected to be published at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html> by June 30, 2016.

b. Mechanism for AUC Consultation

The second major component of the Medicare AUC program is the specification of qualified CDSMs that could be used by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act. We envision a CDSM as an interactive tool that communicates AUC information to the user. Information regarding the clinical presentation of the patient would be incorporated into the CDSM from another health IT system or through data entry by the ordering professional. At a minimum, the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, CDSMs would be integrated within or seamlessly interoperable with existing health IT systems and would automatically receive patient data from the EHR or through an API or other connection. Such integration would minimize burden on practitioners and avoid duplicate documentation. Also useful to clinicians would be the ability to switch between CDSMs that can interoperate based on common standards.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDSMs 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 CDSMs that are independent of certified EHR technology; and a CDSM established by the Secretary. The Secretary does not propose to establish a CDSM at this time.

All CDSMs 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 documentation supporting the appropriateness of the applicable imaging service that is ordered; where there is more than one applicable appropriate use criterion 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 CDSM 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 CDSMs.

As we explained in the CY 2016 PFS proposed and final rules with comment period, 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 continue to 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, as we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. As we did prior to the CY 2016 PFS proposed rule when we met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program, we have used the time prior to the CY 2017 PFS proposed rule to meet with many of the same stakeholders but also a new group of stakeholders specifically related to CDSMs. In addition, we are continuing our stepwise approach to implementing this AUC program. The first phase of the AUC program (specifying AUC including defining what AUC are and specifying the process for developing them) was accomplished through last year's CY 2016 PFS final rule with

comment period. For this second phase, we will use this CY 2017 PFS rulemaking process as the vehicle to establish requirements for CDSMs, and the process to specify qualified CDSMs, in a transparent manner that allows for stakeholder and public involvement. Therefore, the final CDSM requirements and process for CDSMs to become qualified would be published in the CY 2017 PFS final rule with comment period on or about November 1, 2016.

c. AUC Consultation and Reporting

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 qualified CDSM 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 CDSM. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders an applicable imaging service is usually not the same professional who bills Medicare for that service 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 an exception due to a significant hardship. 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 systems.

Since a list of qualified CDSMs is not yet available and will not be available by January 1, 2017, we will not require ordering professionals to meet this requirement by that date.

d. Identification of Outliers

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 proposing to implement these sections in the CY 2017 PFS proposed rule, we propose below a list of priority clinical areas which may serve as part of the basis for identifying outlier ordering professionals.

6. Proposals for Implementation

We propose to amend our regulations at §414.94, “Appropriate Use Criteria for Certain Imaging Services.”

a. Definitions

In §414.94(b), we propose to codify and add language to clarify some of the definitions provided in section 1834(q) 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 propose to codify to facilitate understanding and encourage public comment on the AUC program.

We propose to define CDSM under §414.94(b) as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient’s specific clinical condition. A CDSM would incorporate specified applicable AUC sets from which an ordering professional could select. A CDSM may be a module within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology. If within or available through certified EHR technology, a qualified CDSM would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service.

As prescribed in section 1834(q) of the Act and §414.94(b) of our regulations, the Medicare AUC program imposes requirements only for applicable imaging services furnished in applicable settings. Further, as specified in section 1834(q)(4)(D) of the Act, we propose to amend our regulation at §414.94(b) to state that the applicable payment systems for the Medicare AUC program are the PFS under section 1848(b) of the Act, the prospective payment system for hospital outpatient department services under section 1833(t) of the Act, and the ambulatory surgical center payment systems under section 1833(i) of the Act. Applicable payment systems are relevant to implementation of section 1834(q)(4)(B) of the Act, entitled “Reporting by Furnishing Professionals.”

We remind readers that in PFS rulemaking for CY 2016 we defined applicable imaging service in §414.94(b) as an advanced diagnostic imaging service as defined in 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.

b. Priority Clinical Areas

We propose to establish a new §414.94(e)(5) to set forth the initial list of priority clinical areas.

To compile this proposed list we performed an analysis of Medicare claims data using the CMS Chronic Conditions Data Warehouse (CCW) as the primary data source. The CCW contains 100 percent of Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program. Data were derived from the CCW’s 2014 Part B non-institutional claim line file, which includes Part B services furnished during CY 2014. This is the main file containing final action claims data for non-institutional health care providers, including physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, and freestanding ambulatory surgical centers. The Part B non-institutional claim line file contains the individual line level information from the claim and

includes Healthcare Common Procedure Coding System (HCPCS) code(s), diagnosis code(s) using the International Classification of Diseases, Ninth Revision (ICD-9), service dates, and Medicare payment amount. A publicly available version of this dataset can be downloaded from the CMS website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>. We encourage stakeholders to review this dataset as a source that may help inform public comments related to the proposed priority clinical areas.

In the CY 2016 PFS final rule with comment period, we stated that when identifying priority clinical areas we may consider factors such as incidence and prevalence of disease, the volume and variability of utilization of imaging services, the strength of evidence for their use, and applicability of the clinical area to the Medicare population and to a variety of care settings.

Using the 2014 Medicare claims data referenced above, we ranked ICD-9 codes by the frequency with which they were used as the primary indication for specific imaging procedures, which in turn were identified by the volume of individual Current Procedural Terminology (CPT) codes for which payments were made in 2014. We extracted the top 135 ICD-9 codes from this list and formed clinically-related categories. Next, we searched manually through an electronic list of all ICD-9 codes to find others that would plausibly fit into each clinical grouping. This process required subjective clinical judgment on whether a particular ICD-9 code should be included in a given clinical group. The top eight clinical groupings (by volume of procedures) are what we are proposing as the initial list of priority clinical areas. The eight clinical areas account for roughly 40 percent of part B advanced diagnostic imaging services paid for by Medicare in 2014. We are aware that some stakeholders have suggested beginning the AUC program with no more than five priority clinical areas while others have suggested a far greater number. We believe the proposed eight priority clinical areas strike a reasonable balance that allows us to focus on a significant range and volume of advanced diagnostic imaging

services.

We also considered extracting pulmonary embolism as a separate priority clinical area from the chest pain grouping based on stakeholder consultation and feedback. However, we decided not to identify pulmonary embolism separately, but are asking for public comment on whether pulmonary embolism should be included as a stand-alone priority clinical area. Based on our consultations with physicians, practitioners and other stakeholders, as required by section 218(b) of the PAMA, we attempted to be inclusive when grouping ICD-9 codes into cohesive clinical areas. As an example of how we derived the priority clinical area for low back pain, we grouped together 10 ICD-9 codes, incorporating six from the top 135 and four from the manual search of all ICD-9 codes. Included in this grouping are the ICD-9 codes for displacement of lumbar intervertebral disc without myelopathy (722.10), degeneration of lumbar of lumbosacral intervertebral disc (722.52), intervertebral disc disorder with myelopathy lumbar region (722.73), post-laminectomy syndrome of lumbar region (722.83), lumbago (724.2), sciatica (724.3), thoracic or lumbosacral neuritis or radiculitis unspecified (724.4), spinal stenosis, lumbar region, without neurogenic claudication (724.02), lumbosacral spondylosis without myelopathy (721.3), and spondylosis with myelopathy lumbar region (721.42) which resulted in 1,883,617 services. To see all of the priority clinical area groupings of diagnosis codes, a table is available on the CMS website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>.

Using the above methodology, we developed and are proposing eight priority clinical areas. These reflect both the significance and the high prevalence of some of the most disruptive diseases in the Medicare population.

TABLE 34: Proposed Priority Clinical Areas with Corresponding Claims Data

Proposed Priority Clinical Area	Total Services	% Total Services¹	Total Payments	% Total Payments/1
Chest Pain (includes angina, suspected myocardial infarction, and suspected pulmonary embolism)	4,435,240.00	12%	\$ 470,395,545	14%
Abdominal Pain (any locations and flank pain)	2,973,331.00	8%	\$ 235,424,592	7%
Headache, traumatic and non-traumatic	2,107,868.00	6%	\$ 89,382,087	3%
Low back pain	1,883,617.00	5%	\$ 180,063,352	5%
Suspected stroke	1,810,514.00	5%	\$ 119,574,141	4%
Altered mental status	1,782,794.00	5%	\$ 83,296,007	3%
Cancer of the lung (primary or metastatic, suspected or diagnosed)	1,114,303.00	3%	\$ 154,872,814	5%
Cervical or neck pain	1,045,381.00	3%	\$ 83,899,299	3%

¹ Percentage of 2014 Part B non-institutional claim line file for advanced imaging services from Medicare claims for beneficiaries who are enrolled in the fee-for-service (FFS) program (source: CMS Chronic Conditions Data Warehouse).

CMS also engaged the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC), the MITRE Corporation (MITRE), to begin developing efficient and effective processes for managing current and future health technology assessments. MITRE generated an independent report that presents a summary of findings from claims data from the Medicare population and their utilization of advanced imaging procedures. Coupled with our internal analysis, this report has assisted in identification of proposed priority clinical areas for the Medicare AUC program for advanced diagnostic imaging services. Analysis and methods for this report are available at <https://www.mitre.org/publications/technical-papers/claims-data-analysis-to-define-priority-clinical-areas-for-advanced>.

While this year we are proposing priority clinical areas based on an analysis of claims data alone, we may use a different approach in future rulemaking cycles. As we provided in §414.94(e) of our regulations, we may consider factors other than volume when proposing priority clinical areas including incidence and prevalence of disease, variability of use of particular imaging services, strength of

evidence supporting particular imaging services and the applicability of a clinical area to a variety of care settings and to the Medicare population.

We encourage public comments on this proposed initial list of priority clinical areas, including recommendations for other clinical areas that we should include among our list of priority clinical areas. In particular, we are interested in comments on the above methodology or alternate options; whether the proposed priority clinical areas are appropriate including information on the extent to which these proposed priority clinical areas may be represented by clinical guidelines or AUC in the future. Furthermore, we are interested in public comments, supported by published information, with respect to varying levels of evidence that exist across as well as within priority clinical areas.

c. CDSM Qualifications and Requirements

We are proposing to add a new §414.94(g)(1) to our regulations to establish requirements for qualified CDSMs. Section 1834(q)(3)(A)(iii) of the Act provides relative flexibility for qualified CDSMs, and states that they may include mechanisms that are within certified EHR technology, private sector mechanisms that are independent from certified EHR technology or mechanisms that are established by the Secretary.

We believe that, at least initially, it is in the best interest of the program to establish CDSM requirements that are not prescriptive about specific IT standards. Rather, we are proposing an approach that focuses on the functionality and capabilities of qualified CDSMs. The CDSM, EHR and health IT environments are constantly changing and improving and we want to allow room for growth and innovation. However, in the future, as more stakeholders and other entities including the ONC, AHRQ, and relevant standards development organizations come to consensus regarding standards for CDSMs, then we may consider pointing to such standards as a requirement for qualified CDSMs under this program. We believe standards would make it possible to achieve interoperability, allowing any CDSM

to incorporate any standardized AUC and for sets of AUC to be easily interchangeable among various CDSMs. We will continue to work with the ONC and AHRQ to facilitate movement in this direction.

Recent work under the federally-sponsored Clinical Quality Framework (CQF) initiative has successfully developed an integrated approach that harmonizes standards for electronic clinical quality measurement with those that enable shareable clinical decision support artifacts (for example, AUC). The CQF initiative is working to support semantically interoperable data exchange for (1) sending patient data to a service for clinical decision support guidance and receiving clinical decision support guidance or quality measurement results in return, and (2) enabling a system to consume and internally execute decision support artifacts. As this standard is considered sufficiently mature for widespread adoption, the ONC may consider it for use in future editions of certification criteria for health IT. While the current regulation requires no specific standard, the CMS and ONC are supportive of this approach and additional information can be found at <http://hl7-fhir.github.io/cqif/cqif.html>.

Under §414.94(g)(1), we propose to codify in regulations the seven requirements for qualified CDSMs set forth in section 1834(q)(3)(B)(ii) of the Act. The Act requires qualified CDSMs to make available to the ordering professional specified applicable AUC and the supporting documentation for the applicable imaging service ordered. We do not interpret this requirement to mean that every qualified CDSM must make available every specified applicable AUC. In the CY 2016 PFS final rule with comment period we allowed for the approval of massive libraries of AUC (resulting from approvals for qualified PLEs with comprehensive and extensive libraries), yet we expressed our intention to establish priority clinical areas. While there is a statutory requirement to consult AUC for each applicable imaging service, we recognize that ordering professionals may choose to thoroughly improve their understanding of, and focus their internal quality improvement (QI) programs on, those priority clinical areas; and these areas will in turn serve as the basis for future outlier calculations.

Consistent with that approach, we propose to add a requirement in §414.94(g)(1)(iii) that qualified CDSMs must make available to ordering professionals, at a minimum, specified applicable AUC that reasonably encompass the entire clinical scope of all priority clinical areas. We encourage and expect some CDSMs, based on the needs of the professionals they serve, will choose to include a far more comprehensive set of AUC going above and beyond the minimum set as we understand many ordering professionals want such comprehensive access to AUC. When this Medicare AUC program is fully implemented, all ordering professionals must consult specified applicable AUC through a qualified CDSM for every applicable imaging service that would be furnished in an applicable setting and paid for under an applicable payment system in order for payment to be made for the service. However, when identifying the outlier ordering professionals who will be subject to prior authorization beginning in 2020, we anticipate focusing on consultation with specified applicable AUC within priority clinical areas rather than the universe of specified applicable AUC. The concept of priority clinical areas will allow us to implement an AUC program that combines two approaches to implementation allowing clinicians flexibility to either engage with a rapid rollout of comprehensive specified applicable AUC or adopt a focused approach to consulting AUC. Thus, they can choose their approach and select a CDSM and AUC set(s) that fit their needs and preferences, while being sure that each qualified CDSM will include AUC that address all priority clinical areas.

We further propose to add a requirement in §414.94(g)(1)(iv) of our regulations that qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE. We believe this approach ensures that CDSMs can expand the AUC libraries they can provide access to in order to represent AUC across all priority clinical areas (consistent with the requirements under proposed §414.94(g)(1)(iii)). We do not necessarily expect that a single qualified PLE will develop AUC addressing every priority clinical area domain, especially since we believe that over time and

through future rulemaking, the list of priority clinical areas will expand and cross additional clinical domains. Ensuring that qualified CDSMs are not limited in their technology to incorporating AUC from only one qualified PLE will help to ensure that ordering professionals will not be in a position of consulting a CDSM that cannot offer them access to AUC that address all priority clinical areas. As stakeholders continue to advance CDSM technology, we look forward to standards being developed and widely accepted so that AUC are incorporated in a standardized format across CDSM platforms. Increasing standardization in this area will move the industry closer to the goal of interoperability across CDSMs and EHRs.

We also propose to add a requirement in §414.94(g)(1)(i) that specified applicable AUC and related documentation supporting the appropriateness of the applicable imaging service ordered must be made available within the qualified CDSM. For example, the ordering professional would have immediate access to the full appropriate use criterion, citations supporting the criterion and a summary of key evidence supporting the criterion.

We propose to add a requirement in §414.94(g)(1)(ii), consistent with section 1834(q)(3)(B)(ii)(II) of the Act, that the qualified CDSM must clearly identify the appropriate use criterion consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario. We believe this is important since CDSMs that choose to incorporate a comprehensive AUC library may be offering the ordering professional access to AUC from multiple qualified PLEs. In such scenarios, it is important that the ordering professional knows which appropriate use criterion is being consulted and have the option to choose one over the other if more than one criterion applies to the scenario.

We propose to add a requirement in §414.94(g)(1)(v), consistent with section 1834(q)(3)(B)(ii)(III) of the Act, that the qualified CDSM must provide to the ordering professional a

determination, for each consultation, of the extent to which an applicable imaging service is consistent with specified applicable AUC or a determination of “not applicable” when the mechanism does not contain a criterion that would apply to the consultation. This determination would communicate the appropriateness of the applicable imaging service to the ordering professional. In addition to this determination, we also propose that the CDSM provide the ordering professional with a determination of “not applicable” when the mechanism does not contain an appropriate use criterion applicable to that patient’s specific clinical scenario.

We propose to add a requirement in §414.94(g)(1)(vi), consistent with section 1834(q)(3)(B)(ii)(IV) of the Act, that the qualified CDSM must generate and provide to the ordering professional certification or documentation that documents which qualified CDSM was consulted, the name and NPI of the ordering professional that consulted the CDSM and whether the service ordered would adhere to applicable AUC, whether the service ordered would not adhere to such criteria, or whether such criteria was not applicable for the service ordered. We propose to require under §414.94(g)(1)(vi)(A) that this certification or documentation must be issued each time an ordering professional consults the qualified CDSM. Since Medicare claims will be filed only for services that are rendered to beneficiaries, we will not see CDSM consultation information on the claim form specific to imaging services that are not ordered. We believe that for the CDSM to be able to provide meaningful feedback to ordering professionals, information regarding consultations that do not result in imaging is just as important as information on consultations that do result in an order for advanced imaging.

Thus, we propose to require under §414.94(g)(1)(vi)(B) that the documentation or certification provided by the qualified CDSM must include a unique consultation identifier. This would be a unique code issued by the CDSM that is specific to each consultation by an ordering professional. This type of unique code may serve as a platform for future collaboration and aggregation of consultation data across

CDSMs. In addition, at some point in the future, this unique code may assist in more seamlessly bringing Medicare data together with CDSM clinical data to maximize quality improvement in clinical practices and to iteratively improve the AUC itself.

We propose in §414.94(g)(1)(vii), consistent with section 1834(q)(3)(B)(ii)(V) of the Act, that the specified applicable AUC content within qualified CDSMs be updated at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or to an individual appropriate use criterion. We propose 12 months as the maximum acceptable delay for updating content. We believe that in most cases it will be possible to update AUC content more frequently than every 12 months, particularly for cloud-based CDSMs. We further propose in §414.94(g)(1)(vii)(A) that qualified CDSMs have a protocol in place to more expeditiously remove AUC that are determined by the qualified PLE to be potentially dangerous to patients and/or harmful if followed.

In addition, we propose in §414.94(g)(1)(vii)(B) that qualified CDSMs must make available for consultation specified applicable AUC that address any new priority clinical areas within 12 months of the priority clinical area being finalized by CMS. We believe this would allow the CDSM sufficient time to incorporate the AUC into the CDSM. Thus, any new priority clinical areas finalized, for example, in the CY 2018 PFS final rule with comment period that would be effective January 1, 2018, would need to be incorporated into a qualified CDSM by January 1, 2019. To accommodate this time frame, we would accept a not applicable determination from a CDSM for a consultation on a priority clinical area for dates of service through the 12-month period that ends, in this example, on January 1, 2019. We note that all qualified CDSMs that are approved by June 30, 2017 should be capable of supporting AUC for all priority clinical areas that are finalized in the CY 2017 PFS final rule with comment period.

We propose to add a requirement in §414.94(g)(1)(viii), consistent with section

1834(q)(3)(B)(ii)(VI) of the Act, that the qualified mechanism must meet privacy and security standards under applicable provisions of law. Potentially applicable laws may include the HIPAA Privacy and Security rules.

We propose to add a requirement in §414.94(g)(1)(ix), consistent with section 1834(q)(3)(B)(ii)(VII) of the Act, that qualified CDSMs must provide ordering professionals aggregate feedback in the form of an electronic report on an annual basis (at minimum) regarding their consultations with specified applicable AUC. Our intent is to require records to be retained in a manner consistent with the HIPAA Security Rule. To provide such feedback, and to make detailed consultation information available to ordering professionals, furnishing professionals (when they have authorized access to the CDSM), auditors and CMS, we propose in §414.94(g)(1)(x) that a qualified CDSM must maintain electronic storage of clinical, administrative and demographic information of each unique consult for a minimum of 6 years. We believe CDSMs could fulfill this requirement in a number of ways, including involving a third party in the storage of information as well as for providing feedback to ordering professionals. We recognize that these requirements represent a minimum floor that clinicians may choose to expand upon in their local QI programs.

In the event requirements under §414.94(g)(1) are modified through rulemaking during the course of a qualified CDSM's 5-year approval cycle, we propose in §414.94(g)(1)(xi) that the CDSM would be required to comply with the modification(s) within 12 months of the effective date of the modification.

d. Process for CDSMs to Become Qualified and Determination of Non-Adherence

We propose that CDSMs must apply to CMS to be specified as a qualified CDSM. We propose that CDSM developers who believe their mechanisms meet the regulatory requirements must submit an application to us that documents adherence to each of the requirements to be a qualified CDSM.

We propose to require in §414.94(g)(2) that CDSM developers must submit applications to CMS for review that document adherence to each of the CDSM requirements. Applications to be specified as a qualified CDSM must be submitted by January 1 of a year in order to be reviewed within that year's review cycle. For example, the first applications would be accepted from the date of publication of the PFS final rule until January 1, 2017. A determination on whether the applicants are qualified would be made by June 30, 2017. Applications must be submitted electronically to ImagingAUC@cms.hhs.gov. This process and timeline mirror the qualified PLE application and approval process and timeline. As we did for qualified PLEs, we will post a list of all applicants that we determine to be qualified CDSMs to our website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html> by June 30. We propose that all qualified CDSMs must reapply every 5 years and their applications must be received by January 1 during the 5th year that they are qualified CDSMs. It is important to note that, as with PLE applications, the application for qualified CDSMs is not a CMS form; rather it is created by the applicant. A CDSM that is specified as qualified for the first 5-year cycle beginning on July 1, 2017 would be required to submit an application for requalification by January 1, 2022. A determination would be made by June 30, 2022, and, if approved, the second 5-year cycle would begin on July 1, 2022.

An example of our proposed timeline for applications and the approval cycle is as follows:

- Year 1 = July 2017 to June 2018.
- Year 2 = July 2018 to June 2019.
- Year 3 = July 2019 to June 2020.
- Year 4 = July 2020 to June 2021.
- Year 5 = July 2021 to June 2022 (reapplication is due by January 1, 2022).

We believe it is important for us to have the ability to remove from the list of specified qualified

CDSMs a CDSM that we determine fails to adhere to any of the qualification requirements, including removal outside of the proposed 5-year cycle. We propose to state under §414.94(h) that, at any time, we may remove from the list of qualified CDSMs a CDSM that fails to meet the criteria to be a qualified CDSM or consider this information during the requalification process. Such determinations may be based on public comment or our own review and we may consult with the National Coordinator for Health Information Technology or her designee to assess whether a qualified CDSM continues to adhere to requirements.

We invite comments on how we could streamline and strengthen the approval process for CDSMs in future program years. For instance, CMS may consider a testing framework for CDSMs that would validate adherence to specific standards that enable seamless incorporation of AUC across CDSMs.

e. Consultation by Ordering Professional and Reporting by Furnishing Professional

Although we continue to aggressively move forward to implement this AUC program, ordering professionals will not be expected to consult qualified CDSMs by January 1, 2017. At the earliest, under this proposal, the first qualified CDSM(s) will be specified on June 30, 2017. We anticipate that some ordering professionals could be able to begin consulting AUC through qualified CDSMs very quickly as some may already be aligned with a qualified CDSM.

We anticipate that furnishing professionals may begin reporting as early as January 1, 2018. This reporting delay is necessary to allow time for ordering practitioners who are not already aligned with a qualified CDSM to research and evaluate the qualified CDSMs so they may make an informed decision. While there will be further rulemaking next year, we are announcing this date because the agency expects physicians and other stakeholders/regulated parties to begin preparing themselves to begin reporting on that date. We will adopt procedures for capturing this information on claims forms

and the timing of the reporting requirement through PFS rulemaking for CY 2018.

As we expect to implement the AUC consultation and reporting requirements under section 1834(q)(4)(A) and (B) of the Act on January 1, 2018, we are interested in receiving feedback from the public to include a discussion of specific operational considerations that we should take into account and include in such rulemaking. For example, commenters could consider alternatives for reporting data on claims and for seeking exceptions, as discussed below. We also seek information on the barriers to implementation along this timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims and whether separate rulemaking outside of the payment rule cycle would be preferred.

Under section 1834(q)(4)(B) of the Act, Medicare claims for applicable imaging services furnished in applicable settings can only be paid under the applicable payment systems if certain information is included on the claim including: which qualified CDSM was consulted by the ordering professional for the service; whether the service, based on the CDSM consultation, adheres to specified applicable AUC, does not adhere to specified applicable AUC or whether no criteria in the CDSM were applicable to the patient's clinical scenario; and, the national provider identifier (NPI) of the ordering professional. This section further allows payment for these services only if the claim contains such information beginning January 1, 2017. To develop and operationalize a meaningful solution to collecting new AUC consultation-related information on the claims, we must diligently evaluate our options taking into account the vast number of claims impacted and the limitations of the legacy claims processing system. While we could have moved more quickly to establish some sort of AUC consultation indicator for Medicare claims, any such indicator would have been a relatively meaningless token. Additionally, in the case of advanced imaging services, related claims are already required to append certain HCPCS modifiers and G codes for purposes of proper payments. In the recent

implementation of section 218(a) of the PAMA, we established a HCPCS modifier for CT services rendered on machines that do not meet an equipment standard. It is important that we understand and evaluate how the additional requirements for AUC reporting would impact the information that is already required for advanced imaging services. Moving too quickly to satisfy the reporting requirement could inadvertently result in technical and operational problems that could cause delays in payments.

Section 1834(q)(4)(C) of the Act includes exceptions that allow claims to be paid even though they do not include the information about AUC consultation by the ordering professional. We believe that, unless a statutory exception applies, an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system. We further believe that section 1834(q)(4)(B) of the Act accounts for the possibility that AUC may not be available in a particular qualified CDSM to address every applicable imaging service that might be ordered; and thus, the furnishing professional can meet the requirement to report information on the ordering professional's AUC consultation by indicating that AUC is not applicable to the service ordered.

We are considering the mechanisms for appending the AUC consultation information to various types of Medicare claims and expect to develop requirements for appending such information in the CY 2018 PFS rulemaking process. Stakeholders interested in sharing feedback related to reporting and claims processing are welcome to do so as part of the comment period for this proposed rule. We are particularly interested in receiving feedback on, for example, whether the information should be collected using HCPCS level II G codes or HCPCS modifiers. We will use this feedback to inform CY 2018 rulemaking.

f. Exceptions to Consulting and Reporting Requirements

Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements under section 1834(q)(4)(B) of the Act. First, the statute provides for an exception under section 1834(q)(4)(C)(i) of the Act where an applicable imaging service is ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. We believe this exception is warranted because there can be situations in which a delay in action would jeopardize the health or safety of individuals. Though we believe they occur primarily in the emergency department, these emergent situations could potentially arise in other settings. Furthermore, we recognize that most encounters in an emergency department are not for an emergency medical condition as defined in section 1867(e)(1) of the Act.

We propose to provide for an exception to the AUC consultation and reporting requirements under §414.94(i)(1) for an applicable imaging service ordered for an individual with an emergency medical condition as defined in section 1867(e)(1) of the Act. For example, if a patient, originally determined by the clinician to have an emergency medical condition prior to ordering an applicable imaging service, is later determined not to have had an emergency medical condition at that time, the relevant claims for applicable imaging services would still qualify for an exception. To meet the exception for an emergency medical condition as defined in section 1867(e)(1) of the Act, the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Orders for advanced imaging services for beneficiaries with an emergency medical condition as defined under section 1867(e)(1) of the Act are excepted from the requirement to consult AUC. We intend through the CY 2018 PFS proposed rule to propose more details around how this exception will be

identified on the Medicare claim.

The second exception is under section 1834(q)(4)(ii) of the Act for applicable imaging services ordered for an inpatient and for which payment is made under Medicare Part A. We propose to codify this exception in new §414.94(i)(2). While we are including this exception consistent with statute, we note that if payment is made under Medicare Part A, the service would not be paid under an applicable payment system, such that the AUC consultation and reporting requirements under §414.94 would never apply.

The third exception is under section 1834(q)(4)(iii) of the Act for applicable imaging services ordered by an ordering professional who the Secretary determines, on a case-by-case basis and subject to annual renewal, that consultation with applicable AUC would result in a significant hardship, such as in the case of a professional practicing in a rural area without sufficient Internet access. We propose to codify this exception in new §414.94(i)(3) by specifying that ordering professionals who are granted a significant hardship exception for purposes of the Medicare EHR Incentive Program payment adjustment under §495.102(d)(4)(i), (ii), or (iii)(A)(B) of our regulations would also be granted a significant hardship exception for purposes of the AUC consultation requirement. We are proposing, to the extent technically feasible, that the year for which the eligible professional is excepted from the EHR Incentive Program payment adjustment is the same year that the ordering professional is excepted from the requirement to consult AUC through a qualified CDSM. We propose not to adopt the Meaningful Use significant hardship exception under §495.102(d)(4)(iv)(C) as an exception for purposes of the AUC consultation requirement. Therefore, ordering professionals with a primary specialty of anesthesiology, radiology or pathology will not be categorically excepted from AUC consultation requirements.

We believe there is substantial overlap between the eligible professionals that would seek a

hardship exception under the EHR Incentive Program and those ordering professionals that would seek a hardship exception under the AUC program and, as such, this proposal would be administratively efficient. Using an existing program is the most efficient and expeditious manner to implement the significant hardship exception under the Medicare AUC program. We also believe it is the only administratively feasible option for a national significant hardship identification process that can be implemented by January 1, 2018, though we intend to revisit this option for years after 2018 as the current EHR Incentive Program payment adjustment is set to expire after the 2018 payment year as the Merit-Based Incentive Payment System takes effect. In addition, below we discuss considerations for a supplemental process to account for hardships for ordering professionals that are not eligible to apply for a significant hardship under the EHR Incentive Program (for example, non-physician practitioners) and ordering professionals that incur a significant hardship outside of the EHR Incentive Program application deadline.

The criteria for significant hardships under the EHR Incentive Program relate to insufficient internet connectivity, practicing for less than 2 years, practicing at multiple locations with the inability to control the availability of Certified EHR Technology, lack of face-to-face interaction with patients or a primary specialty designation of anesthesiology, radiology or pathology. We believe that most of these criteria would be relevant to demonstrate a significant hardship for ordering professionals to consult AUC. Regarding hardship exceptions for certain specialty designations, based on Medicare claims data for advanced imaging services from the first 6 months of 2014, approximately 1.2 percent of those claims were for advanced imaging services that had been ordered by a professional with one of the three primary specialty designations. While their combined ordering volume is small, we do not believe that categorical exclusion of certain specialties of which the practitioner selected as their primary specialty designation for Medicare enrollment would necessarily be appropriate under the AUC

program. Since eligible professionals in these three specialties are categorically excepted from the EHR Incentive Program payment adjustment, few of them would have applied for an exception on the other grounds. Therefore, we must consider another mechanism to evaluate whether ordering practitioners with these medical specialties experience a significant hardship for purposes of the AUC program. We understand that there are differences between the purpose and timing of significant hardship exceptions for the EHR Incentive Program and the Medicare AUC program. Foremost, a significant hardship under the EHR Incentive Program is generally based on a hardship that occurred in a prior period, impacting meaningful EHR use that would affect payments in a subsequent calendar year. For example, a professional that submits an application in March 2017 and qualifies for the hardship exception under the EHR Incentive Program would be exempt from the EHR payment adjustment for calendar year 2018. Although significant hardship exceptions for the EHR payment adjustment year generally are based on the existence of a hardship in a prior period, we believe it would be appropriate for these professionals to also qualify for a significant hardship exception for purposes of the AUC consultation requirement during calendar year 2018. It is also our best, most efficient, administratively feasible means of determining significant hardships for ordering professionals for CY 2018.

We also recognize the possibility that an ordering professional could suffer a significant hardship during the AUC program year, and therefore, is immediately unable to consult AUC. In addition, while again we believe there is significant overlap, there may be circumstances where an ordering professional is not considered to be an eligible professional under the EHR Incentive Program (for example, an ordering professional that is not a physician). We are seeking feedback from commenters regarding processes that could be put in place to accommodate ordering professionals with primary specialties that categorically receive significant hardship exceptions under the EHR Incentive Program, real-time hardships that arise during a year, and ordering professionals that are not eligible to apply using the EHR

Incentive Program significant hardship exception process and need to seek a significant hardship exception for the purposes of the AUC program. We believe this would involve only a small number of ordering professionals. To the extent technically feasible, some possibilities for implementing such hardship exceptions may include Medicare Administrative Contractors granting hardships on a case-by-case basis or establishing another mechanism to allow for self-attestation of a significant hardship for a defined period of time (for example, a calendar quarter or a calendar year). We intend to propose a process in the CY 2018 PFS proposed rule.

We invite the public to comment on our proposal for ordering professionals granted a hardship exception for the EHR Incentive Program for payment year 2018 to also be granted a hardship exception to the Medicare AUC program for those years. We propose that the year the practitioner is excepted from the EHR Incentive Program payment adjustment is the same year that the practitioner would be excepted from consulting AUC.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician or other practitioner who orders or furnishes applicable 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 broad.

We continue to 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 CDSM developers. It is for these reasons we are proposing to continue a stepwise approach, adopted through notice and comment rulemaking. We propose this second component to the program to specify qualified CDSMs, identify

the initial list of priority clinical areas, and establish requirements related to CDSMs, as well as consulting and reporting exceptions. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program. Under this proposal, the first list of qualified CDSMs will be posted no later than June 30, 2017, allowing ordering professionals to begin aligning themselves with a qualified CDSM. We anticipate that furnishing professionals could begin reporting AUC information starting as early as January 1, 2018, but will provide details in CY 2018 PFS rulemaking for how to report that information on claims.

In summary, we propose definitions of terms and processes necessary to implement the second component of the AUC program. We invite the public to submit comments on these proposals. We are particularly seeking comment on the proposed priority clinical areas and the requirements that must be met by CDSMs to become qualified. We believe the proposed requirements for qualified CDSMs will allow for flexibility so mechanisms can continue to reflect innovative concepts in decision support and develop customer-driven products to ultimately provide information to the ordering professional in such a manner that will maximize appropriate ordering of advanced diagnostic imaging while seamlessly integrating into workflow. As the stakeholders continue to move to a place of consensus-based standards deemed ready for deployment, we may become more prescriptive in future requirements for CDSMs. We also seek comment on the exceptions to the requirements to consult applicable AUC using CDSMs.