



September 6, 2016

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017 (CMS-1654-P)

Dear Acting Administrator Slavitt:

On behalf of the American Society of Nuclear Cardiology (ASNC), I thank you for the opportunity to comment on proposals related to the CMS-1654-P “Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Revisions to Part B for CY 2017” (the “Proposed Rule”) as published on July 15, 2016 in the *Federal Register*. Specifically, ASNC offers comments on proposals pertaining to the implementation of the appropriate use criteria (AUC) program for advanced imaging services.

ASNC is a 4,500 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

Nuclear cardiology plays a pivotal role in establishing the diagnosis and prognosis of heart disease. Nuclear cardiology involves the use of noninvasive techniques to assess myocardial blood flow, evaluate the pumping function of the heart, as well as to visualize the size and location of blockage or a heart attack. By assessing both the amount of ischemia (or jeopardized heart muscle) and the amount of heart muscle scar, effective risk stratification can be carried out

to determine optimal therapy. Among the techniques of nuclear cardiology is myocardial perfusion imaging (MPI) and Positron Emission Tomography (PET) which will subject nuclear cardiologists, who may serve as either the ordering or furnishing providers of advanced diagnostic imaging tests, to the requirements of the Medicare AUC Program as set forth in the Protecting Access to Medicare Act (PAMA) of 2014.

ASNC would like to preface the following comments by clearly stating that its members strongly support the use of AUC and that when AUC is effectively applied, patients get the right test first.

We respect that CMS is under a mandate to implement the Medicare AUC Program; however, it has been ASNC's long-standing position that consultation of AUC would be better aligned with the Merit-Based Incentive Payment System (MIPS) than as a stand-alone program. Appropriate use is a high-priority area under the quality component of MIPS. Physicians stand to be penalized both under the quality and resource component of MIPS if advanced imaging services are not appropriately utilized. We believe that to be successful under MIPS, ordering and furnishing professionals, as well as their patients, will benefit from AUC consultation and adherence, but not under a separate complex and cumbersome program that is inferior to MIPS, lacks a quality measurement component, and which will create a financial windfall for clinical decision support mechanism (CDSM) developers at the expense of providers with no overwhelming benefit to the Medicare program.

In our comments to CMS in response to the CY 2016 Medicare PFS Proposed Rule we expressed serious concerns with the compressed timeline for implementation of the AUC Program to meet a statutory deadline of Jan. 1, 2017. We appreciate that CMS recognized the complexity of the law and made the decision to delay implementation. While the AUC consultation and reporting requirements could begin as early as Jan. 1, 2018, we believe the implementation date must be dictated not only by the availability of CDSMs but also by their integration into electronic health record (EHR) systems, as well as by physician and claims processing readiness.

We believe that CDSM integration into EHRs and practice readiness will be compromised by the implementation of MACRA. Preparation for a Jan. 1, 2018 effective date of the AUC Program would compete directly with demands on physician practices as they attempt to find their footing in a new Medicare physician payment system. Organizations that have implemented CDSMs and EHRs in large systems have recommended a period of at least 12 – 18 months between publication of a final rule and the effective date for consultation and reporting requirements. Data use contracts must be negotiated and reviewed; physicians, coders, and billing departments must be trained; and provider workflows need to adjust.

CDSM Integration with Electronic Health Record Systems

In the CY 2016 Medicare PFS Final Rule, CMS stated that ideally multiple CDSMs would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology systems. As CMS correctly noted in the rule, this would minimize burden on provider teams and avoid duplicate documentation. We agree. Integration of CDSMs in EHRs should not be considered a provider convenience, but important to the effectiveness of AUC. CDSM integration with an EHR allows data present within the EHR to be used for more effective consultation of AUC. Consultation with AUC will not lead to appropriate ordering of tests if the information that is used for the AUC decision algorithms is incomplete or inaccurate. We do not believe that for physicians who routinely order advanced imaging tests across a wide variety of conditions that the free CDSM will be a viable alternative. In addition to the reasons above for why a CDSM/EHR integration is important, it also minimizes administrative burden that will otherwise be present if patient information must be transcribed from an EHR to a stand-alone CDSM.

CMS states in the proposed rule “AUC, and the CDSMs through which clinicians access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery.” We agree. While a CDSM external to a provider’s primary interface could pull relevant information into the decision support application, health information technology interoperability is still not widespread. Therefore, while a laudable goal, such interface is not widely achievable at this time, thus underscoring the importance of direct CDSM/EHR integration.

Physician Readiness

In 2014, ASNC commissioned a behavioral and performance needs assessment of inter-professional referrals and collaboration in nuclear imaging. The needs assessment found that referrers are challenged to apply AUC when selecting patients for nuclear imaging.

Rapid uptake and proper application of AUC for clinical decision-making requires provider education. ASNC and its partners have undertaken extensive educational efforts directed at primary care physicians on how to consult and correctly apply AUC for advanced imaging tests. Last September, ASNC offered a satellite symposium at its annual meeting titled, “Appropriate Use of Cardiovascular Imaging for the Referring Clinician.” In addition, in May 2016 ASNC hosted a session at the American College of Physicians annual meeting. These programs were specifically designed for referring providers to allow them to gain competence in utilizing AUC when ordering cardiac imaging procedures. The response from the referring community was very positive and desirous of the education.

We hope CMS will recognize the need to provide adequate time for education prior to consultation and reporting requirements taking effect. Clinicians uncomfortable with AUC and the decision support tools may order tests that are less effective in predicting risk but are not

covered under the mandate. Alternatively, they may refer patients for unnecessary consultations to determine what or if testing is necessary. This would be an undesirable outcome for patients and could increase Medicare costs if the right test is not delivered first.

While we appreciate CMS' objective to avoid further delays in implementation of the program, ASNC encourages at a minimum a pilot phase, or non-binding period, of the program during which time ordering professionals could consult AUC using a CDSM for required clinical areas, but those consultations would not count against calculating outliers, nor would furnishing professionals be penalized for any incorrect documentation on claims submitted for advanced imaging tests for which the AUC apply. Alternatively, roll out of the program could begin with health systems and large group practices and, over time, be expanded into the small, independent practice-size setting.

Claims and Billing Readiness

We appreciate the forethought CMS is giving to the reporting and claims processing aspect of implementing the AUC program. There are a number of considerations that must be taken into account for implementing the reporting requirements of the law, including modifications to Medicare claims forms. ANSC appreciates the assessment that the American Medical Association (AMA) has undertaken in this regard, and we concur with their recommendation that CMS create an agency-wide task force to work with the claims standards organization to simultaneously address demands that are about to be placed on claims forms as a result of MACRA and the AUC Program. We further support the AMA's recommendation that in absence of further delay of the AUC Program's implementation, physicians should be allowed to annually attest, subject to audit, that they are consulting a CDSM prior to ordering an advanced imaging test and the rendering physician could similarly attest.

The law stipulates that payment for an applicable imaging service may only be made if the claim for the service includes the following information:

- Which qualified CDSM was consulted by the ordering professional for the service;
- Whether the service adheres to specified applicable AUC, does not adhere to specified applicable AUC, or whether no criteria were applicable to the service ordered; and

- The national provider identifier (NPI) of the ordering professional if different than the furnishing professional.

We also strongly recommend that the ordering professional must supply to the furnishing professional what applicable AUC were consulted, and this information should also be reported by the furnishing professional to CMS for the purposes of identifying outlier ordering

professionals. We suggest that it would be unfair to benchmark ordering professionals broadly by priority clinical area because not all AUC are constructed the same way, and, consequently, competing AUC may produce different results under an identical clinical scenario.

Both the American College of Cardiology Foundation (ACCF) /ASNC and the American College of Radiology (ACR) have AUC that address cardiovascular imaging. Substantial methodological differences exist between each organization’s approach to AUC. The ACCF AUC place a greater reliance of risk stratification based on clinical factors, which results in a far greater specificity of clinical indications.¹ A recent study found significant discordance between the ACCF and ACR AUC for nuclear myocardial perfusion imaging.² In this cohort study, 52.2 percent of 67 ACC AUC ratings and 18.8 percent of 592 patients could not be matched to an ACR rating.³

As depicted in the tables below, the study found far more abnormal imaging studies or individuals with ischemia with an inappropriate designation from the ACR than with the ACC AUC.⁴

Table 2. Ischemia and Nuclear MPI Results Stratified by ACR Appropriateness Categories*

Variable	ACR, No./Total (%)			P Value
	"Usually Appropriate"	"May Be Appropriate"	"Usually Not Appropriate"	
Ischemia SDS >3	52/308 (16.9)	3/57 (5.3)	14/80 (17.5)	.07
Abnormal nuclear MPI	91/324 (28.1)	7/62 (11.3)	29/82 (35.4)	.004

Abbreviations: ACR, American College of Radiology; MPI, myocardial perfusion imaging; SDS, summed difference score.

* The prevalence of abnormal nuclear MPI differed across the appropriateness categories ($P = .004$), while the prevalence of ischemia (defined as $SDS >3$) did not ($P = .07$).

Table 3. Ischemia and Nuclear MPI Results Stratified by ACCF Appropriateness Categories*

Variable	ACCF, No./Total (%)			P Value
	"Appropriate"	"Uncertain"	"Inappropriate"	
Ischemia SDS >3	57/358 (15.9)	11/48 (22.9)	1/39 (2.6)	.03
Abnormal nuclear MPI	104/378 (27.5)	20/49 (40.8)	3/41 (7.3)	.002

Abbreviations: ACCF, American College of Cardiology Foundation; MPI, myocardial perfusion imaging; SDS, summed difference score.

* The prevalence of abnormal nuclear MPI and the prevalence of ischemia (defined as $SDS >3$) differed across the appropriateness categories ($P = .002$ and $P = .03$, respectively).

³ Ibid.

⁴ Ibid.

We understand that CMS could be concerned with ordering professionals “gaming the system” by switching their consultation to different AUC to avoid being identified as an outlier, but we suggest that is unlikely given the expectation that most CDSMs will not include multiple applicable AUC from different PLEs and ordering professionals are unlikely to invest in more than one CDSM. We believe the possible benefits of collecting data on which AUC were consulted far outweighs any risk of physicians attempting to “game the system.”

Another area which we believe warrants careful consideration is the interaction between the AUC Program and local coverage determinations (LCDs). For example, what happens if consultation of AUC produces an appropriate or uncertain indication for an advanced imaging that conflicts with an LCD, or even a national coverage decision? If the ordering provider cannot override a LCD despite the service adhering to applicable AUC, how does CMS intend to account for these situations? For example, the test is appropriate and not ordered, or the ordering professional chooses an alternative test that is lower on the appropriateness scale or inappropriate as a substitution. Will this adversely effect the calculation of outlier ordering physicians?

Priority Clinical Areas

ASNC supports the concept of priority clinical areas for the purpose of determining outlier ordering professionals. We disagree, however, with the methodology that CMS used to arrive at the initial list of priority clinical areas.

In the CY 2016 Medicare PFS Final Rule, CMS stated “We believe the goal of this statutory AUC program is to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging services.” We agree with this statement. Therefore, priority clinical areas should reflect clinical scenarios for which advanced diagnostic imaging tests will be rarely appropriate. We believe this is important from a few perspectives: First, choosing clinical scenarios for which advanced imaging tests are commonly appropriate will lead to outlier ordering professionals at the margins, which may unfairly penalize ordering professionals for situations where clinical decision making overrides an inappropriate indication. Second, clinical scenarios for which advanced diagnostic imaging is typically indicated will not have a significant effect on reducing inappropriate imaging services and meeting what CMS believes is the intended goal of the program. Third, providers are weary of box-checking requirements that detract from patient care.

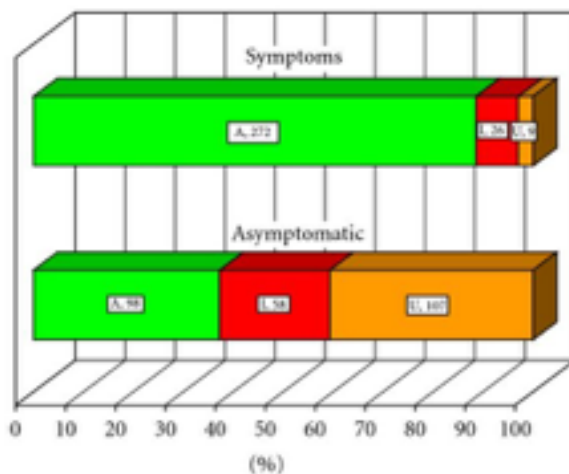
We acknowledge that the rationale with proposing clinical priority areas is to fulfill CMS’ aim of balancing the comprehensive rollout of consulting a potentially vast spectrum of AUC across advanced imaging modalities with a focused approach of only using a limited number of clinical areas to determine which ordering physicians are outliers. Among the eight proposed priority

clinical areas is chest pain (including angina, suspected myocardial infarction, and suspected pulmonary embolism). In identifying the priority clinical areas, CMS used 2014 Medicare

claims data to rank 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 CPT codes for which payments were made in 2014. CMS then extracted the top 135 ICD-9 codes from this list and formed eight clinically-related categories that account for roughly 40 percent of Part B advanced diagnostic imaging services paid for by Medicare in 2014.

ASNC understands CMS' inclination to begin clinical priority areas with areas in which test volumes are highest. However, we strongly disagree with the notion that high volume is correlated with similarly high rates of inappropriate testing. CMS has chosen to focus on chest pain (not otherwise specified)/ chest pain (unspecified) as a clinical priority area largely because of its high volume. However, in the majority of chest pain cases, providing an advanced imaging test to a symptomatic patient in the Medicare population would be an appropriate test.

A 2011 study of AUC for single-photon emission computed tomography (SPECT) found that the most appropriate SPECT was observed in patients with known coronary disease (72 percent) and chest pain syndrome (89 percent).⁵ When comparing symptoms versus asymptomatic, most inappropriate and uncertain SPECT was observed in asymptomatic patients as depicted in the graph below.⁶



Symptoms refer to chest pain or anginal equivalent. Appropriate (green); uncertain (gold); inappropriate (red).

⁵ Regina S. Druz, Lawrence M. Phillips, and Gulru Sharifova, "Clinical Evaluation of the Appropriateness Use Criteria for Single-Photon Emission-Computed Tomography: Differences by Patient Population, Physician Specialty, and Patient Outcomes," *ISRN Cardiology*, vol. 2011, Article ID 798318, 8 pages, 2011. doi:10.5402/2011/798318

⁶ Ibid.

A 2009 study found that more than 90 percent of inappropriate cardiac imaging came from just five indications, including: 1) detection of coronary artery disease in asymptomatic low-risk patients; 2) asymptomatic patients less than two years after percutaneous coronary intervention (PCI); 3) evaluation of chest pain, low probability interpretable ECG and able to exercise, asymptomatic/stable symptoms; 4) known coronary artery disease (CAD) less than one year after catheterization or abnormal prior SPECT; and 5) and pre-operative assessment for low-risk surgery.⁷

These findings were confirmed in a published analysis of 22 studies (that included 23,443 patients) that looked at appropriateness of nuclear myocardial perfusion imaging identified the most common reasons for inappropriate testing, depicted in the table below.⁸

Table 2. Assessment of study components

Study (Ref#)	Study design	Outpatient/ Inpatient	Institution	Single/ multi-center	Restrictive inclusion criteria	Commonest reason for inappropriate testing
Mahajan et al ¹⁹	Retrospective	Inpatient	Academic	Single	No	Non-acute chest pain
Medolago et al ²⁰	Prospective	Both	Academic	Multi	No	Non-acute chest pain
Oliveira et al ²¹	Retrospective	Both	Academic	Single	No	Asymptomatic patient until 1 year after revascularization
Johnson et al ²²	Prospective	Outpatient	Community	Multi	No	Low risk symptomatic patients
Winchester et al ¹²	Retrospective	Both	Academic	Single	No	Low risk asymptomatic patients
Lafude et al ¹³	Retrospective	Both	Academic	Single	No	Low pretest probability of CAD, ECG interpretable, and able to exercise
Singh et al ¹⁴	Retrospective	Both	Academic	Single	No	Pre-operative assessment
Khawaja et al ²⁸	Retrospective	Both	Academic	Single	Yes	NR
Doukky et al ²⁰	Prospective	Outpatient	Community	Multi	No	NR
Aldweib et al ¹⁵	Retrospective	Both	Academic	Single	No	Pre-operative assessment
Lin et al ²³	Prospective	Outpatient	Community	Multi	Yes	Low risk asymptomatic patients
Moralidis et al ²⁴	Prospective	Both	Academic	Multi	No	Pre-operative assessment
Seine et al ³¹	Retrospective	NR	Academic	Multi	No	NR
Nelson et al ³²	Retrospective	Both	Academic	Multi	No	Asymptomatic patients <2 years after PCI
Gholamrezanezhad et al ³³	Prospective	NR	Community	Multi	No	NR
Gupta et al ¹⁶	Retrospective	Both	Community	Single	No	NR
Druz et al ³⁴	Prospective	Both	Academic	Single	No	Low risk asymptomatic patients
Koh et al ¹⁷	Prospective	NR	Academic	Single	No	Pre-operative assessment
Carryer et al ³⁵	Retrospective	Both	Academic	Single	No	Low risk asymptomatic patients
Hendel et al ³⁶	Prospective	NR	Academic	Multi	No	Low risk asymptomatic patients
Mehta et al ¹⁸	Retrospective	NR	Academic	Single	No	Low risk symptomatic patients
Gibbons et al ¹⁰	Retrospective	Both	Academic	Single	No	Low risk asymptomatic patients

CAD, coronary artery disease; ECG, electrocardiogram; NR, not reported; PCI, percutaneous coronary intervention

By including chest pain as a priority clinical area, ordering physicians will consult AUC for a clinical scenario that will infrequently yield an inappropriate response. As a result, a high yield

⁷ Hendel RC, Cerqueira M, Douglas PS, Caruth KC, Allen JM, Jensen NC, et al. A Multicenter Assessment of the use of Single-use Photon Emission Computed Tomography Myocardial Perfusion Imaging with Appropriateness Criteria. *J Am Coll Cardiol.* 2010 Jan 12;55(2):156-62. doi: 10.1016/j.jacc.2009.11.004.

⁸ Elgendy I, Mahmoud A, Shuster J, Doukky R, Winchester D. Outcomes after inappropriate nuclear myocardial perfusion imaging: A meta- analysis. *J. Nucl. Cardiol.* (2016) 23:680-689 DOI 10.1007/s12350-015-0240-2

reduction of inappropriate tests will not occur while ordering professionals bypass AUC for areas for which there is greater clinical uncertainty.

Moreover, the data used to develop clinical priority areas did not focus on the sites of service in which the services were provided. This is an important distinction because the law excludes emergent cases from the requirement that the ordering physician consult AUC. Chest pain in particular has an especially high number of services that originate from the emergency department. ASNC encourages CMS to parse out data based on site of service to get an accurate understanding of the volume of affected services that originate outside of the emergency department before finalizing clinical priority areas.

Choosing Wisely and Clinical Priority Areas

ASNC supports the mission of the *Choosing Wisely* campaign and was among the first societies to develop a list of unnecessary medical tests and to discourage their use in clinical scenarios where they do not provide patient value. It appears that many of the clinical priority areas in other specialties closely track *Choosing Wisely* recommendations. For example, low back pain mirrors a recommendation from the American College of Physicians directing physicians not to obtain imaging studies in patients with non-specific low back pain, and the ACR directs its members to refrain from imaging for uncomplicated headaches. By aligning priority clinical areas with *Choosing Wisely*, CMS can better fulfill the goal of the law to reduce inappropriate imaging services.

In addition to not yielding a high level of inappropriate tests, the chest pain clinical priority area focuses on a Medicare population that is grossly over-inclusive. If chest pain is finalized as a priority clinical area, then it will need to be narrowed down with appropriate use to testing built around the more narrowed clinical scenarios. For example, exertional precordial chest pain in healthy 40-year-old male with a normal ECG will have different appropriate test options than a diabetic with exertional chest pain who cannot ambulate.

If the clinical scenarios for cardiovascular imaging are not modified for the purpose of the priority clinical areas, then ASNC strongly encourages CMS to carry the discussion of defining priority clinical areas into future rulemaking so these complex issues can be adequately resolved rather than finalizing chest pain, as proposed, as a priority clinical area.

ASNC, along with other cardiovascular societies including the ACC, has developed *Choosing Wisely* recommendations which we believe should constitute priority clinical areas for cardiovascular imaging. We ask CMS to develop codes or modifiers that would be tied the cardiovascular AUC consultation requirement for the following clinical situations:

- detection of coronary artery disease, asymptomatic, low-risk patients
- asymptomatic patients less than two years after PCI, evaluation of chest pain
- low probability interpretable ECG and able to exercise, asymptomatic/stable symptoms
- known CAD less than one year after catheterization or abnormal prior SPECT
- pre-operative assessment for low risk surgery

Use of ICD Codes

While CMS has not yet proposed how it determines to identify outlier ordering professionals, we suggest that using diagnosis codes will be problematic for cardiovascular-related conditions because they cannot be neatly defined by a set of ICD codes. Furthermore, ICD-10 codes will not be a viable way of identifying outlier ordering professionals because there will never be an ICD-10 code for a patient who is asymptomatic, even for testing in a pre-operative patient. The priority clinical areas chosen for the AUC Program have a direct implication on the identification of ordering outlier professionals. While the links are more clear-cut for certain clinical scenarios, it is not the case for heart disease.

Display of Appropriate Use Criteria in the Clinical Decisions Support Mechanism

While we tend to agree with CMS that there is no one correct approach to communicating the level of appropriateness to the ordering professional, what information is displayed to ordering professionals is critically important. We firmly believe that there needs to be clear definition of terms if CDSMs display information such as radiation exposure and cost of test. We believe these terms in particular can be misleading, and, too much for the primary care ordering professional to clearly understand without greater context. Both radiation exposure and cost carries connotations and emotions that may misleadingly influence the ordering physician's decision. For example, radiation exposure must take into account numerous variables, including age of equipment, and the age of the patient — particularly in a Medicare-age population — where the benefit of a test for which there is radiation exposure outweighs the risk.

Displays should be denotative and not contain connotative verbiage or symbols that will interfere with good clinical judgment. We believe this type of information, provided in context, should be offered to ordering professionals, along with other related documentation available within the CDSM, supporting the appropriateness of applicable imaging services.

Defining Clinical Decision Support Mechanisms

In its proposed definition of a CDSM, CMS states a qualified CDSM within or available through certified EHR technology would incorporate relevant patient-specific information into the assessment of the appropriateness of an applicable imaging service. We suggest that patient-

specific information should factor into the assessment of the appropriateness of advanced imaging technology regardless of whether a CDSM is incorporated into or independent from an EHR. Absent such capability, this further solidifies ASNC's position that the AUC Program should not be launched until CDSM integration with EHRs can occur.

Requirements for Clinical Decision Support Mechanisms

ASNC offers the following comments to the proposed requirements for qualified CDSMs.

Proposed Requirement: 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. However, every qualified CDSM does not need to make available every specified applicable AUC.

ASNC strongly supports that every qualified CDSM would not need to make available every specified applicable AUC. Consequently, the ordering professional would not need to consult applicable AUC for an advanced imaging test if the applicable AUC is not in their CDSM. We believe that by requiring every qualified CDSM to make available every specified applicable AUC, fewer CDSMs will be able to meet the requirement, resulting in fewer choices for physicians and less market competition.

We appreciate that by proposing to require qualified CDSMs to include, at a minimum, applicable AUC that encompass all priority clinical areas, CMS is attempting to accommodate those ordering professionals who will order advanced imaging tests across a wide range of conditions. We understand that absent this requirement, ordering professionals, namely primary care providers, could be saddled with the burden of acquiring and using more than one CDSM.

Still, we are concerned that the proposal does not afford flexibility for specialty physicians to purchase and utilize CDSMs that are specific to their scope of practice. We believe it is unnecessary, for example, for a cardiology practice to purchase a CDSM that includes AUC for lung cancer. We encourage CMS to further consider qualifying CDSMs with a more narrow scope of applicable AUC. Ultimately, demand will drive the CDSM market, but there needs to be greater CDSM flexibility from the outset. For providers who acquire and use a more narrow or specialty specific CDSM, we envision the free CDSM serving as a "back up" for consulting applicable AUC for priority clinical areas not addressed in a CDSM. Alternatively, CMS could require consultation of AUC for priority areas based on a ordering threshold. Providers who rarely order advance imaging tests for a particular priority clinical area would not be required to consult AUC for that clinical area.

ASNC maintains the position that holding ordering professionals liable for the consultation of all applicable AUC in their CDSM while using priority clinical areas for identifying outlier ordering professionals strictly benefits the ordering professional and is fundamentally unfair to the furnishing professional. Therefore, we ask CMS to modify its proposal to only require ordering professionals to consult applicable AUC for priority clinical areas. Consequently, furnishing professionals would only need to document required information to CMS on priority clinical areas. We believe this modification to CMS' proposal would further reduce the burden on ordering and furnishing professionals.

Under the law, the furnishing professional will not be paid for an advanced diagnostic test to which the AUC program applies unless the ordering professional first consults AUC using a qualified CDS. We understand that if an ordering professional consults a CDSM that does not include applicable AUC, then the CDSM will return a determination of "not applicable" which would be passed to the furnishing professional. Because furnishing professionals often have multiple referral sources, we suggest it could be less disruptive to coding and billing systems if the AUC documentation requirements are limited to only the priority clinical areas. Also, by limiting the program consulting and reporting requirements to the priority clinical areas, it creates a level of certainty for the furnishing professional. The furnishing professional will know exactly when a referral should include AUC consultation documentation. We are also concerned that current requirements will create confusion among ordering professionals. To facilitate this more limited consulting and reporting approach, we suggest that when the ordering professional consults the CDSM, the CDSM should be required to denote if the determination was for a priority clinical area, which, in turn, would inform the ordering professional that required documentation of the consultation must accompany the imaging referral.

Under this proposal nothing would preclude a CDSM from including a larger library of applicable AUC, but the ordering and furnishing professionals would know from the outset which clinical scenarios trigger the consultation, documentation and reporting requirements. This would prevent scenarios in which an ordering professional consults a CDSM with a broader library of applicable AUC only to find out that applicable AUC for a clinical scenario doesn't exist in the CDSM.

Proposed Requirement: Qualified CDSMs must be able to incorporate specified applicable AUC from more than one qualified PLE.

We appreciate CMS' proposal to require that CDSMs must be able to incorporate AUC from more than one PLE. ASNC does not oppose the proposal, and believes the limitations of not requiring AUC from more than one PLE in a CDSM — including the potential exclusion of applicable AUC from the program — can be mitigated through a modification in CMS' proposal to allow more narrow CDSMs to be qualified under the program.

Proposed Requirement: 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 agree with CMS that it is important for the ordering professional to know which appropriate use criterion is being consulted if the tool makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario. We believe it is critically important that the CDSM provide the ordering professional the option to choose one criterion over the other if more than one criterion applies to the clinical scenario. Meaning, the CDSM should not be allowed to have a default appropriate use criterion. When more than one exists for a clinical scenario, the ordering professional must be prompted to select which criterion to consult.

Proposed Requirement: 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.

By limiting the consultation and reporting requirements to only the clinical priority areas, per our recommendation above, it will mitigate the fruitless task of consulting a CDSM only to find out that the tool does not include applicable AUC for the clinical scenario in question.

Proposed Requirement: 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.

Per our comments above the CDSM must also provide to the ordering professional which AUC was consulted. It is also important that this requirement recognize that not all AUC consultations will result in a clear "appropriate" or "not appropriate" determination. Therefore, the CDSM must be able also be able to provide to the ordering professional documentation when the appropriateness of the test is "uncertain" and at the clinical judgement of the patient's physician.

Proposed Requirement: 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. CMS believes 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.

ASNC supports this requirement. However, we ask CMS to consider whether there should be a way for a provider to consult AUC for educational purposes without it being counted in their aggregate consultation “scores.”

Proposed Requirement: 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 that two timelines are required. First, there should be a timeline by which a CDSM must incorporate new priority clinical areas. There should be separate timeline by which there would be an expectation that ordering professionals would need to consult AUC for any new priority clinical areas, particularly if the CDSM is integrated in the ordering professional’s EHR. In such cases, a 12-month timeline may be unrealistic.

Proposed Requirement: 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.

Consistent with our comments above, we do not believe that CDSMs should be required to support AUC beyond priority clinical areas. However, CMS should modify its proposal to allow qualified CDSMs that include a more narrow scope of priority clinical areas for specialists who may not order advanced imaging tests across all priority areas.

Proposed Requirement: 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.

ASNC believes that providers must understand their ordering patterns for practice improvement to occur. Therefore, we support this proposed requirement. The form and timeliness of this feedback will be critical to its usefulness.

Proposed Requirement: All qualified CDSMs must reapply every five years.

We believe the five-year requirement affords physicians and other health care professionals far more predictability that is currently experienced by the year-to-year re-qualification requirement for Qualified Clinical Data Registries under other CMS quality programs. However, if a qualified CDSM reapplies and does not receive re-qualification, then the ordering professional should be allowed a grace period from the consultation requirements while they acquire and transition to a new CDSM.

Mr. Andrew Slavitt
Page 15 of 15
September 6, 2016

Thank you for your time and consideration of these comments. ASNC looks forward to continuing its conversations with CMS in implementing the AUC Program. Should you have any questions or require additional information, please contact Georgia Hearn at ghearn@asnc.org or Camille Bonta at cbonta@summithealthconsulting.com.

Sincerely,

Brian Abbott, MD

A handwritten signature in black ink, appearing to read "B. Abbott", with a stylized flourish at the end.

President
American Society of Nuclear Cardiology