Summary of the CMS Proposed Regulation

Implementation of Section 218(b) of the Protecting Access to Medicare Act -- Promoting Evidence Based Care

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the Protecting Access to Medicare Act of 2014 (Public Law No. 113-93) directs the Department of Health & Human Services to implement a Clinical Decision Support (CDS) program for advanced imaging services provided under Medicare.

On July 15, The Centers for Medicare & Medicaid Services (CMS) released its proposed Medicare Physician Fee Schedule (PFS) rule for 2016. A section of the proposed regulation addresses implementation of Section 218(b). *CMS will accept public comments on the proposed rule until Sept. 8, 2015 and intends to issue the final 2016 PFS by Nov. 1, 2015.*

Set forth below is brief background on Section 218(b) and a summary of the CMS proposal.

A. Background:

Section 218(b) of the Protecting Access to Medicare Act of 2014 (PAMA) requires Medicare providers that order certain advanced diagnostic imaging services to consult Appropriate Use Criteria (AUC) via a clinical decision support mechanism.

The services covered by this requirement include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (include positron emission tomography), and other diagnostic imaging services specified by CMS in consultation with the medical community and stakeholders, but excluding x-ray, ultrasound, and fluoroscopy services.

The four major components of the AUC program are:

- Establishment of applicable AUC in consultation with physicians, practitioners, and other stakeholders (by November 15. 2015);
- Identification of an initial list of clinical decision support (CDS) mechanisms for ordering physicians to consult AUC (by April 1, 2016);
- Consultation of AUC by ordering professionals and reporting on such consultation by furnishing professionals (January 1, 2017); and

- Annual identification of outlier ordering professionals for services furnished after January 1, 2017 and establishment of a prior authorization requirement for such professionals (by January 1, 2020).

For a more in-depth analysis of the legislative provisions, please see the Coalition's summary of the legislation.

B. Proposed Regulation:

Set forth below is a discussion of key items in the proposed regulation.

Phased regulatory implementation.

In the proposed rule, CMS indicates that it will take a step-by-step process to implementing the CDS requirement. Specifically, CMS will use the Physician Fee Schedule annual rule making not only this year, but also for CYs 2017 and 2018 to develop the program.

The CY 2016 proposed rule focuses primarily on the first component of the program – the establishment of Appropriate Use Criteria (AUC). Under the law, such AUC must be developed or endorsed by "provider-led entities."

Focus on qualifying the provider-led entity, not on reviewing individual AUC.

In implementing this element of the program, CMS has decided that it will not put itself in the role of reviewing and approving each and every individual criteria, or reviewing and passing judgment on a collective set of AUC that may be developed or endorsed by a provider-led entity. Instead, it will put the focus on establishing a fairly rigorous process by which an interested party can seek to be approved as a provider-led entity. The criteria developed, modified, or endorsed by such an approved entity would then be considered "specified applicable" AUC for purposes of the program.

CMS envisions that approved provider-led entities may adopt differing implementation approaches – including CDS products that robustly cover a broad range of ordering situations (and might be most suitable to providers in a smaller practice settings) to products that may only address a handful of ordering scenarios but that implement those criteria as part of comprehensive quality improvement program (which might be most suitable for a large health system). This in turn will lead to a flexible environment that generates competing sets of AUC and competing CDS mechanisms.

Defining "provider-led entities."

An important aspect of the rule is the definition of a "provider-led entity". CMS proposes that this term should encompass national professional medical societies (for example the American College of Radiology or the American Academy of Family Practice) or organizations that are comprised *primarily* of providers and are *actively engaged* in the practice and delivery of healthcare (for example hospitals and health systems).

Gaining qualification as a provider-led entity.

In addition to meeting the definition, applicants seeking approval as a provider-led entity must clearly demonstrate how they satisfy six essential qualification requirements:

- *Robust evidentiary review*—including systematic reviews of published literature, guidelines, and statements from professional medical societies and other information and using an accepted methodology for evidence evaluation.
- *AUC development process led by multidisciplinary teams*—with autonomous governance, and made up of at least three members who contribute substantial work to the development of AUCs. One member must have expertise in the clinical topic related to the criterion and one must have expertise in the imaging studies related to the criterion.
- *Disclosure of conflicts of interest.* A process must exist for the identification and public disclosure of conflicts related to the multi-disciplinary team, including indirect conflicts and those involving immediate family members.
- *Transparency regarding all AUC* – each criterion that is part of the AUC or that is being considered for development, modification or endorsement must be maintained on the entities website. This must include grading of key decision points in individual criteria using a *formal, widely accepted evidentiary review process* to facilitate understanding of the extent to which various aspects are consensus based or evidence based.
- *Public transparency regarding the process for developing, modifying, and endorsing AUCs* – also posted on a website and including the process for continual and timely review of criteria.

Once a provider-led entity becomes qualified under this process, the AUCs that are developed or endorsed by that entity would be considered to be AUCs "specified" by CMS for purposes of Section 218(b).

Applications for approval as a Provider-led entity will be due by January 1st of each year, and CMS is not proposing a specific application format. CMS will post a list of all qualified entities no later than June 30th. Qualified provider-led entities must re-apply to retain their status every six years.

Process for challenging AUC.

CMS is proposing to use the annual PFS rulemaking process to provide an opportunity for interested parties to challenge any criteria that is developed, modified or endorsed by a provider-led entity on the basis that it is not evidence-based. Any criterion that is identified under this process would be subject to further review by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). This information would be considered in the re-qualification process.

Priority Clinical Areas.

With an eye toward the requirement to have a process in place by January 1, 2020 to identify outlier ordering professionals, CMS has indicated that it intends to implement that activity through the use of "priority clinical areas of AUC." To identify those areas, CMS may consider incidence and prevalence of disease; volume and variability of utilization; strength of evidence; applicability to variety of care settings; and relevance to the Medicare population. Beginning in the CY 2017 PFS rulemaking process, CMS will be soliciting input on this identification process and will also utilize MEDCAC for this purpose.

Areas in which CMS is seeking feedback.

CMS is particularly interested in stakeholder comment on its proposed definition of, and process for, qualification of an applicant as a provider-led entity as only qualified provider-led entities will have the opportunity to develop, modify or endorse AUC. They are also interested in comments on their proposed approach regarding the identification of priority clinical areas of AUC and the proposed process for identification of AUC that are not evidence based.