The Calendar Year (CY) 2017 Physician Fee Schedule Final Rule

Summary of Provisions Related to Implementation of Section 218(b) of the Protecting Access to Medicare Act (PAMA)

On November 2, the Centers for Medicare & Medicaid Services (CMS) released the *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model (CMS-1654-F).*

A section of the final regulation addresses implementation of Section 218(b).

A. Background:

The Final Rule sets forth the second major set of directives around the implementation of Section 218(b) of the Protecting Access to Medicare Act (PAMA) which requires that ordering clinicians consult appropriate use criteria in deciding whether to order certain advanced diagnostic imaging services.

The first rulemaking, which was finalized last fall, articulated some of CMS general thinking around the program, set out a number of definitions and created an annual process by which "provider-led entities" could seek to be qualified to undertake an evidence-based and transparent process to develop, modify or endorse appropriate use criteria (AUC). Pursuant to the first round of applications, CMS on June 30th posted the first list of eleven qualified PLEs (qPLEs).

The Final Rule focuses on the second major implementation element – defining and providing a process for the qualification of clinical decision support mechanisms (CDSMs). It also identifies eight "priority clinical areas" where the adherence of ordering clinicians to available AUC will used to determine "outlier" physicians. It also identifies certain exemptions from the program.

Future rulemakings will establish the process by which clinicians must consult AUC for applicable advanced imaging services and document that consultation. Future rulemakings will also detail the process of identifying ""outlier" physicians who will be subject to certain prior authorization.

B. Final Regulation

Below is a discussion of the key items in the final regulation pertaining to Section 218.

Implementation Timeline:

The statute calls for implementation of the appropriate use criteria consultation requirement by January 1, 2017. In last year's rulemaking, CMS indicated that it was unlikely they would be able to adhere to that deadline. The proposed rule indicated that the timetable will slip. Accordingly, the final rule notes that CMS anticipates the first list of qualified Clinical Decision Support Mechanism (CDSMs) will be posted no later than June 30, 2017 and reporting of AUC information as early as January 1, 2018.

Clinical Decision Support Mechanism (CDSMs) Definition:

CMS finalized its proposal to amend the regulation and define CDSM 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.

Medicare Applicability:

CMS finalized the addition of a definition clarifying that the applicable payment systems for purposes of the Medicare AUC program are the physician fee schedule (PFS), the Hospital Outpatient Prospective Payment System (HOPPS), and the Ambulatory Surgical Center (ASC) payment system.

Provider Led Entities:

Provider-led entity (PLE) means a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. Once a PLE is qualified the AUC that are developed or endorsed by the entity would be considered to be specified applicable AUC.

To be qualified by CMS, a PLE must adhere to the evidence-based processes described in 42 CFR 414.94(c)(1) when developing or modifying AUC. PLEs must apply to CMS to become qualified. The application must include a statement as to how the entity meets the definition of a PLE and document adherence to each of the qualification requirements. Applications sent to the CMS Imaging AUC resource box ImagingAUC@cms.hhs.gov must be received by Jan 1.

CMS posted the first list of PLEs (who can apply to be qualified to develop AUC) to their website.

Additional Phases of the AUC Program:

Since the qualified CDSM list is not yet available, CMS finalized that it will not require ordering professionals to meet the third phase requirement, consulting with a qualified CDSM when ordering applicable imaging services, by the original January 1, 2017 deadline.

CMS indicates that it went through a process of reviewing non-institutional claims data from its Chronic Conditions Data Warehouse (CCW) and ranking relevant ICD-9 codes by the frequency they were used as the primary indication for specific imaging procedures. The agency extracted the top 135 ICD-9 codes and formed them into clinically related categories. A manual search was also performed to augment that data with other appropriate ICD-9 codes. The result was a set of eight priority clinical areas accounting for roughly 40% of advanced diagnostic imaging services paid by Medicare in 2014. CMS will determine the process for identifying outliers to the program in future rulemaking.

Priority Clinical Areas:

CMS finalized a modified list of priority clinical areas for the implementation of the AUC program and utilization of CDSMs, which includes:

- Coronary artery disease (suspected or diagnosed);
- Suspected pulmonary embolism;
- Headache (traumatic or non-traumatic);
- Hip pain;
- Low back pain;
- Shoulder pain (to include suspected rotator cuff injury);

- Cancer of the lung (primary or metastatic, suspected or diagnosed); and
- Cervical or neck pain.
- The proposed list included chest pain, abdominal pain (any locations and flank pain), suspected stroke, and altered mental status but were removed and replaced with coronary artery disease (suspected or diagnosed), suspected pulmonary embolism, hip pain, and shoulder pain based on stakeholder comment regarding lack of solid evidence in certain clinical areas.

CDSMs Qualifying Requirements:

CMS finalized a list of requirements for qualified CDSMs; this list includes:

- Make available specified applicable AUC and its related supporting documentation;
- Identify the AUC consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario;
- Make available specified applicable AUC that reasonably address common and important clinical scenarios within all priority clinical areas;
- Be able to incorporate specified applicable AUC from more than one qualified PLE;
- Determine, for each consultation, the extent to which the applicable imaging service is consistent with the specific applicable AUC;
- Generate and provide a certification/documentation when a relevant CDSM is consulted;
- Modifications to AUC within the CDSM must comply with set timeline requirements;
- Meet privacy and security standards under applicable provisions of the law;
- Provide to the ordering professional aggregate feedback regarding their consultations with specified applicable AUC in the form of an electronic report on at least an annual basis;
- Maintain electronic storage of clinical, administrative, and demographic information of each unique consultation for a minimum of 6 years;
- Comply with modification(s) to any of these requirements made through rulemaking within 12 months of the effective date of modification; and
- Notify ordering professionals upon de-qualification.

CDSM Qualifying Process:

The rule creates an annual process by which a CDSM can apply and seek qualification under the program. The timetable is aligned with the qPLE process and timeline.

CDSMs must submit an application to CMS documenting adherence to each requirement by January 1 of the review year cycle. Under the final rule, the first application cycle has been extended (from January 1) to March 1, 2017 and determinations will be made at the earliest by June 30, 2017. CDSMs must reapply every five years along the same January 1 deadline, thus the second cycle would begin on July 1, 2022. CMS plans to post a list of all qualified CDSM applicants on their website and notes that they may remove a CDSM that no longer qualifies.

Program Exceptions:

CMS finalized that ordering professionals will not be subject to the Section 218(b) consultation requirements in the following three circumstances: (i) where the services provided are emergency services provided to individuals with emergency medical conditions (as defined in Section 1867(e)(1) of the Social Security Act; (ii) where services are provided to an inpatient under Medicare Part A; or (iii) where the services are provided by an ordering professional who has a hardship exemption under the Medicare electronic health records (EHR) payment adjustment program.