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

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

General Background:

On July 7, 2016, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule for the CY 2017 Medicare physician fee schedule (PFS). The proposed rule appears in the July 15, 2016, Federal Register and can be downloaded from the Federal Register at: https://www.federalregister.gov/public-inspection. CMS will accept comments until September 6, 2016.

The proposed 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 new proposed 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 requirements.

Items in the Proposed Rule:

Implementation Timetable:

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 again indicates that the timetable will slip.

With a projected date for qualifying CDSMs of June 30, 2017, CMS indicates that furnishing professionals may begin to report as soon as January 1, 2018.

Medicare Applicability:

The proposed rule would add 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.

Program Exceptions:

The proposed rule indicates 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.

Priority Clinical Areas:

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.

Proposed Priority Clinical Area	Total Services	% Total Services[1]	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%

Further detail is in a report by Mitre that can be accessed here: https://www.mitre.org/publications/technical-papers/claims-data-analysis-to-define-priorityclinical-areas-for-advanced

CMS requests comment on the proposed areas, the use of claims data only (as opposed to other basis for selection including disease prevalence, variability in use, strength of evidence or applicability to care settings and populations) and whether pulmonary embolism should be its own category.

Clinical Decision Support Mechanism (CDSM) Requirements:

The proposed rule sets out requirements for a CDSM to seek to become qualified under the Section 218(b) program (a qCDSM).

In discussing the proposed regulation, CMS notes that some CDSMs in current existence may provide feedback along a continuum of appropriateness (e.g. a numeric scale or color coding approach) while others may drive the user toward dichotomous "yes/no" feedback based on clinical inputs. The agency indicates that it does not presently have a preference for either approach but that they are interested in receiving comment on how various rating approaches can be applied in determining whether an order "adheres" to the AUC that was consulted or if the AUC is "not applicable" to the order.

CMS also discusses the issue of IT standardization and indicates that at this time they are focused on an approach that defines the functionalities and capabilities of a qCDSM. In the future, however, as the process of consensus building among standards organizations and stakeholders such as the Agency for Health Research and Quality (AHRQ) and the Office of the National Coordinator for HIT (ONC) progresses, CMS may consider embracing such standards as qCDSM requirements.

The proposed regulation would provide a definition of qCDSM 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." These tools may be modules integrated into electronic health record systems or they may be freestanding. CMS indicates in its discussion that the federal government does not intend at this time to create their own qCDSM.

The proposed regulation then sets out a number of requirements that a CDSM must meet to be qualified. Some of these requirements were specified in the underlying statute and some are requirements that CMS has added or augmented in the proposed rule –

- Make available applicable AUC and related documentation regarding the appropriateness of the ordered imaging services.

- Identify the appropriate use criteria consulted if the qCDSM makes available more than one criterion relevant to a patient's clinical scenario.

- At a minimum, make available specified applicable AUC that "reasonably encompass" the entire clinical scope of all priority clinical areas.

- Have the ability to incorporate AUC from "more than one" qPLE.

- In each case that the qCDSM is consulted (i.e. not only when an order is generated), provide certification or documentation that includes a unique "consultation identifier" to the ordering professional as to (i) which qCDSM was consulted, (ii) the name and National Provider Identifier (NPI) of the ordering professional, and (iii) whether the service ordered would adhere/not adhere to the specified AUC or whether such AUC was not applicable to the ordered service.

- Update AUC content not less than every 12 months to incorporate revisions or updates made by the relevant qPLEs. Within 12 months of CMS finalizing any new clinical priority area, AUC that reasonably encompass the entire clinical scope of that area must be made available. Additionally, a protocol must exist to "expeditiously" remove any AUC determined by the qPLE to be dangerous or harmful.

- Meet applicable privacy and security requirements.

- Not less than annually, provide ordering professionals with aggregate feedback regarding their consultations via an electronic report.

- Store clinical, administrative and demographic information on each unique consultation for a minimum of six years.

- Comply with any modification to these requirements within 12 months of such Modification being adopted by CMS.

CDSM Qualifying Process:

The proposed 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 the program requirements by January 1st. For the first year, applications will be accepted from the date that the CY 2017 Physician Final Rule is finalized and published (likely in November, 2016) through January 1, 2017. Decisions regarding which applicants achieve qCDSM status will be made by June 30, 2017 and posted on the CMS website. In subsequent years, January 1 will also be the application deadline. All qCDSMs must re-apply every five years along the same January 1 deadline.

If a CDSM is found to be "non-adherent" with qualification requirements, CMS may terminate its qualified status or consider this information during the reapplication process.