ACR Detailed Summary of the Appropriate Use Criteria Provisions of the 2019 Medicare Physician Fee Schedule Proposed Rule

Background and Program Overview

The Protecting Access to Medicare Act of 2014 included a provision for the mandatory use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Through the CY 2016 rulemaking process, CMS addressed the initial component of the AUC program, specifying applicable AUC. CMS established a process for the development of AUC, defined provider-led entities (PLEs), and established the process by which PLEs may become qualified to develop AUC. The first list of qualified PLEs was posted on the CMS website in late June 2016.

The CY 2017 Medicare Physician Fee Schedule (MPFS) final rule identified the requirements clinical decision support mechanisms (CDSMs) must meet for qualification including an opportunity for preliminary qualification for mechanisms still working toward full adherence, and established a process by which CDSMs may become qualified. The first list of qualified CDSMs was posted to the CMS website in conjunction with the CY 2018 proposed rule in July 2017.

In addition, CMS defined applicable payment systems under this program (MPFS, Hospital Outpatient Prospective Payment System (OPPS), and Ambulatory Surgical Center (ASC) payment system), specified the first list of priority clinical areas for the identification of outlier ordering professionals, and identified exceptions to the requirements that ordering professionals consults specified applicable AUC when ordering applicable imaging services.

The CY 2018 MPFS addressed the program implementation date and claims processing instructions for reporting AUC consultation. The 2018 final rule established a January 1, 2020 start date for Congressionally- mandated AUC program for advanced diagnostic imaging services. On and after this date, ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. The program will begin with a one year educational and operations testing period where claims will not be denied for errors in reporting the proper AUC consultation information. CMS also established a voluntary reporting period from July 2018 through the end of 2019 during which ordering professionals who are ready to participate in the AUC program may do so through the use of modifier "QQ". To incentivize early use of AUC consultation, CMS established in the Quality Payment Program (QPP) a high-weight improvement activity for ordering professionals who perform an AUC consultation using a qualified CDSM for the performance period that began on January 1, 2018.

The CY 2019 proposed rule proposes an addition to the definition of applicable setting, clarification around who may perform the required AUC consultation using a qualified CDSM under the program, clarification that reporting is required across claim types and by both the furnishing professional and furnishing facility, changes to the policy for significant hardship exceptions for ordering professionals under the program, mechanisms for claims-based reporting, and a request for feedback on the methodology to identify outlier ordering professionals.

Expanding Applicable Settings

Section 1834(q)(1)(D) of the Act specifies that the AUC consultation and reporting requirements apply only in an applicable setting, including a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and "any other provider-led outpatient setting determined appropriate by the Secretary". **CMS is proposing to revise the definition of applicable setting to include independent diagnostic testing facilities (IDTFs). CMS is soliciting comments on this proposal and on the possible inclusion of any other applicable setting.**

The agency believes that the addition of IDTFs to the definition of applicable setting will ensure that the AUC program is in place across outpatient settings in which outpatient advanced diagnostic imaging services are furnished and would appropriately and consistently apply the program. CMS also points out that the application of the AUC program is not only limited to applicable settings, but also to services for which payment is made under applicable payment systems (the MPFS, OPPS and ASC payment systems).

Consultations by Ordering Professionals

In response to comments in the 2018 rulemaking cycle seeking clarification on who is required to perform the consultation of AUC through a qualified CDSM, **CMS is proposing that the consultation may be performed by "auxiliary personnel incident to the ordering physician or non-physician practitioner's professional service".** While the specific proposal language states "auxiliary personnel", the preamble language uses the phrase "clinical staff working under the direction of the ordering professional, subject to applicable State licensure and scope of practice law".

CMS recognizes that the statute does not explicitly provide for consultations under the AUC program to be fulfilled by other professionals, individuals or organizations on behalf of the ordering professional; however, the agency is making efforts to seek ways to minimize the burden of this new program. The rule notes that it is important to note that ordering professional is ultimately responsible for the consultation as their NPI is reported by the furnishing professional on the claim for the applicable imaging service and that it is the ordering professional who could be identified as an outlier ordering professional and become subject to prior authorization based on their ordering pattern.

Reporting AUC Consultation Information

When CMS initially codified the AUC consultation reporting requirement in through rulemaking in the CY 2018 PFS final rule, the agency specified only that "furnishing professionals" must report AUC consultation information on claims for applicable imaging services. This led some stakeholders to believe that AUC consultation information would be required only on practitioner claims. To better reflect the statutory requirements, **CMS is proposing to revise the regulations to clarify that AUC consultation information must be reported on <u>all</u> claims for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (including both the professional and technical components).**

Claims-Based Reporting

In the CY 2018 MPFS proposed rule, CMS proposed using a combination of G-codes and modifiers to report the required AUC consultation information on the Medicare claim. In response to numerous public comments objecting to this potential solution, the agency considered additional approaches to reporting AUC information, including reporting of a unique consultation identifier (UCI) as suggested by the ACR as a less burdensome approach.

CMS had the opportunity to engage with stakeholders in the months since the publication of the CY 2018 MPFS final rule and understands that there are continued challenges with the UCI approach. The majority of solutions involving a UCI are claim-level solutions that do not allow attribution of the CDSM used or AUC adherence status to individual CPT codes for advanced diagnostic imaging services if more than one such code is included on a single claim. As such, CMS believes the approach of using a UCI would not identify whether an AUC consultation was performed for each applicable imaging service reported or be useful for the purposes of identifying outlier ordering professionals.

After exploring the UCI option, CMS concluded that it is not feasible to create a uniform UCI taxonomy, determine a location of the UCI on the claims form, obtain the support and permission by national bodies to use claim fields for this purpose, and solve the underlying issue that the UCI seems limited to claim-level reporting on time for the January 1, 2020 implementation date. Therefore, **CMS proposes to use code structures that are already in place (such as G-codes and modifiers) to establish reporting requirements, allowing for implementation to proceed on January 1, 2020. The agency will consider future opportunities to use a UCI and will continue to engage with stakeholders.**

Under the proposal, each qualified CDSM would be assigned a G-code with a code descriptor containing the name of the qualified CDSM. If there is more than one advanced diagnostic imaging service on a claim, CMS could attribute a single G-code to all of the applicable imaging services on the claim, which would be appropriate if each AUC consultation for each service was through the same CDSM. If a different CDSM was used for each service (for example, when services on a single claim were ordered by more than one ordering professional and each ordering professional used a different CDSM) then multiple G-codes could be needed on the claim. Each G-code would appear on the claim individually as its own line item, which could result in confusion. As a potential solution, CMS considered the use of modifiers, which would appear on the same line as the CPT code that identifies the specific billed service.

Three modifiers would be developed to report the result of the AUC consultation as: 1) the imaging service would adhere to the applicable AUC, 2) the imaging service would not adhere to the criteria, or 3) such criteria were not applicable to the imaging service ordered. These modifiers, when placed on the same line with the CPT code for the advanced diagnostic imaging service, would allow the information to be easily accessed in the Medicare claims data and matched with the imaging service.

Significant Hardship Exception

CMS is proposing the following as situations where an ordering professional would not be required to consult AUC using a qualified CDSM when ordering advanced diagnostic imaging services:

- **Insufficient internet access;**
- **EHR or CDSM vendor issues (including temporary technical problems, installation or upgrades that impede access or CMS de-qualification of a CDSM vendor); or**
- **Extreme and uncontrollable circumstances (including natural or man-made disasters).**

The agency proposes that ordering professionals would self-attest if they are experiencing a significant hardship at the time of placing an advanced diagnostic imaging order and such attestation be supported with documentation of the significant hardship. Ordering professionals would communicate the information to the furnishing professional with the order and it would be reflected on the furnishing professional's and furnishing facility's claim by appending a HCPCS modifier. Claims that include the significant hardship modifier would not be required to include AUC consultation information.

In previous rulemaking, CMS proposed linking the significant hardship exceptions for the AUC program to other programs such as the EHR Incentive Program and/or MIPS. CMS believes that the current proposal is more straightforward and less burdensome, creating a process that is independent from other Medicare programs. The agency notes that the AUC program requires provisions for real-time significant hardship exceptions rather than a complex process of applying for an exception.

CMS invites public comment on any additional circumstances that would cause the act of consulting AUC to be particularly difficult or challenging for the ordering professional. The agency notes that circumstances such as the ordering professional being in clinical practice for a short period of time or having limited numbers of Medicare patients would not impede clinicians from consulting AUC as required by the program.

Identification of Outliers

CMS invites comments on a possible methodology for the identification of outlier ordering physicians who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services. The agency is specifically seeking comments on the data elements and thresholds that CMS should consider when identifying outliers.

The proposed rule indicates that CMS does not intend to use data from the educational and operations testing period in CY 2020 in the analysis used to develop the outlier methodology. Therefore, the agency expects to address outlier identification and prior authorization more fully in CY 2022 or 2023 rulemaking.