Update for AHRA Members as of November 2, 2021

2022 Physician Fee Schedule Final Rule

CMS Finalizes Delay, Appears Ready to Implement Appropriate Use Criteria in 2023

On November 2, 2021 the Centers for Medicare and Medicaid Services (CMS) released the 2022 Medicare Physician Fee Schedule (PFS) Final Rule. The final rule delays, for the *fourth* time, the "payment penalty phase" of the Appropriate Use Criteria (AUC) policy until January 1, 2023 or the first January after the Public Health Emergency (PHE) ends, whichever comes later.

As a reminder, we are currently in the educational and operational testing phase of the AUC program. AUC information may be appended to a Medicare claim, but it is not necessary for payment. However, when the payment penalty phase begins, advanced imaging claims subject to the AUC policy must have the proper AUC information included for Medicare to reimburse those claims.

When the *third* delay of the AUC program was announced in 2020, many in the imaging community began to question if the AUC program was ever actually going to be fully implemented. At that time, the claims-processing challenges seemed insurmountable, CMS had to shift their regulatory focus to the PHE and there was no clear path forward for AUC. Therefore, in early 2021, AHRA pressed CMS to publicly list the lingering implementation issues, so that the imaging community could help CMS identify solutions.

To their credit, CMS listened to AHRA's call for more transparency regarding the status of the AUC program. In the 2022 PFS proposed rule, CMS responded by listing the nine "challenging" claims-processing issues that needed solutions before moving the program to the next phase. After identifying these problems in the proposed rule and soliciting feedback from the imaging community through the formal comment process, CMS was able to address **all of these claims-processing issues in the final rule.**

One of the biggest lingering challenges with the next phase of AUC implementation was the fact that there was no process to allow for multiple ordering professional NPI numbers to be on the same electronic CMS-1500 claim form. In the proposed rule, CMS said that in these scenarios, practitioners would have no choice but to split claims if there was more than one ordering professional. However, after reviewing feedback from the imaging community on potential solutions, CMS was able to identify a mechanism for a single advanced imaging claim to contain NPIs from multiple ordering professionals.

CMS adopted many of AHRA's recommendations including AHRA's suggestion that advanced imaging claims with improper AUC information be returned for correction instead of being denied. CMS also adopted AHRA's suggestion to retire, instead of re-define, modifier MH which will help avoid confusion in the payment penalty phase. Together, these policy solutions provide an excellent illustration of how stakeholder comments can impact and improve the final policy.

The nine claims-processing issues are covered in greater detail below. In general, they involve identifying which claims are subject to, and which claims are not subject to, AUC.

Not only did CMS make significant progress on claims-processing issues, but they also provided some very important clarifications of scope of the AUC program.

Prior to this final rule, AHRA was concerned that ordering professionals could exert pressure on the furnishing professionals to consult AUC on behalf of the ordering professional. AHRA commented that such a policy would have defeated the purpose of the program and put the onus of AUC consultation on furnishing professionals instead of on ordering professionals as intended by Congress.

Thankfully, in the final rule, CMS makes it clear that "furnishing professionals may not consult AUC on behalf of or in place of the ordering professional" which will prevent ordering professionals from assigning the responsibility of consulting AUC to furnishing professionals.

CMS also clarifies that when the furnishing professional needs to modify an order consistent with the policy enumerated in Chapter 15 of the Medicare Benefit Policy Manual, and **is unable** to reach the ordering professional, the furnishing professional may proceed with the modified order and append the information from the original AUC consultation. However, if the furnishing professional **is able** to contact the ordering professional, the ordering professional would need to consult AUC regarding the new order and provide that information for inclusion on the modified claim.

There is no denying that the uncertainty surrounding the Appropriate Use Criteria Program has been a major challenge for the medical imaging community. The delays have made planning and preparing for the next phase of AUC difficult. While it is impossible to guarantee that the timeline won't slip again (in fact, it will automatically be pushed back if the PHE continues into 2023), **CMS <u>does</u> appear ready to operationalize the "payment penalty phase" of AUC.**

As always, AHRA's regulatory affairs committee will monitor all AUC policy developments and update the AHRA membership as necessary.

Appropriate Use Criteria for Advanced Diagnostic Imaging ~ Detailed Summary

For those interested in more detailed information regarding the AUC updates included in the 2022 PFS final rule, we have included a longer summary below:

Background and Overview

The Protecting Access to Medicare Act of 2014 (PAMA) established a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. The payment penalty phase of this program was initially scheduled to begin on January 1, 2017 but was delayed four separate times through the rulemaking process. An "educational and operations testing period" began on January 1, 2020, which was extended through the end of 2021 due to the COVID-19 public health emergency (PHE).

In the CY 2016 rulemaking process, CMS addressed the initial component of the AUC program, by defining the development of AUC, defining provider-led entities (PLEs), and establishing the process by which PLEs may become qualified to develop AUC. The first list of qualified PLEs was posted on the CMS website in June 2016.

The CY 2017 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 this proposed rule.

CMS also defined applicable payment systems under this program (MPFS, Hospital Outpatient Prospective Payment System (HOPPS), 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 consult specified applicable AUC when ordering applicable imaging services. In the CY 2019 MPFS final rule, independent diagnostic testing facilities (IDTFs) were added to the definition of applicable settings.

The CY 2018 MPFS final rule addressed consultation and reporting requirements. In this rule, CMS established a program start date of January 1, 2020, beginning with a one year "educational and operations testing period." CMS specified that for services ordered on or after this date, ordering professionals must consult specified applicable AUC via a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the claim. CMS specified that during the testing period, claims would not be denied for failure to include proper AUC consultation information. In addition, CMS established a voluntary reporting program from July 2018 through the end of 2019. Consultation of AUC using a qualified CDSM was designated as a high-weight improvement activity for ordering professionals for the Merit-based Incentive Payment System (MIPS) beginning January 1, 2018.

When the AUC program is fully implemented, the following information must be included on all claims for applicable advanced diagnostic imaging services:

1. The qualified CDSM consulted by the ordering professional;
2. Whether the service ordered would or would not adhere to specified AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and
3. The NPI of the ordering professional.

Detailed claims processing instructions are published on the CMS website here.

Timing of Payment Penalties

CMS finalized a flexible effective date for the AUC program payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID-19.

Based on previous rulemaking, the AUC program was scheduled to enter the payment penalty phase on January 1, 2022. In the Proposed Rule, CMS recognized the circumstances of physicians and other practitioners due to the PHE for COVID-19 and that additional time may be needed to prepare for the payment penalty phase. Additionally, CMS indicated that the earliest the CMS claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. CMS acknowledged that an effective date for the claims processing edits in October is not aligned with typical annual updates to the systems used by healthcare providers. Therefore, the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023.

Clarification of AUC Program Scope

Modified Orders

CMS has finalized its proposal that when the furnishing professional is unable to reach the ordering professional is not required to obtain new order and may proceed with additional or different imaging as described in the Medicare Benefits Policy Manual (BPM), so the AUC consultation information for the original order is to be appended to the claim for the service(s) ultimately furnished. Note, that in instances where the furnishing professional determines additional or replacement imaging services should be performed and he or she is able to reach the ordering professional for a new order, then the ordering professional will consult AUC for the new order(s) and provide that information with the new order(s) for inclusion on the claim.

CMS acknowledged that updates or modifications to orders for imaging services may be necessary in certain situations once the beneficiary is under the care of the furnishing professional. Medicare BPM Chapter 15, sections 80.6.1-4 addresses situations where the furnishing professional performs imaging services that are different from ordered services. The rules state that a different or additional imaging service not included on the order generally may not perform the test until a new order from the treating physician/practitioner has been received.

Extreme and Uncontrollable Circumstances Hardship Exception

In this section CMS provided several clarifications and comments regarding what does and does not qualify as a hardship by their definition. In the CY 2019 final rule, CMS described the extreme and uncontrollable hardship exception as including natural or man-made disasters that have a significant impact on healthcare operations, area infrastructure or communication systems.

CMS finalized its proposal that stakeholders may attest to a significant hardship exception for the AUC program due to COVID-19 throughout the PHE. When the AUC program progresses into the payment penalty phase, this option will continue be available for ordering professionals beyond the date the PHE expires.

CMS also addressed the question as to whether an AUC consultation is required on second opinion interpretations. CMS believes that the AUC consultation and reporting requirements apply to second opinions in the same way that they apply to original patient assessments, but they clarify that the AUC consultation information specific to the advanced diagnostic imaging

services that was furnished (the original) order would be appended to the claim for the professional component (PC). If, based on the second opinion, further tests must be ordered, they would require separate and additional AUC consultation on these new/additional orders.

CMS clarified that diagnostic imaging services furnished pursuant to or as part of a clinical trial do not qualify for as an exception.

Claims Processing

Ordering Professional NPI

There are locations on both the practitioner and institutional claim types to report the NPI of the ordering professional. The institutional claim uses the K3 segment and the practitioner claim uses the referring professional field. In order to fully implement the AUC program, CMS must establish a claims processing edit to require these fields to be populated on all advanced diagnostic imaging claims subject to the AUC program.

Additionally, there are situations where multiple advanced diagnostic imaging services are ordered by more than one ordering professional that may be reported on a single claim.

After additional review CMS agrees in the Final Rule that the practitioner who orders the advanced diagnostic imaging service can be identified at the line level on professional component claims (837P) and they will adjust their implementation accordingly. They anticipate that separate claims will not be required when services are submitted for multiple ordering practitioners on the same claim form. They will continue to evaluate which line-item field is most appropriate to populate (ordering or referring professional fields on the claim) and will be developing claims processing instructions that allow for more than one practitioner that orders advanced diagnostic imaging services to be reported on the practitioner claim.

Critical Access Hospitals

CMS finalized its proposal that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting (such as CAH) not be subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. A new modifier will be utilized to identify these circumstances.

Imaging services furnished in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program. Generally, all claims for advanced diagnostic imaging services, both the professional component (PC) and technical component (TC), must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. When advanced diagnostic imaging services are performed in the CAH setting, this is not an applicable setting and as such, neither the PC nor TC claim is required to include AUC consultation information.

CMS wishes to automate the identification of claims for AUC non-applicable sites and will continue to search for a mechanism to allow this to occur.

CMS clarified that ordering professionals that order advanced diagnostic imaging services in a CAH do not qualify for an exception to the AUC consultation requirement.

Maryland Total Cost of Care Model

Since services furnished under the Maryland Total Cost of Care Model are not paid under an applicable payment system, the advanced diagnostic imaging services furnished under the model are not subject to the program requirements.

CMS has reaffirmed that they will continue to work to set up claims processing edits using the CMS Certification Number (CCN) in box 32 to identify advanced diagnostic imaging services furnished under the Maryland Total Cost of Care Model for claims which are not subject to the AUC program requirements.

Inpatients Converted to Outpatients

CMS is finalizing its proposal to allow institutional claims with condition code 44 to bypass AUC claims processing edits.

There are situations where a beneficiary's hospital inpatient status is changed to outpatient. If the criteria for this to occur are met, condition code 44 (inpatient admission changed to outpatient) is appended to the institutional claim. Professional claims would include place of service code 21 (inpatient hospital) since the expectation, until just prior to discharge, would be that the patient is an inpatient status. CMS anticipates that less than half of one percent of claims will include condition code 44.

Deny or Return Claims that Fail AUC Claims Processing Edits

CMS finalized its proposal to return (instead of deny) claims that do not pass the AUC claims processing edits for correction and resubmission when the penalty phase begins. CMS will be establishing claims processing edits and instructions and will be post the documents on the AUC website: https://www.cms/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program

Medicare as a Secondary Payer

CMS finalized its proposal to allows claims that identify Medicare as a secondary payer (using block 1 or the equivalent of the practitioners claims and using FL 50/51 of the electronic equivalent of institutional claims) to bypass the AC program claims processing edits.

Date of Service and Date of Order

CMS finalized its proposal to identify claims for imaging services ordered prior to but furnished on or after the effective date of the AUC program claims processing edits, using a new HCPCS modifier that will identify claims that are not subject to AUC claims processing edits.

HCPCS Modifiers

CMS has established two sets of modifiers for the AUC program. The first set is to be included on the same claim line as the G-code identifying the CDSM that was consulted and reports whether or not the imaging service adheres to the AUC.

- Modifier ME – Imaging service adheres to the AUC
- Modifier MF – Imaging service does not adhere to the AUC
- Modifier MG – The qualified CDSM does not contain AUC that applies to the order

The second set of HCPCS modifiers is available for use when the ordering professional does not consult a qualified CDSM. These claims would not include a G-codes for a CDSM since there was no consultation and as such, the modifier would be included on the same line as the procedure code for the imaging service that was performed.

- Modifier MA – Patients with a suspected or confirmed emergency medical condition
- Modifier MB – Insufficient internet access
- Modifier MC – EHR or CDSM vendor issues
- Modifier MD – Extreme and uncontrollable circumstances

Modifier QQ was created for use during the voluntary reporting period before more detailed modifiers and codes were created. This modifier continues to be available for use through the educational and operations testing period.

Modifier MH was created for use during the educational and operations testing period to identify claims for which AUC consultation information was not provided to the furnishing professional and facility. CMS has stated when the AUC program enters the penalty phase, this modifier will no longer be available since all claims will be required to include AUC consultation or a specific reason the information is not required.

CMS restated that the use of MA modifier is not limited to emergency department settings. This exception is for applicable imaging services for individuals with an emergency medical condition defined by the applicable statue. The exception is applicable even if it is determined later than the patient did not in fact have an emergency medical condition.

CMS reinforced that since the statute explicitly includes the emergency department as an applicable setting under the AUC program, they are unable to categorically exclude all advanced diagnostic imaging services furnished in the emergency department, including those furnished to patients whose insurance is unknown at the time of treatment.

CMS agreed with commenters regarding the potential definition change for modifier MH and will not be repurposing it for use on claims as proposed.

CMS acknowledges the challenges faced by furnishing professionals in requiring the ordering professional to perform the AUC consultation but is obligated to implement the AUC provisions and does not have the authority to modify or mitigate the requirements. They will continue to work on education and outreach and explore opportunities to update an expand their written

outreach materials to help inform or remind ordering professionals of their responsibilities under the AUC program.

CMS is finalizing its proposal to end the use of modifier QQ when the payment penalty phase begins and will establish a new modifier to identify claims where the ordering professional is not required to consult AUC and the already established modifiers do not apply. This new modifier will apply when claims systems edits cannot automatically exclude the claims to include the scenarios discussed in this final rule.

Additional Claims Processing Information

CMS finalized its proposal to limit AUC claims processing edits to apply only to the following:

- Institutional Claims
  - Bill 13x (hospital outpatient)
- Professional Claims with place of service codes
  - 11 – Office
  - 15 – Mobile unit
  - 19 – Off campus outpatient hospital
  - 22 – On campus outpatient hospital
  - 23 – Emergency room
  - 24 - ASC