

Please Provide Responses to the Fields Below Electronically to be Accepted

Medicare *Red Tape* Relief Project

Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017

Name of Submitting Organization: American Association of Neurological Surgeons/Congress of Neurological Surgeons

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Statutory Regulatory

Please describe the submitting organization's interaction with the Medicare program:

The American Association of Neurological Surgeons (AANS), founded in 1931, and the Congress of Neurological Surgeons (CNS), founded in 1951, are the two largest scientific and educational associations for neurosurgical professionals in the world. Timely access to quality neurosurgical care is essential to the health and well-being of society, and as the voice of neurosurgery before legislative, regulatory and other health care stakeholders, the AANS and CNS advocate for our specialty and patients on a wide-variety of health care policy matters, including Medicare policy. Neurological surgery is the medical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the entire nervous system, including the spinal column, spinal cord, brain and peripheral nerves. For more information, please visit www.aans.org, www.cns.org and www.neurosurgeryblog.org.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as "Appendix [insert label]"

In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description: Medicare Appropriate Use Criteria (AUC) for Imaging (Priority Issue #1)

Summary:

The AANS and CNS support appropriate use criteria (AUC) for advanced diagnostic imaging. Indeed, our clinical experts work collaboratively with the American College of Radiology on developing AUC for imaging related to neurologic conditions. However, ensuring that patients get the most clinically appropriate diagnostic imaging test promptly should not mean complicated, cumbersome and costly regulatory-imposed burdens on physician practices, as well as on the hospitals and ambulatory surgery centers in which they practice.

The "Protecting Access to Medicare Act of 2014" (P.L. 113-93) establishes a program requiring clinicians to consult with AUC for advanced diagnostic imaging services. To be paid for the service, health care professionals who furnish an advanced imaging test must document the ordering

professional's consultation of federally approved AUC using a federally qualified clinical decision support mechanism (CDSM). The law also directs the Centers for Medicare & Medicaid Services (CMS) to require prior authorization beginning in 2020 for ordering outlier professionals related to clinical priority areas, identified by CMS as:

- 1) coronary artery disease (suspected or diagnosed);
- 2) suspected pulmonary embolism;
- 3) headache (traumatic and non-traumatic);
- 4) hip pain;
- 5) low back pain;
- 6) shoulder pain (to include rotator cuff injury);
- 7) cancer of the lung (primary or metastatic, suspected or diagnosed); and
- 8) cervical or neck pain.

In 2015 and 2016, CMS used the process of rulemaking to begin laying out the parameters of the AUC Program. The 2016 Medicare Physician Fee Schedule (PFS) final rule established requirements for provider-led entities (PLEs). These requirements allow PLEs to demonstrate they engage in a rigorous evidence-based process for developing, modifying or endorsing AUC. AUC become specified, and therefore eligible for inclusion in the program, when they are developed or modified by a qualified PLE, or when a qualified PLE endorses AUC developed by another entity. The final 2017 Medicare PFS rule established requirements CDMS would need meet to become qualified under the AUC Program. Most notably the requirement that CDSMs must incorporate specified, applicable AUC that comprise the entire clinical scope of all the above specified clinical priority areas. It is expected that during the initial years of the program, outlier ordering professionals will be identified based upon their adherence to AUC for these priorities areas. The rule also included the agency's decision to not require that ordering professionals meet program requirements by Jan. 1, 2017 as specified in the law. Finally, the 2018 proposed Medicare PFS rule proposes that clinicians must begin reporting AUC consultations in 2019, but services would be paid regardless of whether or not claims submitted for payment include the correct AUC consultation documentation.

CMS continues to work through significant challenges related to the program, as evidenced by its delayed implementation and a recent request for feedback on whether additional delays beyond the newly proposed 2019 implementation date are necessary. The agency has yet to finalize all of the policies that will enable physician practices to adequately prepare for the program and to make informed practice changes, including investments in CDSMs, updating of reporting and billing systems, and incorporating consultation into practice patterns. The first and limited set of qualified CDSMs were only first announced in July 2017, and it is still unclear to what extent they are easily accessible, applicable and implementable across practices. In general, the acquisition and implementation of a CDSM that integrates with the clinician's EHR system may be cost prohibitive or hampered by electronic health record (EHR) vendor readiness; thereby increasing the administrative burden on clinicians. While the program is required to include at least one free CDSM, these are often web-based or stand-alone products that do not easily integrate with EHRs. In this regard, the Government Accountability Organization (GAO), in a September 2015 report (Considerations for Expansion of the Appropriate Use Criteria Program; GAO-15-816), found that providers using web-based or stand-alone software applications experienced frustration with the lack of integration between the CDSM and their EHR system and experienced workflow inefficiencies.

Furthermore, the program is duplicative of — and even inferior to — the Quality Payment Program (QPP), which already holds clinicians accountable for quality and patient outcomes (something that the AUC program fails to do), as well as for resource use, including the use of diagnostic tests and procedures. Given the implementation of the QPP, this separate program is redundant, and CMS can readily incorporate the use of AUCs for diagnostic imaging into the QPP.

The AANS and CNS believes that this program places an excessive burden on physicians across a broad range of specialties with little evidence of clinical benefit. CMS has acknowledged the number of clinicians affected by the program is “massive,” crossing almost every medical specialty and having a particular impact on primary care physicians since their scope of practice can be vast. This program will require neurosurgeons ordering advanced diagnostic imaging for three of these eight clinical areas — headache, low back pain and cervical or neck pain — to consult with AUC. Neuroimaging is a key component of diagnosing, evaluating and treating disorders of the central nervous system—which includes the brain, spinal cord and vertebral column (spine). A thorough understanding of neuroanatomy, neuropathology, neuropathophysiology and neuroimaging is, therefore, essential to ensure that patients receive high quality, reliable and precise diagnostic imaging studies of the nervous system. Neurological surgeons receive extensive training in these key areas and are therefore qualified and certified to order and interpret diagnostic imaging procedures on the nervous system. Adding this additional requirement to consult AUC for neurosurgeons is, therefore, unnecessary.

Related Statute/Regulation:

- 42 USC 1395m(q)
- 42 CFR 414.94
- <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html>

Proposed Solution:

Ideally, the AANS and CNS urge Congress to terminate the AUC program for advanced diagnostic imaging given the duplication and limited value of the Medicare AUC program in light of the QPP. To the extent that Congress needs additional time to investigate the extent of duplication and marginal value of the AUC program, the AANS and CNS requests that Congress or CMS further delay the effective date until at least 2021, or until CMS can adequately address technical and workflow challenges with its implementation and any interaction between the QPP and the AUC requirements. Finally, CMS should expand the use of hardship exemptions if the AUC requirements are implemented.