The Honorable Orrin Hatch Chairman Committee on Finance U.S Senate Washington, DC 20510 The Honorable Ron Wyden Ranking Member Committee on Finance U.S. Senate Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

As medical societies whose members frequently order and rely on advanced diagnostic imaging for the diagnosis and treatment of their patients, we are deeply concerned with the timeline for implementation of the Medicare Appropriate Use Criteria (AUC) Program as required by the *Protecting Access to Medicare Act of 2014* (PAMA)" (P.L. 113-93). Compounding this concern is the disproportional burden primary care physicians will face in 2017 when trying to comply with these new requirements, which will fall at the same time that physicians are expected to meet new requirements of the *Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)*. While we recognize the importance of encouraging appropriate utilization of high-cost services, we want to work with CMS to ensure that the program is rolled out smoothly and successfully. We appreciate that the Centers for Medicare & Medicaid Services (CMS) continues to work diligently with stakeholders to meet the Program deadlines set by Congress. However, we have serious reservations with CMS' proposed implementation timeline, which will make it very difficult for physicians to comply with program requirements, as well as for health information technology (HIT) systems to be updated to support clinical decision support (CDS). We, therefore, respectfully request that Congress delay the Program.

PAMA requires that beginning January 1, 2017, physicians must consult AUC prior to ordering certain advanced diagnostic imaging services. Professionals who furnish these tests must document the ordering professional's consultation of AUC to be paid for the service. The law also directs the CMS to require prior authorization beginning in 2020 for ordering outlier professionals. We believe a delay of the January 1, 2017 effective date will allow CMS to continue developing Program requirements within the original timeline, while giving physician practices, hospitals and HIT vendors more time to prepare and implement Program requirements.

In the CY 2016 Medicare Physician Fee Schedule (PFS) Proposed Rule, CMS laid out the process by which it will specify applicable AUC. It did not, however, include proposals to implement the Program. We acknowledge CMS' decision to not include proposals for implementing the Program until a process for specifying AUC is established because the AUC will serve as the inputs to any qualified CDS mechanism, which is the route by which AUC will be consulted. Consequently, much implementation of the Program is being left to CY 2017 rulemaking, including the process by which CMS will specify CDS, and the rules around how physicians and other health professionals will choose, document and use AUC.

Most concerning to our organizations is that CMS has already conceded that it will miss the April 1, 2016 statutory deadline to identify mechanisms by which AUC would be consulted. In the 2016 Proposed Rule, CMS stated that the initial list of specified CDS mechanisms will be published sometime after the CY 2017 PFS final rule. As a result, physicians and HIT vendors will not know what they must do to comply with the new requirement until the final rule is published in November 2016 and until the list of CDS systems or other mechanisms is published sometime after that. It will be virtually impossible for many practices, especially small practices, to incorporate into their workflow consultation of an approved set of AUC in the few weeks before the January 1, 2017 implementation deadline.

Furthermore, in the 2016 Proposed Rule CMS highlighted that a general agreement has emerged that AUC and the CDS mechanisms must be integrated into a practice's clinical workflow and should facilitate, not obstruct, evidence-based care delivery. We agree, and, as CMS suggests, ideally CDS mechanisms will integrate directly into, or be seamlessly interoperable with, existing HIT systems. In a September 1, 2015 letter to Karen DeSalvo, MD, National Coordinator for Health Information Technology, the Health IT Policy Committee (a public advisory body to the National Coordinator) stated that in preparation for future certified HIT being able to apply standardized AUC as part of its CDS, national AUC guidelines should be written in a standard format, using standard data elements. The Policy Committee notes in the letter that currently available CDS standards may not be ready to serve these needs. Based on these assessments, we believe the AUC Program should not be implemented until certified HIT includes CDS functionality incorporating AUC for advanced imaging.

CMS concluded in the 2016 Proposed Rule that PAMA includes "rapid timelines" for establishing the AUC Program, and that the number of clinicians impacted 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. We agree with CMS' assessment that the best approach to implementation is one that is "diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, and AUC and CDS mechanism developers." We do not believe the current timeline under which CMS is being required to act supports this "best approach" to implementation.

Our organizations are committed to working collaboratively with CMS and Congress to ensure the AUC Program's success. We look forward to working with you to establish a timeline that will not hamper the ability of physicians and other health care professionals to meet Program requirements.

Sincerely,

American Academy of Family Physicians American Academy of Neurology American Association of Neurological Surgeons American College of Cardiology American College of Osteopathic Family Physicians American College of Physicians American Osteopathic Association American Society of Nuclear Cardiology American Urological Association American Medical Group Association American Society of Neuroimaging Congress of Neurological Surgeons Heart Rhythm Society MedAxiom Medical Group Management Association The Society for Cardiovascular Angiography and Interventions

Society of Nuclear Medicine and Molecular Imaging