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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

Re: CMS–4189–P Medicare Program; Secure Electronic Prior Authorization for Medicare Part D

Dear Administrator Verma:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology ("ASCO") in response to the proposed rule regarding Secure Electronic Prior Authorization for Medicare Part D, which was published in the Federal Register on June 19, 2019 (84 Fed. Reg. 28450).

ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

ASCO supports the intent of the rule in taking important steps to streamline prior authorization within the Medicare Part D program by adopting the NCPDP SCRIPT Standard Version 20170171 to secure electronic prior authorization. With the rising cost of health care and prescription drugs, policymakers, providers and payers are strategizing to find more cost-effective ways to manage resources. Although tools like prior authorization can play a role in managing cost, we urge the Agency to exercise caution in order to avoid unintended consequences of restricting or delaying access to care, resulting in harmful outcomes.

ASCO members have repeatedly raised concerns about prior authorization as a barrier to appropriate care. In our 2016 "Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies" we outlined the following recommendations to facilitate appropriate implementation of prior authorization policies:

- Develop and use standardized prior authorization request forms and processes to alleviate the administrative burdens placed on treating oncology teams or practices
- Use a public process by which plans determine prior authorization policies for cancer treatment, reflecting the most up-to-date standards of care and including consultation with oncologists
- Restrict prior authorization policies to drugs where specific concerns about inappropriate use and/or undesirable variation exist
- Ensure individuals making prior authorization determinations in cancer care are appropriately trained oncologists and provide treating oncologists with direct access to that individual to discuss the clinical circumstances as necessary
- Integrate prior authorization processes into electronic health records to support authorization at the points of care, minimizing delays in treatment and administrative burden on providers
- Establish efficient and responsive appeals processes, including 48-hour completion of review/decision on appeals for oncology and expedited review for patients whose clinical circumstances require urgent treatment
- Do not use the appeals mechanisms to compensate for underlying deficiencies in prior authorization policies or process
- Monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies as a result of prior authorization requirements, including suboptimal clinical outcomes, increases in adverse events, and increases in emergency department visits
- Ensure continuity for patients receiving a course of therapy upon enrollment in a health plan to prevent mandatory substitution or interruptions in treatment

The Agency's proposal to implement a technology standard for electronic prior authorization is a positive step in realizing many of the recommendations in ASCO's statement. If correctly implemented, the rule could standardize and streamline the process, reduce delays in care, and alleviate some of the administrative burden of the existing process. Additionally, electronic prior authorization has the potential to allow for real-time resolution of prior authorization requests. ASCO has supported the implementation of real-time benefit tools in other aspects of the Medicare program. However, there are some additional concerns related to the implementation of a technology standard to facilitate electronic prior authorization that ASCO encourages the Agency to address.

We urge the Agency to be more specific about the new additional fields it believes are necessary to further electronic prior authorization, as these fields will contain important information to support a prior authorization request. The most important information is often patient-specific, which currently is only revealed during peer-to-peer conversations, many steps into the prior authorization process. Therefore, where possible, plans must be willing to accept this information in the initial request to streamline this component of the prior authorization process as well. It is also important to specify which fields would be populated by the plan versus the prescribing physician. These aspects could vary based on the specific prior authorization policy a Part D plan chooses to implement. An automated prior authorization process should not shift more of the burden to clinicians but should instead streamline data field population as much as possible.

The clinical barriers posed by prior authorization will not be resolved by simply implementing an electronic submission standard. ASCO urges the Agency to go beyond the electronic standards

outlined in the rule and examine the impact of prior authorization policies on clinical outcomes. It is critical to understand the impact of prior authorization policies on clinical outcomes, as providers increasingly are being held accountable for them. Plans will be required to use a single technology standard for electronic prior authorization, but there is no similar requirement for the use of a single set of standards directing the development of the actual content of prior authorization policies. Such a standard is necessary to ensure the delivery of evidence-based care. This is critical for cancer patients whose clinical concerns could be exacerbated because plans rely on different clinical considerations when developing their prior authorization policies.

There are several approaches that the Agency can take to promote more robust access to high-quality cancer therapies. One promising approach is the implementation of high-value clinical pathways as a mechanism to promote the appropriate selection of anti-cancer therapies. High-value clinical pathways promote access to the right drug, for the right patient at the right time. We urge CMS to explore mechanisms to promote the use of high-value clinical pathways by Part D plan sponsors to ensure more appropriate use of prior authorization in their prescription management efforts.

Finally, while we understand that the NCPDP standard chosen can be easily integrated into most EHRs, we are concerned about the potential cost that practices will incur to switch to the new technology standard. Indeed, the rule states that most EHRs already incorporate the technology standard into their system. However, it is unknown if EHR vendors will impose additional costs on providers for activation and whether subsequent costs will be incurred as EHRs and the NCPDP standard are updated. Additionally, the rule discusses transaction costs for the transfer of prior authorization requests and responses between the plans and prescribing physicians. We encourage the Agency to stipulate that these transaction costs not be passed on to providers or patients.

We encourage the Agency to work with Part D plans to ensure that additional aspects of ASCO's recommendations are integrated into their prior authorization policies.

Thank you for the opportunity to provide input on this important rule. ASCO looks forward to working with you to reduce barriers that inhibit access to timely care for all patients. If you have any additional questions, please feel free to contact Karen Hagerty at karen.hagerty@asco.org.

Sincerely,

Howard A. "Skip" Burris III, MD, FACP, FASCO

President, American Society of Clinical Oncology