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December 23, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted Electronically at www.regulations.gov

Re: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (CMS-9123-P)

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the *Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health* proposed rule published in the Federal Register on December 10, 2020.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We 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.

ASCO supports the intent of the rule in taking important steps to streamline prior authorization within Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs). 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 when implemented appropriately and transparently, we urge the Agency to exercise caution in to avoid the restriction of or delay in accessing 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 outline recommendations to facilitate appropriate implementation of prior authorization policies.[1]

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The Agency's proposal to implement a technology standard for electronic prior authorization is a positive step in realizing some of the recommendations in ASCO's statement. If correctly implemented, the rule could help to standardize and streamline the process, reduce delays in care, and alleviate some of the administrative burden of the existing process. However, we also have concerns related to the implementation of electronic prior authorization across the scope of the proposed rule.

Outpatient drugs should be included in the prior authorization proposals of this rule. The omission of outpatient drugs from this rule is deeply concerning and provides no relief for the provider and their patients, who will continue to experience delays in obtaining necessary therapy. ASCO strongly encourages CMS to require payers to include information regarding pending or active prior authorizations for prescription drugs and/or covered outpatient drugs as it does for other items and services discussed in the rule. A significant portion of cancer treatment requires patient access to life-saving outpatient drugs, and the prior authorization requirements associated with these drugs are extremely burdensome for oncologists and their patients. Electronic prior authorization is currently required for drugs in Medicare Part D; the differential treatment of beneficiaries of Medicaid, CHIP, and QHPs will lead to delays in these patients obtaining needed drugs.

Qualified Health Plans should not be exempt from any of the provisions in this rule. QHPs are exempt from several major provisions in this rule, including the provider access API requirements, payer-to-payer API, and the proposed timelines for standard and expedited prior authorization requests. By offering an exemption to QHPs, over 8 million Americans who have coverage through the FFEs[2] could potentially be without access to streamlined and expedited health and prior authorization information. The Administration indicates that the intent of the rule is to make it easier for beneficiaries covered by Medicaid, the Children's Health Insurance Program or individual market plans to more easily access and share their health information and for prior authorization decisions to be determined more quickly. By excluding QHPs from significant provisions in this rule, CMS is in direct conflict with its intent. Furthermore, we would suggest that CMS extend these proposals to Medicare Advantage plans as well. All beneficiaries, regardless of health coverage, should have the benefit of streamlined prior authorization processes.

Patient Access APIs

ASCO supports CMS' proposal to require that information about any pending or active prior authorization decisions for items and services be made available to patients through the Patient Access API no later than one business day after a provider initiates the request. As CMS states in the

[1] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-UM-Update.pdf

[2] https://www.cms.gov/newsroom/fact-sheets/2020-federal-health-insurance-exchange-enrollment-period-final-weekly-enrollment-snapshot

rule, the intent of the rule is to ensure that beneficiaries have expedient access to health information. ASCO supports policies which grant beneficiaries timely access to their health information.

ASCO supports CMS' proposal to require impacted payers to report metrics about patient use of the Patient Access API to CMS. The barriers posed by prior authorization will not be resolved by simply implementing an electronic submission standard. If the underlying problems inherent to prior authorization remain (e.g. lack of transparency, prior authorization unnecessarily routinely used across vast swathes of items and services, etc.), then CMS will simply have mandated the creation of an electronic system to facilitate those abuses.

ASCO urges the Agency to go beyond the electronic standards outlined in the rule and examine the impact of prior authorization requirements on access to care by developing a single set of standards for prior authorization policies; these standards should then be incorporated into the payer's star rating. It is critical to understand the impact of prior authorization policies on clinical outcomes, as providers are increasingly held accountable for them. As proposed, 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 and the fair application of prior authorization requirements across patient populations. This is critical for cancer patients whose plans rely on different considerations when developing their prior authorization policies.

Provider Access APIs

ASCO supports CMS' proposal to require impacted payers implement a "Bulk Data Provider Access" API to access data for multiple patients at one time. Accessible data would include claims and encounter information in addition to the status of pending or active prior authorizations. The ability to access this information for multiple patients at once would reduce burden and increase efficiencies.

Prior Authorization Documentation and Burden Reduction through APIs

Through feedback from industry and stakeholders CMS has found that current prior authorization processes are burdensome; inconsistent from payer to payer; lacking in clarity on the rules that determine a prior authorization decision and documentation requirements; inconsistent with decentralized documentation requirements which vary from payer to payer; and may require the use of proprietary portals. A key message the agency heard through this feedback was that payers should disclose their prior authorization requirements in a standard format.

To streamline access to information, CMS proposes to require a Documentation Requirement Lookup Service (DRLS) API. This API would include information on the list of services and items, not including prescription drugs and/or covered outpatient drugs, for which prior authorization is required, and details on documentation requirements. **ASCO strongly supports the proposal for a DRLS API as it has the potential to improve efficiency, reduce the number of unnecessary requests, and minimize follow-up.** ASCO also strongly supports CMS' proposal to list the items and services requiring prior authorization and associated documentation requirements on a public-facing website. As stated above, ASCO strongly urges CMS to include prescription and covered outpatient drugs on the public-facing list of items and services along with the documentation requirements.

In order to ease the burden of submitting a prior authorization request, CMS is proposing that impacted payers implement a Prior Authorization Support (PAS) API to facilitate the submission of a HIPAA compliant prior authorization request and response, including any required forms or documentation. **ASCO recommends that payers 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.**

In response to feedback that payers do not provide consistent communications about the reasons for denials or information that is required for approval, CMS is proposing that impacted payers provide a clear and specific reason for a denial (e.g. medical documentation was not provided, the service is not determined to be medically necessary). **ASCO strongly supports clear, concise, and specific documentation of the reason for denial. Should CMS finalize this proposal in the form of a drop-down menu, "other" should not be an option as this is not clear nor is it a specific reason and will not enable physicians or beneficiaries to appeal appropriately and efficiently.** Additionally, CMS has received feedback that providers may receive denials of claims for approved prior authorization services and items, resulting in significant time on appeals. ASCO asserts that providers should never receive claim denials for approved prior authorization services and items – in addition to causing stress and confusion for the patient and enormous administrative inefficiencies for the provider, denials of items or services previously authorized delegitimizes a priori any "approved" prior authorization as it calls into question its validity and reliability if the patient and provider cannot rely on it as confirming coverage.

Delays to lifesaving treatment caused by prior authorization are unacceptable; therefore, we do not support the proposal that an expedited prior authorization decision must be reached within 72 hours of receipt and no more than 7 calendar days after receiving a request for standard decision. **ASCO supports the establishment of efficient and responsive processes, including 48-hour completion of review/decision on standard requests, appeals, and expedited reviews for oncology.** Medically appropriate cancer care demands patient access to the most appropriate drug at the most appropriate time, and this proposal does not ensure patient access in a timely manner. In the interest of supporting high-value, high-quality care, ASCO supports policies that promote full access to the most appropriate oncology drug regimens at the most appropriate time for patients with cancer.

"Gold-carding" is a process in which a payer relaxes or reduces prior authorization requirements for providers who consistently order or prescribe treatments and drugs in accordance with evidence-based guidelines receive little in the way of prior authorization denials, or otherwise demonstrate high compliance with a payer's requirements. CMS encourages other payers to adopt such policies but does not make any proposals related to gold-carding in this rule. **ASCO supports the use of gold-carding or similar policies and encourages CMS to further explore this option.**

CMS should require payers to ensure continuity for patients receiving a course of therapy upon enrollment in a health plan to prevent mandatory substitution or interruptions in treatment. ASCO supports policies that ensure cancer patients have uninterrupted access to the necessary treatment therapies as indicated in the initial plan of care. CMS should not impose restrictions regarding requirements for repeat prior authorization for items and services for chronic conditions and should institute approvals for long term authorizations with an affirmation process to be scheduled at regular intervals. Furthermore, in an effort to ensure continuity and coordination of care, prior authorization decisions should follow a patient when they change from one qualified health to another health plan impacted by this proposed rule. **To reduce physician burden and to ensure patients do not find**

themselves without access to life-saving therapies, ASCO recommends that prior authorization approval follow the patient should they switch plans and/or payers.

ASCO supports the development and implementation of standardized prior authorization request forms and processes to alleviate the administrative burdens placed on treating oncology teams or practices. CMS should work closely with the American Medical Association (AMA), medical specialty organizations, and payers to develop and widely implement standardized request forms. In January 2017, ASCO joined the AMA and 16 other healthcare organizations in establishing Prior Authorization and Utilization Management Reform Principles urging health plans, benefit managers and others to reform utilization management programs.[3] These principles emphasized the importance of clinical validity; continuity of care; transparency and fairness; timely access and administrative efficiency; and alternatives and exemptions in order to ensure patient access to appropriate care while reducing the administrative burden associated with policy compliance.

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Data

We appreciate that CMS recognizes social risk factors (for example, housing instability, food insecurity) impact beneficiary health and utilization outcomes. As value-based payment has grown, so has provider interest in data on social risk factors. Currently, social risk data are often fragmented and duplicative due to a lack of clear standards for recording and exchanging these data. As such, CMS has asked for information on barriers to adopting standards, and opportunities to accelerate adoption of standards, related to social risk data. ASCO has long worked toward improving health equity and is currently exploring opportunities for standardizing data collection on social determinants of health, possible through the mCODE® initiative. We look forward to sharing our work and participating with CMS and others to establish standardized social risk data elements.

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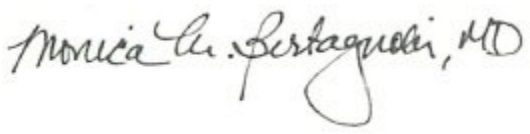
We appreciate the opportunity to comment on the *Reducing Provider and Patient Burden by Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health* proposed rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



Monica Bertagnolli, MD, FACS, FASCO

Chair of the Board

Association for Clinical Oncology

[3] https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf