January 4, 2021

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-9123-P
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted Electronically to http://www.regulations.gov


Dear Administrator Verma:

On behalf of more than 100,000 specialty physicians, the undersigned members of the Alliance of Specialty Medicine (the “Alliance”) write in response to proposals outlined in the aforementioned proposed rule. The Alliance is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. As such, we applaud both CMS and the Office of the National Coordinator for Health Information Technology (ONC) for its cross-agency effort to advance interoperability among health care providers, payers, and patients, and to reduce patient and provider burden through proposed changes to prior authorization practices.

Prior authorization, in particular, is a cumbersome and lengthy process for our members. The process for obtaining these approvals typically requires physicians or their staff to spend the equivalent of two or more days each week negotiating with insurance companies — time that would be better spent taking care of patients. Patients are also now experiencing significant barriers to medically necessary care due to prior authorization requirements for items and services that are eventually routinely approved. Recent surveys of specialty physicians have found that:

- Nearly 90% have delayed or avoided prescribing a treatment due to the prior authorization process;
- 95% report that this increased administrative burden has influenced their ability to practice medicine;
- 82% state that prior authorization either always (37%) or often (45%) delays access to necessary care;

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• Prior authorization causes patients to abandon treatment altogether, with 32% reporting that patients often abandon treatment and 50% reporting that patients sometimes abandon treatment;
• Nearly two-thirds report having staff who work exclusively on prior authorizations, with one-half estimating that staff spend 10-20 hours/week dedicated to fulfilling prior authorization requests and another 13% spending 21-40 hours/week; and
• Ultimately, the majority of services are approved (71%), with one-third of physicians getting approved 90% or more of the time.

While the proposals in this rule would make major improvements to current prior authorization processes, we are concerned about the limited reach of these critical policies. Generally, the proposals in this rule apply to state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan issuers on the Federally-Facilitated Exchanges. Although this rule does not directly impact Medicare FFS, CMS notes its intent to adopt these proposed provisions, if finalized, so that Medicare FFS beneficiaries would also benefit. However, these provisions do not apply to Medicare Advantage plans. **We strongly urge CMS to apply these same policies to Medicare Advantage plans, where inefficiencies related to data access and prior authorization processes are especially pronounced.**

Additionally, the proposals in this rule related to prior authorization processes only apply to “items and services” and do not include prescription drugs and/or covered outpatient drugs. **The Alliance strongly recommends that CMS expand the reach of the prior authorization proposals so that they also apply to information about prescription drugs and/or covered outpatient drugs.**

**Patient Access APIs**

In the CMS Interoperability and Patient Access final rule, CMS required certain payers — specifically MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs — to implement and maintain standards-based Patient Access Application Programming Interfaces (APIs). Through the Patient Access API, impacted payers must allow patients to easily access, among other things, their claims and encounter information and a specified sub-set of their clinical information through third-party applications of their choice. In this rule, CMS proposes multiple policies to enhance the Patient Access API, including a requirement that impacted payers make available to patients information about any pending and active prior authorization decisions (and related clinical documentation and forms) for items and services no later than one (1) business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization.

**The Alliance strongly supports providing patients with greater access to information about prior authorization requests made on their behalf. This proposal would help patients have a more active role in their healthcare and would help to reduce burden on both providers and payers working through often complex and tedious prior authorization requests.** We agree with CMS that if a patient can see the supporting documentation shared with their payer, they might better understand what is being evaluated and even potentially help the provider and payer by producing missing documentation or information when needed. Importantly, this could also help to reduce the need for patients to make repeated calls to the provider and payer to understand the status of a request, thus potentially avoiding unnecessary delays in care and reducing burden on providers and payers. **However, as noted earlier, we strongly urge CMS to hold Medicare Advantage plans to these same requirements and to require**
that the prior authorization policies apply equally to prescription drugs and/or covered outpatient drugs.

Provider Access APIs
In the CMS Interoperability and Patient Access final rule, CMS required impacted payers to make certain health information available to third-party apps with the approval and direction of a patient through the Patient Access API for patient use. CMS also discussed the benefits of sharing patient health information with providers but did not impose any such requirements on payers. In this rule, CMS proposes to require that impacted payers implement and maintain a standards-based Provider Access API to facilitate the exchange of current patient data from payers to providers, including adjudicated claims and encounter data (not including cost information), clinical data, and information related to pending and active prior authorization decisions. CMS proposes that the Provider Access API allow providers access to an individual patient’s information and access to multiple patients’ information at the same time.

As we have expressed in the past to both CMS and ONC, the Alliance strongly supports granting providers ongoing access to information about their patients, particularly as patients move throughout the healthcare system, between providers and health plans, and in and out of coverage. We agree with CMS that if providers could access information about the care their patient received outside of the provider’s care network prior to a patient’s visit, including pending and active prior authorization decisions, the information might improve clinical efficiency and provide a more comprehensive understanding of the patient’s health, thus reducing unnecessary duplication, saving time during appointments and improving the quality of care delivered. Importantly, coordinated access to this information could also improve the patient’s care experience by sparing them from having to fill out the same medical history forms repeatedly.

Again, we urge CMS to broaden the impact of this proposal so that Medicare Advantage plans are also required to share the same information, including information related to prior authorization decisions, with a patient’s provider via the Provider Access API upon a provider’s request. CMS also should expand the requirements related to sharing information about prior authorization decisions so that they include prescription drugs and/or covered outpatient drugs, as this information is vitally important to many of our members and their patients.

Documentation and Prior Authorization Burden Reduction through APIs
CMS proposes to require that impacted payers implement and maintain a standards-based API populated with their list of covered items and services for which prior authorization is required, and with the organization’s documentation requirements for submitting a prior authorization request, including a description of the required documentation. CMS also proposes that impacted payers implement an API that facilitates a HIPAA compliant prior authorization request and response, including any forms or medical record documentation required by the payer for items or services for which the provider is seeking authorization. If finalized, the payer would be required, when sending the response, to include information regarding whether the organization approves (and for how long), denies, or requests more information for the prior authorization request, along with a reason for denial in the case of a denial. As part of this proposal, impacted payers also would be required to publicly report, at least annually, prior authorization metrics, such as a list of all items and services that require prior authorization and the percentage of standard prior authorization requests that were approved or denies, reported separately for each item and service.
The Alliance thanks CMS for proposing several policies associated with the prior authorization process to streamline health care and reduce the burden on patients, providers, and payers. We agree that these proposals have great potential to decrease the paperwork associated with providers determining which items and services need prior authorization and what documentation is necessary to submit the prior authorization request. As CMS notes, electronic prior authorizations are not used consistently between payers and providers. The burden of navigating the various submission mechanisms—including numerous payer-specific web portals and fax numbers—falls on the provider, is time-consuming, and can detract from providing care to patients. We also agree with CMS that these proposals could reduce burden on payers who would receive fewer incomplete prior authorization requests and fewer denied and appealed requests only due to missing or incorrect documentation.

CMS notes in this section of the rule that if these APIs are successfully implemented by impacted payers as proposed, the demand for these functionalities would motivate electronic health record (EHR) vendors to invest in integrating these APIs directly into a provider’s workflow. The Alliance has long been an advocate for establishing an electronic prior authorization process, particularly among Medicare Advantage plans. However, we request that CMS monitor the extent to which health IT developers actually implement these prior authorization-focused functions within their EHRs. If uptake is low or inconsistent, we encourage CMS to consider adding certification criteria to the ONC Health IT Certification Program that address these functionalities. Integration of prior authorization requirements within EHR systems is critical to ensuring that providers can track and manage active prior authorizations with minimal burden and submit requests at the point of care.

The Alliance also strongly supports CMS’ proposal to publicly report prior authorization metrics, particularly requiring plans to report on the extent of their use of prior authorization and the rate of delays and denials. This proposal would not only provide important information to patients when making decisions about a plan and to providers when selecting payer networks to join, but it would bring some critically needed transparency and efficiency to a process that has largely remained under the radar.

Finally, the Alliance again urges CMS to extend these policies to Medicare Advantage plans and extend the same documentation and request/response requirements to prescription drugs and covered outpatient drugs.

In this section of the rule, CMS also requests feedback on additional topics pertaining to prior authorization. Many of the Alliance’s concerns about prior authorization are addressed in this rule. Still, we encourage CMS to consider these additional requests that could further streamline prior authorization processes and ensure that patients have timely access to appropriate care:

- Minimize the use of prior authorization for services that are routinely approved, which could include incentivizing “gold-carding” or similar programs that are used by payers to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance (e.g., data indicating adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria);
- Prohibit additional prior authorization for medically-necessary services performed during a surgical or invasive procedure that already received, or did not initially require prior authorization;
- Ensure prior authorization requests are reviewed by qualified medical personnel; and
- Ensure that plans adhere to evidence-based medicine guidelines.
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The Alliance appreciates the opportunity to share feedback on these important proposals. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

Alliance of Specialty Medicine