Alliance of Specialty Medicine

Sound Policy. Quality Care.

March 18, 2022

Micky Tripathi, PhD, MPP
National Coordinator for Health IT
Office of the National Coordinator for Health IT
Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201
Submitted electronically via Regulations.gov

RE: Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria

Dear Dr. Tripathi:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians and is deeply committed to improving access to specialty medical care through the advancement of sound health policy. Today, we write to share feedback in response to the aforementioned request for information (RFI) from the perspective of practicing specialty medicine providers.

Utilization Management Challenges

Utilization management protocols, including prior authorization and step therapy, create more angst and frustration for specialty physicians and their patients than any other administrative task associated with the practice of medicine. These payor-driven cost-control tactics are a primary cause of significant delays in patient access to medically necessary items and services (e.g., diagnostic tests, procedures and medication therapies), diverting clinical staff away from patient care activities and creating multiple inefficiencies that result in increased costs. These sentiments are reflected in our survey of more than 1,000 specialty physicians, where specialists reported the following:

- 82% state that prior authorization either always (37%) or often (45%) delays access to necessary care;
- Prior authorization causes patients to abandon treatment altogether, with 32% reporting that patients often abandon treatment and 50% reporting that patients sometimes abandon treatment;

- 94% report that this increased administrative burden has influenced their ability to practice medicine;
- 63% report having staff who work exclusively on prior authorizations, with one-half estimating that staff spend 10-20 hours/week fulfilling prior authorization requests and another 13% spending 21-40 hours/week;
- Ultimately, the majority of services are approved (71%), with one-third of physicians getting approved 90% or more of the time; and
- At the same time, even when prior authorization requirements were met, one-fifth of physicians reported *still* receiving a denial 20 or more times in the preceding year.

Amplifying the frustrations with prior authorization, one respondent commented, *"Never have I spent more time on administrative issues that do nothing but delay appropriate diagnostic and therapeutic intervention."* Another said, "*I have patients that have been hospitalized and almost died due to the delays imposed by prior authorizations and inexperienced unknowledgeable 'physicians'...making decisions on complex rheumatologic treatments being given to seriously ill rheumatology patients – this is shameful, if not criminal."*

Unfortunately, specialists have little recourse with insurers to address these challenges. One respondent explained, *"I take all insurances basically to improve access of care [in] my area even at personal losses. I am not sure how much longer we can do this."*

Policymaking Efforts

Lawmakers widely recognize the challenges with utilization management and have been working in a bipartisan manner to establish policies that would streamline and standardize these processes through legislative efforts, including introduction of the Improving Seniors Timely Access to Care Act (H.R. 3173/S. 3018) and Safe Step Act (H.R. 2163/S. 464).[1,2,3] If enacted, these bills would achieve the following:

Improving Seniors' Timely Access to Care Act

- Establish an electronic prior authorization process that would streamline approvals and denials;
- Establish national standards for clinical documents that would reduce administrative burdens health care providers and Medicare Advantage plans;
- Create a process for real-time decisions for certain items and services that are routinely approved;
- Increase transparency that would improve communication channels and utilization between Medicare Advantage plans, health care providers, and patients;
- Ensure appropriate care by encouraging Medicare Advantage plans to adopt policies that adhere to evidence-based guidelines; and

[1] DelBene, Kelly, Bera, Bucshon Introduce Bipartisan Legislation to Make Care More Efficient for Seniors by Reforming Prior Authorization, May 12, 2021, https://delbene.house.gov/news/documentsingle.aspx?DocumentID=2809

[2] Senators Push CMS to Make Changes to Prior Authorization to Reduce Administrative Burden for Providers, Protect Seniors from Unnecessary Delays in Access to Treatment, Oct 12, 2021, https://www.thune.senate.gov/public/index.cfm/press-releases?ID=2F0DCB42-7721-45A2-AC36-F9642F2A03BB

[3] Ruiz, Bipartisan Doctors in Congress Introduce Safe Step Act to Require Insurance Companies to Put Patients' Health First, March 26, 2021, https://ruiz.house.gov/media-center/press-releases/news-ruiz-bipartisan-doctors-congress-introduce-safe-step-act-require

- Require beneficiary protections that would ensure the electronic prior authorization serves seniors first.

Safe Step Act

- Establishes a clear exemption process by requiring insurers to implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.
- Outlines 5 exceptions to fail first protocols, which requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
    - A patient already tried and failed on the required drug. *A patient has already tried the medicine and failed before.*
    - Delayed treatment will cause irreversible consequences. *The drug is reasonably expected to be ineffective, and a delay of effective treatment would leave to severe or irreversible consequences.*
    - Required drug will cause harm to the patient. *The treatment is contraindicated or has caused/is likely to cause an adverse reaction.*
    - Required drug will prevent a patient from working or fulfilling Activities of Daily Living. *The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living. Activities of daily living (ADLs) mean basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).*
    - Patient is stable on their current medication. *The patient is already stable on the prescription drug selected by his or her provider, and that drug has been covered by their previous or current insurance plan.*
- Requires a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.

CMS already has the authority to implement the provisions included in the *Improving Seniors' Timely Access to Care Act* through regulation, and we encourage CMS to promulgate rulemaking to implement these policies. While the *Safe Step Act* applies to ERISA plans, the aforementioned provisions should be used to inform key revisions to step therapy policies in Medicare Advantage (MA), which continues to be a significant challenge for patients and specialists.

Through its recently established Office of Burden Reduction and Health Informatics and its MA and Part D rulemaking activities, CMS has gathered information on utilization management issues. Most recently, CMS' Center for Program Integrity held a Virtual Focus Group to hear from stakeholders as the agency works to "improve its processes and eliminate unnecessary requirements for medical review and prior authorization."

As mentioned above, through rulemaking to modernize Part D and MA, the Alliance supported now-finalized policies that "require Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's electronic prescribing (eRx) system or electronic health record (EHR)." In our formal comments, we specifically recommended that CMS require plans to include information on their processes for obtaining an exemption from step-therapy and/or other requirements, where appropriate. We also recommended that CMS establish a connection through the RTBT to the plans' prior authorization process. For straightforward prior authorizations where limited information is needed to render a determination, we urged CMS to require plans to automate approvals so they occur within minutes. For more complex prior authorizations where more

detailed information may be necessary, we urged CMS to require plans to automate the process as much as possible and render determinations within 24 hours.

At 42 CFR §423.160(b)(7) through (8), the following is now required (see screenshot):

(7) ***Real time benefit tools.*** No later than January 1, 2021, implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug.

(8) ***Electronic prior authorization.***

(i) Beginning January 1, 2021, Part D sponsors and prescribers may use the National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and Part D sponsors for the following transactions:

(A) PAInitiationRequest and PAInitiationResponse.

(B) PARequest and PAResponse.

(C) PAAppealRequest and PAAppealResponse.

(D) PACancelRequest and PACancelResponse.

(ii) Beginning January 1, 2022, Part D sponsors and prescribers must use the standard specified in paragraph (b)(8)(i) of this section for the transactions listed in paragraphs (b)(8)(i)(A) through (D) of this section.

While a step in the right direction, these requirements do not go far enough to address the challenges specialists and patients continue to face with utilization management.

As part of CMS' Interoperability and Patient Access rulemaking, the Alliance and other stakeholders urged CMS to address utilization management by requiring "the inclusion of information regarding prior authorization decisions, drug pricing, and a direct phone number for patients to call providers and their staff about prior authorization issues," and to make that information available to patients and providers. Stakeholders were generally supportive of certain payer-to-payer data exchange requirements that "could improve care coordination by reducing burden on both beneficiaries and providers by limiting the need for duplicative letters of medical necessity, preventing inappropriate step therapy, and reducing unnecessary utilization reviews and prior authorizations" but also raised concerns about payers "increased access to clinical information impacting coverage decision-making" and urged CMS to require that payers attest that the exchanged data cannot be used to deny or delay treatment, increase rates, or implement step therapy."

Shortly after, and in response to stakeholder feedback, ONC and CMS released its proposed Interoperability and Prior Authorization rule that aimed to improve the patient experience and access to care by requiring certain insurers to:

- Implement and maintain a prior authorization Documentation Requirement Lookup Service application programming interface (API) and a FHIR-based Prior Authorization Support API;

- Respond to prior authorization requests within certain timeframes; and
- Publicly report certain metrics about prior authorization processes for transparency, among other changes.

The Alliance and many other physician organizations registered strong support for these proposals. We specifically noted in our comment letter that 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. We urged ONC and CMS to apply the proposed requirements to MA plans and ensure that prior authorization policies apply equally to prescription drugs and/or covered outpatient drugs. We also requested that ONC 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 encouraged ONC to consider adding certification criteria to the ONC Health It Certification Program that address these functionalities. Unfortunately, CMS withdrew the regulation.

Moving Forward

Improving utilization management processes, including through the widespread adoption of electronic prior authorization processes, should be a top priority of both ONC and CMS and apply to all federally authorized plans, including MA plans. We are disappointed that federal agencies have walked back proposals that would have drastically reduced the biggest pain point for specialists and their patients but stand ready to assist with moving a revised set of regulations forward that would address our concerns and those of the rest of medicine. Generally, our previous comments on these issues address the questions posed in this RFI concerning patient and provider impact. The time is now for CMS and ONC to take action and — once and for all — put patients over paperwork.

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Thank you for considering our feedback as you promulgate rulemaking to address these and related issues. Should you have any questions or wish to schedule a meeting, please contact us at info@specialtydocs.org.

Sincerely,

American Association of Neurological Surgeons
American Academy of Otolaryngology-Head and Neck Surgery
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists