Alliance of Specialty Medicine

Sound Policy. Quality Care.

March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges

Dear Administrator Brooks-LaSure,

The Alliance of Specialty Medicine (the "Alliance"), representing more than 100,000 specialty physicians from sixteen specialty and subspecialty societies, is deeply committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we write to provide feedback on proposed policy changes to advance interoperability and improve prior authorization (PA).

The Alliance very much appreciates CMS proposing this rule, which aims to reduce provider burden, increase transparency, and improve care coordination— all of which will result in higher quality patient care. In particular, we would like to thank Mary Greene, MD, and her team in the CMS Office of Burden Reduction & Health Informatics for meeting with the Alliance over the past few years and taking our concerns regarding utilization management practices, patient safety, and physician burden seriously. Most of the prior authorization proposals in this rule, together with related proposals included in the recently released *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs* proposed rule (CMS-4201-P), will play a critical role in reducing care delays and improving patient outcomes. We are particularly appreciative that CMS proposes to extend these policies to MA. In 2022, one in five Medicare beneficiaries lived in a county where at least 60% of all Medicare beneficiaries in that county were enrolled in MA plans, and that number is expected to grow.[1] Prior authorization practices within MA plans, in particular, have resulted in inappropriate, unnecessary and even life-threatening barriers to care for our patients.

[1] https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/

While we are generally very supportive of the proposals in this rule to advance interoperability and to improve prior authorization, we offer some general concerns and comments below before addressing specific proposals:

- **Ambiguous enforcement mechanisms**. The enforcement mechanisms related to the proposals to advance interoperability, as well as the proposals to improve prior authorization, are unclear. For example, it is not clear what would happen if an impacted payer did not comply with these new requirements. There does not seem to be any real consequence (other than proposed public reporting mandates) for payer non-compliance. CMS mentioned on a recent call that they were not specific about compliance mechanisms because each impacted payer has its own processes and enforcement mechanisms, some of which fall under state jurisdiction (e.g., for Medicaid plans). If that is the case, ***we request that CMS provide a clearer outline of current regulations that apply to impacted payers so that the public can determine whether existing enforcement mechanisms are sufficient to ensure compliance with these new requirements.***

- **Urgent implementation dates**. The implementation date for most of the proposals in this rule is 2026. The Alliance appreciates that it will take some time for payers to adopt new technological requirements to support enhanced and more timely data exchange, including as it relates to prior authorization. We also recognize the need to get it right rather than forcing payers to adopt premature standards that might not meet the goals of this rule and might result in even more complexity for end users. ***However, we request that CMS closely monitor the landscape and closely monitor the industry's readiness. If at any point CMS believes that these policies can be implemented earlier than 2026, then we urge CMS to flip the switch and proceed. We also urge CMS to require payers to regularly report to CMS on their readiness. This would allow CMS to track payer progress and could prevent a situation where payers claim, at the 11th hour, that they are not ready to meet the implementation deadlines and need an extension***. These improvements to interoperability and prior authorization are absolutely critical for the safety of our patients and the efficiency of our health care system, and they need to be implemented as soon as possible.

- **Inclusion of drugs**. CMS states clearly that the prior authorization proposals throughout this rule only apply to items and services but exclude drugs. As discussed in more detail in the sections below, the Alliance urges CMS to extend the proposed prior authorization policies and associated payer requirements to all drugs, including outpatient drugs and those ***administered by a physician, rather than limit them to items and services only.***

- **Applicability to Medicare Fee-for-Service (FFS)**. CMS states multiple times that the proposals in this rule do not directly pertain to Medicare FFS. In regards to the proposals aimed at advancing interoperability (e.g., the Patient and Provider Access Application Programming Interfaces (APIs)), we appreciate CMS's work to date to test these concepts in FFS and ***urge CMS to implement these provisions, once finalized, within Medicare FFS so that beneficiaries, providers, and other payers can benefit from data availability.***

On the other hand, as we discuss below, ***we strongly oppose the use of prior authorization under Medicare FFS. We urge CMS to suspend any existing FFS prior authorization policies rather than attempt to extend the proposals in this rule to FFS.***

- **Applicability of Information Blocking Regulations**. It is unclear to what extent previously finalized information blocking regulations would apply to impacted payers in the context of the Patient, Provider and Payer-to-Payer API proposals, as well as the Prior Authorization Requirements, Documentation, and Decision (PARDD) API. The *21st Century Cures Act: Interoperability, Information Blocking* final rule generally prohibits practices by specific "actors" that are likely to interfere with, prevent, or materially discourage access, exchange and use electronic health information. The rule defines actors as: 1) health care providers; 2) health information technology (IT) developers of certified health IT; and 3) health information networks (HIN) or health information exchanges (HIE). However, health plans and payers are not expressly included in this definition, which raises questions about the extent to which they are subject to information blocking regulations and whether they would be obligated under these existing regulations to share information with patients, payers and providers through the APIs discussed in this rule. Additionally, the information blocking regulations prescribe specific criteria for when it is and is not appropriate to charge a fee for data access. The regulations specifically restrict physicians (and other actors) from charging patients to access their health information through APIs. However, the regulations do not seem to dictate the same requirements for health plans, and we have concerns that health plans will pass down the costs of complying with these new mandates to their network physicians and/or patients or implement other potentially coercive contractual clauses related to the implementation of these mandates. ***The Alliance requests clarification on to what extent the Information Blocking regulations would impact the proposals in this rule.***

Advancing Interoperability

General Comments

This section of the rule includes three core interoperability proposals that aim to enhance data exchange between payers and patients, payers and providers and between payers when patients switch health plans. All of these proposals would require that payers share data using standards-based (i.e., Fast Healthcare Interoperability Resources (FHIR)) APIs so that the data can be more easily accessed by the recipient directly through health apps, electronic health records (EHRs), or other practice management platforms. Payers would be required to make available through these APIs claims and encounter data, as well as all data classes and data elements included in the USCDI v.1 — such as Immunizations, Procedures, and Assessment and Plan of Treatment — should the payer maintain such information. Payers would also be required to share information related to prior authorization requests and decisions (including related administrative and clinical documentation) for items and services, but not drugs. Payers would generally be required to make data available via these APIs within one business day of receiving a request. ***The Alliance is generally supportive of these proposals — particularly CMS's proposals to add a Provider Access API, to include prior authorization requests and decisions in the categories of data that must be made available through all of the proposed APIs, and require all APIs***

to adhere to a generally consistent set of standards that align with standards previously adopted by the Office of the National Coordinator (ONC) for Health Information Technology.

Regarding the inclusion of prior authorization data across all three APIs, ***we request that CMS broaden this policy so that it applies to requests and decisions for drugs, as well as items and services.***

CMS also proposes to require that information about prior authorizations be available via each of the proposed APIs for as long as the authorization is active and at least one year after the last status change***.*** While we understand that requiring payers to share a patient's entire prior authorization history could create a burden for payers and may include data that lack clinical relevance, ***we believe that CMS should extend this lookback period to at least five years after the last status change since those decisions could still be relevant to the patient's ongoing care.***

Regarding the requirement that payers make claims and encounter data available through these APIs within one business day after a request, ***we urge CMS to track any potential unintended consequences of this policy.*** The Alliance values the importance of providing patients (and providers) with access to their health information in as timely a fashion as possible. However, as we expressed earlier in our comments on CMS's Interoperability and Patient Access proposed rule, we are concerned that payers might place undue pressure on physicians to accelerate the submission of claims and encounter data solely for the purpose of complying with these API requirements. Most clinicians are already submitting this data in as timely a manner as possible since it is tied to reimbursement. ***We request that CMS monitor payer practices closely and schedule regular check-ins with patient and provider stakeholders to understand any negative impacts of these policies.***

As we stated earlier, ***we also seek clarity on whether payers would be considered information blocking "actors" in the context of the Patient Access API, as well as the Provider Access and Payer-to-Payer API***. If they are, then it is our understanding that they must provide patient data upon request without delay (rather than within one business day). However, it is unclear if and under what circumstances payers are considered "actors." ***These definitions and payer obligations should be clearly delineated so that providers and patients understand their rights under these policies.***

Patient Access API

For the Patient Access API, the Alliance appreciates CMS's proposal that impacted payers must make enhancements to the previously finalized Patient Access API, including adding information about prior authorizations to the categories of data that must be made available to patients through the Patient Access API so long as it applies to drugs in addition to items and services.

We remind CMS that as patients gain access to a broader array of information, they may reach out to their physicians more frequently with inquiries about claims and cost-sharing information, as well as payer PA decisions, over which the clinician may have little direct control. As we have previously stated, it is critical that CMS's regulatory policies — including physician payment policies — evolve to reflect the additional demands placed on physicians as patients gain more access to their data and become more engaged partners in their care.

Provider Access API

The Alliance generally supports the Provider Access API and appreciates CMS responding to our past requests for this tool. Greater and more immediate access to payer data, including prior authorization information, will help reduce duplicate tests and procedures, avoid diagnostic errors, and improve care coordination. These efficiencies will save money and time for providers and payers, who might receive fewer duplicate requests for services and fewer appeals. The Provider API will also ensure that providers can access patient data directly from payers so that the patient does not have to serve as the middleman. ***However, we once again request that the prior authorization requirements apply to both drugs and items and services.***

Under this proposal, payers would only have to share data with providers in their network. ***The Alliance believes that CMS should expand this requirement to include all providers, regardless of whether they are enrolled with the payers, so long as they can verify a relationship with the patient.*** For these proposals to have the maximum positive impact on care coordination, out-of-network providers should also be able to request data from a payer that covers their patient. While we recognize that CMS has concerns about data privacy and program integrity, we believe there are relatively simple ways to validate a treatment relationship between a patient and provider when a contractual relationship does not exist between the provider and the payer. As CMS states in the rule, many providers already verify coverage with a payer before a new patient's first appointment, and something as simple as an upcoming appointment can be used to verify the provider-patient treatment relationship.

Finally, it is our understanding that under this proposal, to the extent that payers do not receive and maintain clinical data on a patient (e.g., clinical notes, imaging results, and lab results) as part of their normal operations, they would be under no obligation to make such data available to patients through the API. Given the importance of clinical data, especially to physicians who are managing the care of the patient, ***we request that CMS clarify how it plans to support the integration of administrative data made available by health plans with clinical data that may be housed in an EHR so that providers have a complete picture of the patient's health and medical care.*** If APIs provide access to little more than what is already included in a payer's Explanation of Benefits, this initiative will bring little value to physicians.

For Payer-to-Payer Data Exchange

CMS also proposes to require impacted payers to implement and maintain a Payer-to-Payer data exchange using an FHIR API, which generally aligns with the Provider Access and Patient Access APIs. Payers would be required to exchange the same set of data that is being proposed for the Provider Access API, including prior authorization data, with other payers when a patient has concurrent payers or changes payers. However, CMS is not proposing to require payers to review, consider, or honor active prior authorization decisions of a patient's former payer.

The Alliance supports the intent of the Payer-to-Payer API. We believe that requiring payers to share patient information with other payers when a patient has concurrent payers or changes payers will help minimize unnecessary administrative paperwork, duplication of services, and other inefficiencies. We would also support a requirement that payers honor active prior authorization decisions of a patient's former payer to ensure that a patient can continue to get the care that a provider or insurer has already determined was clinically necessary. If prior authorization decisions are rooted in clinical

appropriateness, as they should be, then there is no reason why these determinations should vary from one payer to another.

Finally, although the Alliance opposes the use of step therapy, ***at a minimum, we urge CMS to require payers to except patients from step therapy protocols if they were previously satisfied under another plan.***

Improving Prior Authorization Practices

The Alliance has repeatedly urged CMS to address egregious utilization management practices by MA plans and other payers, including prior authorization, which ignores physician clinical expertise and disrupts patient care. Some of the biggest challenges that specialty physicians face are delays in prior authorization decisions, inconsistent payer policies, and prior authorization for routinely approved items and services. A recent Alliance member survey found:

- Almost 50% of respondents characterized PA as having a "significantly" negative impact on patient clinical outcomes;
- Over 60% of respondents were denied payment for preauthorized services at least twice in the preceding year, with almost 20% of those having experienced this at least twenty times in just one year;
- Over 87% of respondents reported that PA requests were eventually approved in the majority of cases.

These challenges are especially acute in the context of MA plans. A recent report issued by the Office of Inspector General (OIG) raised concerns about beneficiary access to medically necessary care, citing widespread and persistent problems related to inappropriate delays and denials of services by MA plans even when requests met Medicare coverage rules and MA billing rules.[2]

To address these issues, the Alliance has repeatedly asked CMS to strengthen oversight of MA plan utilization management practices, including data collection of denials, delays and approval rates; require transparency of these data to hold plans accountable; and standardize MA prior authorization processes to minimize delays in patient care. ***We are very pleased to see our requests reflected in this proposed rule.***

As previously discussed, CMS seeks comment on whether the proposals in this section of the rule could be implemented as proposed for the Medicare FFS program. Historically, Medicare FFS has only required prior authorization in limited circumstances (i.e., specific hospital outpatient department services). ***The Alliance strongly opposes using prior authorization in Medicare FFS. We urge CMS to suspend any existing FFS prior authorization policies rather than attempt to extend the proposals in this rule to FFS. We echo earlier concerns expressed by Congress and the Medicare Payment Advisory Commission that expanding prior authorization into FFS could adversely impact patient access to necessary care***.

[2] Office of Inspector General. (2022). Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care (publication No. OEI-09-18-00260). Accessed at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

Additionally, ***the Alliance urges CMS to extend these electronic prior authorization policies and associated payer requirements to outpatient drugs, including drugs administered by a physician, rather than limit them to items and services only.*** We are concerned and confused by CMS's decision to expressly exclude drugs from this proposal. ***We request clarification from CMS on what it views as materially different between prior authorization for items and services versus prior authorization for drugs***. While there might already be processes in place for electronic PA of retail Part D drugs, they do not apply to Part B drugs administered by a physician in the office, which requires a different set of processes and reliance on other parts of the EHR compared to sending a prescription electronically to a pharmacy. ***Again, we urge CMS to extend its proposals in this section to all drugs, including in-office drugs, to ensure that these proposals have the maximum positive impact on patients and their physicians.***

Implementing an API for Prior Authorization Requirements, Documentation, and Decision (PARDD)

In this section, CMS proposes that beginning January 1, 2026, impacted payers would be required to implement a standards-based API (referred to as the FHIR PARDD API) to support and streamline prior authorization processes. Payers would be required to populate the API with their list of covered items and services, excluding drugs, for which prior authorization is required, as well as any documentation requirements. The PARDD API must also include functionality to determine requirements for any other data, forms, or medical record documentation required by the payer for the items or services for which the provider is seeking prior authorization and to communicate those decisions.

When drafting this rule, CMS considered whether to require that payers only prepare the PARDD API for a specific set of services most commonly requiring prior authorization across payers. CMS also considered whether to require payers to make prior authorization rules and documentation requirements available through the API incrementally. ***The Alliance opposes imposing any limitations on the set of services to which the PARDD API would apply, as well as a phased-in implementation approach because of the challenges and confusion it could create for providers who would have to navigate different rules and different levels of readiness among payers.*** There are already enormous variations in payer PA policies for the same items and services. Physicians and their staff must dedicate substantial time and resources to identifying each distinct policy. It is essential that CMS standardize processes across items and services, as well as drugs, to the greatest extent possible to minimize unnecessary physician paperwork and delays in patient care. Regarding the implementation timeline, we believe that CMS's proposal to require payers to fully implement the PARDD API by January 1, 2026, leaves payers with sufficient time to comply fully with these requirements.

CMS also proposes specific technical standards with which the PARDD API must comply. In addition, CMS strongly encourages but does not require certain implementation guides (IGs) to support API development. ***The Alliance supports using standards-based APIs, and industry-wide adoption of uniform standards will help enhance interoperability and minimize complexity. At the same time, we support CMS's proposal to offer developers the flexibility to voluntarily adopt certain standards that are not yet considered mature by the industry.*** Prematurely mandating standards could result in more harm than good regarding disrupted clinical workflows and diverted resources. Going forward, ***we urge CMS to more closely track and participate in the standards development process to ensure that all perspectives are considered — particularly that of the physician and other end users.***

At the same time, we are concerned that there is currently no requirement that certified health IT developers adopt the technology necessary to access payers' PARDD APIs. We appreciate that CMS continues to seek feedback on electronic prior authorization standards and certification criteria that could be adopted under ONC's HIT Certification Program. However, we request that CMS coordinate with ONC to address this critical gap as soon as possible. For the proposals in this rule to have a meaningful and positive impact on physician burden and unnecessary delays in patient care, prior authorization processes must be integrated directly within the EHR workflow. If physicians must rely on separate payer portals or other manual data extraction processes to access and send information related to prior authorization requests, then the benefits of the proposals in this rule will not be fully realized.

Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations

CMS also proposes that PARDD API responses from the payer to the provider would be required to include information regarding payer approval (and for how long) or denial (with a specific reason) of the request or a request for more information from the provider to support the prior authorization request***. The Alliance strongly supports CMS's proposal to automate the request and response aspects of prior authorization. We also strongly support requiring impacted payers to provide a reason for denial, regardless of the method used to send the prior authorization decision (e.g., even if they are not using the API and instead using fax or mail).***

Requirements for Prior Authorization Decision Timeframes and Communications

To address prior authorization decision timeframes, CMS proposes that impacted payers must provide notice of prior authorization decisions as expeditiously as a beneficiary's health condition requires but no later than seven calendar days for standard requests and no later than 72 hours for expedited requests.

While the Alliance appreciates CMS's attempt to shorten prior authorization timeframes, ***we do not believe the proposed timeframes are sufficient. The Alliance strongly believes that by adopting the automated processes and standards in this rule, impacted payers can communicate prior authorization decisions in a shorter timeframe than proposed. We, therefore, urge CMS to require impacted payers to respond within 48 hours for standard requests and within 24 hours for expedited/urgent requests. Ideally, we would like to see plans use automated processes to render real-time approvals for routinely approved items and services and/or more straightforward PA requests (i.e., where limited information is needed to render a determination) and for plans to render a determination in less than 24 hours for more complex requests (i.e., where more detailed information may be necessary). The ultimate goal should be for payers to respond as often as possible in real-time.***

For many specialty-focused conditions, time can make a significant and sometimes life-altering difference in the patient's outcome. For example, in the case of retinal disease, the longer a patient waits to be treated, the higher they are at risk of losing vision. In other situations, if a physician could get real-time approval for a procedure or drug, the patient could be treated on the spot rather than having to make arrangements to return for another appointment. This would ensure more timely treatments,

save time and resources for patients and their caregivers, and free up chair time for other patients in need of care, which is especially critical as physicians continue to struggle to manage high patient volumes due to COVID-19 disruptions. Overall, more real-time response times will result in greater efficiencies across the health system and, most importantly, improve patients' timely access to care and clinical outcomes.

As payers transition to electronic prior authorization, the more standardized and automated processes proposed in this rule will naturally allow for more real-time responses. Even CMS states in the rule that it "believes that as prior authorization processes become more efficient, shorter timeframes may be possible for certain types of requests." Later in this rule, CMS expresses concern regarding possible low provider utilization of electronic prior authorization processes. The Alliance firmly believes that physicians will inherently gravitate towards electronic prior authorization solutions as more timely and automated mechanisms are implemented by payers — particularly, more immediate payer response times.

At the same time, ***the Alliance is very concerned that CMS has not proposed any mechanisms to ensure that payers comply with these deadlines***. As we stated earlier, it is also unclear whether payers are subject to ONC's information blocking regulations and whether those federal regulations can be used to enforce compliance related to electronic prior authorization processes and timelines. Instead, CMS simply advises that "If a payer fails to meet the timeline for approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision." CMS goes on to state that "impacted payers may choose to evaluate process improvements to meet the proposed timeframes and API in this proposed rule, and consider how to efficiently support provider inquiries on status should responses or timeframes be missed." The Alliance views these statements as unacceptable. Without an enforcement mechanism — such as a penalty for non-compliance or requiring that payers approve a request should they fail to meet the decision timeframe — these shortened timeframes will be ineffectual and will simply serve as window dressing. ***It is also unacceptable to put the onus on the provider to check in with the payer on the status of a delayed response.*** The main goals of this rule are to reduce provider burden and minimize unnecessary delays in care. However, if payers are afforded latitude regarding response times, this proposal will do little to change the status quo.

Public Reporting of Prior Authorization Metrics

CMS also proposes that by March 31, 2026, impacted payers must annually report certain aggregated prior authorization metrics from the previous year, including:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved, denied, and approved after appeal, with each metric aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved and denied, aggregated for all items and services.

- The average and median time that elapsed between the submission of a request and a determination by the payer for standard and expedited prior authorizations, aggregated for all items and services.

The Alliance very much supports requiring payers to publicly report prior authorization metrics. As we have expressed for many years, data collection of denials, delays and approval rates is critical for better understanding inappropriate utilization management practices among payers and strengthening oversight. Unfortunately, these data currently sit in a black box, so we appreciate that CMS is trying to bring transparency and accountability to the process. ***However, we request that CMS also require payers to publicly report their top reasons for denials.*** This will help CMS to understand better whether denials are mainly due to administrative factors, such as missing information (e.g., service code or date of birth) in the filed paperwork, whether a service is not covered by Medicare, or other clinical factors, such as inadequate supporting evidence or a medically unnecessary determination. ***It is also critical that payers disclose prior authorization data on an individual service basis, as disclosure on an aggregate basis will be confusing, indecipherable, and essentially meaningless to both providers and patients. If data are reported in the aggregate, then we strongly urge CMS to require, at a minimum, that payers provide the functionality for data to be sorted according to the type of services (i.e., diagnostic test, surgical procedure, drugs, DME, other) to make it more meaningful for patients and to allow them to sort out how plans may be performing based on type of service.***

"Gold-Carding" Programs for Prior Authorization

Although CMS does not make any formal proposals in this section, it is considering for future rulemaking to include a gold-carding measure as a factor in quality ratings for MA organizations and qualified health plans (QHPs) as a way for these payers to raise their scores in the quality star ratings. CMS is also considering making gold-carding a requirement in payers' prior authorization policies.

The Alliance strongly supports CMS' suggestions for payers to implement gold-carding programs. Gold-carding programs either exempt providers from prior authorization or provide a more streamlined medical necessity review process for providers with a demonstrated track record for complying with payer requirements. As a result, these programs alleviate unnecessary and duplicative administrative burdens and help to facilitate more efficient and timely delivery of health care services to patients. CMS should work with relevant stakeholders, particularly the physician community, to develop these requirements.

It also is important that gold-carding programs are adopted universally across items, services, drugs and payers to minimize confusion and have a meaningful impact. Currently, within states, there is a patchwork of gold-carding programs that may apply only to specific drugs or services and may vary by payer. These disparate policies are challenging for physicians to navigate and reduce the value of such programs.

Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category

To incentivize providers' use of electronic prior authorization solutions, CMS proposes adding a new measure titled "Electronic Prior Authorization" in the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category. The measure — which clinicians would be required to

report beginning in 2026 — would evaluate how often a clinician requests prior authorizations electronically. The measure would not be scored initially, but clinicians would be required to report a numerator and denominator to identify the percentage of prior authorizations requested electronically from a PARDD API using data from certified EHR technology (CEHRT).

The Alliance strongly urges CMS not to adopt this measure for multiple reasons. While we understand the need to ensure efficiencies from payer implementation of APIs are realized, the root of the problem is not the rate at which physicians utilize electronic systems to request PAs but the payers' prior authorization policies themselves. MIPS is intended to improve clinical practice, care delivery, and, ultimately, patient outcomes. Payer prior authorization policies completely contradict these goals by creating unnecessary paperwork and delays in patient care that lead to worse outcomes. ***A measure evaluating physician prior authorization request patterns is misdirected and has no place in MIPS.*** Furthermore, mandating that physicians report yet another MIPS measure would only add to the layers of administrative burden that physicians are already drowning under, which is antithetical to what CMS is trying to achieve through this rule. A MIPS measure will not incentivize physicians to use these technologies. Physicians will be naturally incentivized to engage in electronic prior authorization processes if they carry minimal burden, do not cause unreasonable delays in care, and lead to care that is in their patient's best interest.

As discussed earlier, ***the Alliance also opposes this Promoting Interoperability measure because of the ongoing lack of federal health IT certification criteria to ensure EHRs can communicate with payers' PARDD APIs.*** Until this requirement is worked into ONC's Health IT Certification Program, physicians could face barriers when requesting prior authorizations electronically from a PARDD API using data from CEHRT. We are encouraged to hear that CMS is working closely with ONC to move towards the adoption of standards for electronic prior authorization workflows, but this is still a big missing piece that must be addressed to ensure that electronic prior authorization processes are embedded within the EHR workflow and that physicians can process requests with the least amount of manual documentation/data capture and offline interactions with the payer.

Other Issues

As noted earlier, the Alliance recently commented on CMS's *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs* proposed rule (CMS-4201-P), which we are attaching to this letter. ***It is critical that as part of a broader effort to improve prior authorization processes, that CMS finalize certain policies in the MA rule in conjunction with this rule. For example, we reiterate the importance of requiring that prior authorization medical necessity reviews are conducted by licensed physicians in the same or similar specialty as the treating physician. Most specialists and subspecialists have participated in so-called "peer-to-peer" utilization management review processes, only to be told by a non-physician or physician with limited or no expertise in the clinical subject under review that the patient does not appear to be a candidate for the service.***

Although not discussed in either rule, ***the Alliance also recommends that if a physician receives prior approval for a service, then they should be paid for that service***. Our members have reported situations where payers have denied payments after approving a service, which demonstrates a lack of adherence to clinical evidence and adds to administrative burden.

The Alliance appreciates CMS addressing many of its long-held concerns through this rule and for the opportunity to provide feedback. Should you have any questions or would like to meet with the Alliance to discuss our comments further, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
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
North American Spine Society
Society of Interventional Radiology

Attachment

Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure,

The Alliance of Specialty Medicine (the "Alliance"), representing more than 100,000 specialty physicians from sixteen specialty and subspecialty societies, is deeply committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we write to provide feedback on proposed policy changes for Medicare Advantage Organizations (MAOs) and their impact on access to specialty medical care.

Utilization Management Requirements

The Alliance greatly appreciates CMS' proposals to meaningfully improve utilization management (UM) in the Medicare Advantage (MA) program and urges CMS to finalize these policies. These proposed reforms come after years of provider and patient advocacy and multiple agency initiatives to reduce administrative burdens. We are extremely pleased that CMS has heard our concerns and recognizes the need to take action. These proposed reforms are particularly important for specialty physicians and their patients, who are often subject to prior authorizations and other UM tactics. They are particularly timely as the MA program continues to grow, with 60% of beneficiaries expected to be enrolled by 2032.[1] Again, ***we laud CMS for the proposed policies in this rulemaking and urge their finalization.***

[1] https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/

Generally, UM processes delay enrollee access to medically necessary care and treatments and create considerable, unnecessary administrative burdens for specialty physicians. Equally concerning, these tactics are a leading cause of physician burnout, forcing many to retire early or leave the practice of medicine. While UM processes, such as prior authorization, may be appropriate in some situations, the Office of Inspector General found that MA plans use prior authorizations to deny *medically necessary* care, that is, care that met coverage requirements under traditional Medicare and was supported by the enrollee's medical records.

We understand that CMS' UM proposals for "items and services" will, if finalized, apply to physician-administered medications covered by MA plans but not to pharmacy benefit drugs covered by Part D (whether as part of an MA plan or as a standalone plan). ***While patients needing provider-administered medications welcome these proposals, the Alliance urges CMS to institute more robust continuity of care provisions for Part D medications. Additionally, the Alliance asks CMS to rescind its 2018 step therapy guidance empowering MA plans to apply step therapy to Part B medications or at least ensure that the memo's continuity of care provisions are consistent with those in the proposed rule, as discussed in detail below.*** For many specialists and their patients enrolled in MA plans, prior authorization, step therapy, and non-medical switching are constant barriers to medically necessary drug therapies, regardless of whether these drugs are covered via the medical or pharmacy benefit. Enrollees that have complex, chronic diseases — including rheumatoid and psoriatic arthritis, ulcerative colitis and inflammatory bowel disease, and macular degeneration — require complex therapies to manage their condition effectively. Absent these therapies, patients with the aforementioned autoimmune diseases will face debilitating pain, and those with macular degeneration will face blindness. In fact, an article in PharmacoEconomics concluded that *"[c]ompared with patients in plans without access restrictions or with [prior authorization] only, [rheumatoid arthritis] and [psoriatic arthritis]* ***patients in insurance plans with step therapy had lower odds of treatment effectiveness*** *[emphasis added], mainly due to lower odds of adhering to treatment, during the 12 months following subcutaneous [biologic disease-modifying antirheumatic drugs] initiation."*[2]

CMS claims that step therapy puts MAOs in a stronger position to negotiate lower prices with drug manufacturers and reduce cost-sharing for enrollees. However, a 2020 *Health Affairs* article provides more color to this assertion, explaining that *"[a]pplying rebates to reduce premiums saves an equal amount for all enrollees, but* ***basing cost sharing on the list price of drugs (as is done in Part D) increases out-of-pocket costs for those using drugs with rebates, especially for those patients taking highly rebated drugs*** [emphasis added]."[3] Some of the most highly-rebated drugs are specialty medications, including the biologics used to treat the aforementioned conditions. Prohibiting step therapy on these medications would greatly improve access to them.

As noted, the Alliance has previously asked CMS to withdraw its 2018 step therapy guidance to MAOs, highlighting the problems associated with the policies described in the memo and how they harm enrollees, especially those who rely on complex medications that are most frequently subject to step therapy.[4] This

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[2] https://link.springer.com/epdf/10.1007/s41669-019-0152-1?author_access_token=wn16qxqmbu8Y_A-omSP0Zve4RwlQNchNByi7wbcMAY7RP9W-hCIFOibQHi4l6PB9b5joHSXGA0k7qbFjo6QnM0Ej28kBPej-vh8ykFXYLJMUTTqkvuDVm1VBKf0Bb_cQSxdQGJP3vTIux9AOlxUCUQ==

[3] https://www.healthaffairs.org/do/10.1377/forefront.20200911.841771/

[4] https://specialtydocs.org/wp-content/uploads/2019/05/Alliance_Part_B_Step_Therapy_Letter_Sept_2018.pdf

rulemaking presents an opportunity for CMS to withdraw the memo and reinstate the prohibition on step therapy for Part B drugs in MA. If CMS does not wish to withdraw the memo at this time, at a minimum, the agency should update the memo to be expressly consistent with the continuity of care policies (once finalized). That will streamline these patient protections by ensuring that any new enrollee undergoing an active course of treatment cannot be subjected to new or additional UM requirements, such as step therapy, for the first 90 days of enrollment. Such a policy would be consistent with the 2018 memo, which stresses the importance of continuity of care and prohibits step therapy for enrollees who are actively being treated with the affected product but stops short of clarifying that this provision applies to all enrollees — both existing enrollees and new enrollees who "come in with" an ongoing prescription covered by their previous plan.

Again, we appreciate the proposed policies, which respond to the patient and medical communities' concerns about the impact of utilization management on patient care and physician workforce. We urge CMS to finalize these policies but include all drugs — both medical and pharmacy benefits — in the final rule. We also urge CMS to withdraw the 2018 step therapy memo or make the aforementioned clarification to ensure that continuity of care is protected.

Gold Carding

Among its UM proposals, CMS encourages MA plans to adopt gold-carding programs. The agency notes that gold-carding enables certain providers to be exempt from prior authorization and provides a more streamlined medical necessity review process for providers who have demonstrated compliance with MA plan requirements. These programs also alleviate the burden associated with prior authorization and could facilitate more efficient and timely delivery of health care services to MA enrollees. ***We agree with CMS about the benefit of gold-carding programs but strongly urge the agency to establish requirements for them, as most plans are unlikely to do so on their own without a specific mandate.***

Review of Medical Necessity Decisions

CMS proposes to revise its regulations by adding that the physician or other appropriate health care professional conducting a medical necessity review for the MAO must have expertise in the field of medicine appropriate for the item or service being requested before the MAO issues an adverse decision. CMS' policy aim is appreciated, but ***we strongly urge the agency to require reviewers to be licensed physicians in the same or similar specialty or subspecialty as the treating physician.***

Most specialists and subspecialists have participated in so-called "peer-to-peer" UM review processes, only to be told by a non-physician or physician with limited or no expertise in the specialty or the delivery of the service subject to UM that the patient does not appear to be a candidate for the service. Although allied health professionals play a critical and necessary role in health care, it is inappropriate to, for example, have a nurse practitioner determine the medical necessity of intravitreal injections requested by a retina specialist for patients with neovascular (wet) macular degeneration, particularly as these health care professionals are not generally authorized to administer these medications.[5] It would also be inappropriate for a primary care

[5] The FDA label for EYLEA states that the medication "must only be administered by a qualified physician." https://www.regeneron.com/downloads/eylea_fpi.pdf

physician to determine the necessity of spine surgery or the medical necessity of biologic medication administrations by rheumatologists for rheumatoid arthritis.

We ask CMS to modify the regulatory language in the final rule to reflect that reviewers must be licensed physicians in the same or similar specialty or subspecialty as the treating physician.

Medicare Advantage Network Adequacy: Access to Services

CMS confirms MAOs' obligation to provide access to appropriate providers, including credentialed specialists, for medically necessary treatment and services and proposes to add to its regulations that MAOs must arrange for any medically necessary covered benefit outside of the plan provider network at in-network cost-sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. The Alliance appreciates the intent behind this proposal but notes that it will not meaningfully improve access to medically necessary services. Many MAOs already have processes in place to provide access to out-of-network care, which are fraught with obstacles and unnecessary hurdles, prompting many enrollees to delay or forego needed care. The more appropriate solution to ensuring access to medically necessary covered benefits is requiring MAOs to have an adequate network of providers, including specialists and subspecialists.

As the Alliance has previously shared, ***most enrollees do not realize the limitations of their plan's provider network until they are faced with a critical need for specialty medical services.*** CMS recognizes the importance of a robust MAO network to ensure access to care, particularly for underserved populations, but leverages its authority to "pick and choose" which specialists offer the most value based on the Administration's policy priorities rather than the health care needs of enrollees. This is evidenced by proposals elsewhere in this rule that would add behavioral health specialties to network adequacy requirements and revise provider directory requirements to include new elements (i.e., provider's cultural and linguistic capabilities, provider's waived to treat patient with medications for opioid use disorder), despite CMS data showing a very low prevalence of drug and substance abuse among the Medicare population, but extremely high rates of other conditions, such as heart disease, arthritis, and diabetes.[6]

Despite the provider community's repeated attempts to secure improvements to MAO network adequacy criteria, CMS continues to base MAO network adequacy on a narrow list of primary specialties and not any subspecialists.[7] In addition, CMS fails to require MAOs to provide physicians with any explanation or rationale for their exclusion or termination from the MAO network, including options for entering or re-entering networks. CMS has not responded to any of our requests through the annual notice-and-comment rulemaking, making it difficult to understand the agency's rationale for not adopting any of the recommended actions.

MAOs require the full range of specialty and subspecialty providers — those ***best*** equipped to manage a growing population of seniors with multiple chronic and acute health conditions — which will help reduce program costs and improve enrollee health and quality of life. To that end, ***we again ask CMS to act on the following recommendations aimed at improving access to specialty and subspecialty care:***

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[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/cc_charts.zip

[7] According to its most recent guidance, CMS measures 27 provider specialty types and 13 facility specialty types to assess the adequacy of the network for each service area. https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance06132022.pdf

- ***Require MAOs to accurately identify physician specialties and subspecialties when calculating network adequacy using the Healthcare Provider Taxonomy code set developed by the National Uniform Claims Committee,[8] which distinguishes between specialty and subspecialty physicians.***
- ***Develop Quality Rating System (QRS) measures for plans that:***
  - ***Account for specialty and subspecialty care, which may include aligning QRS measures with physician-level performance metrics in CMS' Quality Payment Program; and***
  - ***Tie maintaining an adequate network to a health plan's quality rating.***
- ***Require plans to provide detailed information on the cause for exclusion or termination from the network, including options for entering or re-entering the network.***
- ***Require plans to maintain accurate, real-time provider directories that include specialty and subspecialty designations.***

Enrollee Notification Requirements for Medicare Advantage Provider Contract Terminations

The Alliance appreciates CMS' proposals to establish enrollee notification requirements for MA provider contract terminations. However, we have asked across multiple rulemaking cycles that CMS establish *provider* notification requirements, so physicians who are either excluded or terminated from an MAO network (1) understand the rationale behind the MAO decision excluding or terminating them from the network, including any performance metrics used and the associated methodology, and (2) are provided options for entry or re-entry in the MAO network.

For many specialists and subspecialists, particularly in areas with high MAO penetration, participation in the network is essential to having a patient panel that ensures practice viability. However, specialty physicians — especially subspecialists — are frequently blocked or eliminated from networks without explanation. In fact, one subspecialty — Micrographic Dermatologic Surgeons (aka Mohs surgeons) — was wholly barred from MA networks in Missouri for several years.

It is not unreasonable for physicians to expect that adverse decisions related to their in-network participation are clearly explained and offer an opportunity for recourse. ***We again urge CMS to establish <u>provider</u> notification requirements that afford physicians an explanation for why they have been excluded or terminated from the network, including any performance metrics used and the associated methodology, and are provided options for entry or re-entry into the MAO network.***

Medicare Advantage and Part D Marketing

The Alliance supports CMS' reforms for MA and Part D plan marketing and urges the agency to finalize these policies. CMS shared in its 2023 Advance Notice that it reviewed MA plan complaints, finding that they "primarily originate from beneficiary confusion around misleading marketing materials and/or inadequate training of marketing personnel." Through policy proposals outlined in this rulemaking, CMS is meaningfully addressing the concerns raised, including those of specialty medical providers. We noted how many of our patients with specialty medical conditions learn after enrolling in an MA plan that their specialist is not in the

[8] https://taxonomy.nucc.org

network, and their medications are not on the plan's formulary or are cost-prohibitive. This is particularly common for patients with autoimmune diseases, such as rheumatoid arthritis.

CMS proposals to modify the pre-enrollment checklist by requiring plans to explain the implications of choosing an MA or Part D plan and that they are better informed about the details surrounding the plan for which they are enrolling (e.g., whether their doctors are in the network, whether their medications are on the plan's formulary, etc.), are important improvements. ***We urge CMS to finalize these policies and to continue providing necessary oversight.***

Changes to an Approved Formulary

The Alliance agrees with CMS that formulary stability is extremely important to ensuring enrollees maintain access to a medication(s), which may be what leads them to select a specific MA plan. We also appreciate that CMS recognizes how formulary changes can lead to non-medical switching, which poses undue threats to enrollee health and outcomes. As many of our member organizations rely on biologic medications to treat specialty health conditions, we greatly appreciate CMS's proposal to limit reference biological product substitutions to *interchangeable* biological products. ***We urge CMS' to finalize its proposed provisions for the approval of formulary changes.***

Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

The Alliance has previously commented on additional quality measure concepts that would improve access and quality, including measures that would transform care and drive quality through value-based initiatives. We continue to believe additional measures are essential to address challenges observed in MAOs and urge CMS to:

- ***Establish a star measure awarding points to MA plans that maintain an adequate network of specialty and subspecialty physicians.*** As we explain in our comments, MA plans impede access to medically necessary services by maintaining "narrow networks" that prevent specialty and subspecialty physicians from participating as in-network providers. Specialty and subspecialty physicians continue to be eliminated from MA plans, frequently in the middle of a plan year, leaving enrollees with limited or no access to care for chronic health conditions, such as glaucoma, macular degeneration, rheumatoid arthritis, lupus, and skin cancer, which are best managed by specialists with expertise in those disease areas. When a plan does not have an adequate network of specialty and subspecialty providers, it is impossible for seniors to access the full range of providers and treatments they may need, thus diminishing quality and outcomes. Often, enrollees may not realize they need specialty medical care until after they have enrolled in a plan and new symptoms present or an existing condition worsens. Establishing a measure tied to network adequacy would incentivize MA plans to retain specialty and subspecialty physicians as "in-network."
- ***Establish a star measure based on a survey of physicians' experiences with MA plans, which could be developed in collaboration with the Alliance and other professional associations.*** Questions should focus on the following:
    - Network adequacy, including the accuracy of physician directories and physician termination and reinstatement practices;
    - Payment and reimbursement practices, including the sufficiency of payment rates, the volume of denials and post-payment medical reviews, and other tactics that deny or slow payment after services are rendered;

- Utilization management, including prior authorization practices, step-therapy requirements, non-medical switching of medications, and other administrative barriers that inappropriately diminish or slow beneficiary access to medically necessary diagnostic and therapeutic services and treatment; and,
- Other administrative burdens, including the number and type of medical record documentation requests.

Other Concerns

CMS previously sought feedback on the nature and extent of medical record documentation requests by MA plans, including ideas to address this burden. As noted earlier, MA plans continue to misrepresent medical record requests to specialty physician practices as CMS-initiated mandatory Risk Adjustment Data Validation (RADV) audits. In reality, these requests are usually plan-initiated and designed to identify additional diagnosis codes, which increase the MA plan "risk score," with corresponding increases in their Medicare payments.

Preparing for these deceptive audits is daunting for already-burdened physician practices. More importantly, plans are overreaching to establish additional diagnoses. These concerns are not new to CMS, its policy advisors, or oversight agencies, and we believe this burden will increase now that CMS has issued final rules updating the RADV program.[9]

As we have previously shared, the scope and volume of medical record requests are tremendous, with some seeking hundreds of records per physician. Furthermore, these requests include untenable submission deadlines, sometimes just days after the request. Practices that fail to comply have been told their contracted rates will be lowered, or worse, that they may be terminated as in-network providers.

To address these issues, ***we urge CMS to require MA plans to:***

- ***Follow a standardized process for all medical record requests;***
- ***Clearly identify the nature of their medical record request (e.g., RADV, other purpose, etc.) and provide written documentation when requests are mandated as part of CMS-initiated audits;***
- ***Provide reasonable deadlines for medical record submissions, as well as a process for extending the submission deadline for extenuating circumstances;***
- ***Limit the number and volume of medical record requests (e.g., no more than once per year and no more than 20 records per physician);***
- ***Allow practices to submit medical records through a secure web portal, on CD/DVD, or by fax when possible; and***
- ***Reimburse practices for completing medical record requests at a rate no less than is set under State law.***

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We appreciate the opportunity to provide feedback on the proposals in this rule that aim to improve access to specialty and subspecialty care. Should you have any questions or would like to meet with the Alliance to discuss these recommendations further, please contact us at info@specialtydocs.org.

[9] https://www.cms.gov/newsroom/press-releases/cms-issues-final-rule-protect-medicare-strengthen-medicare-advantage-and-hold-insurers-accountable

Sincerely,

American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
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
North American Spine Society