RRC

Regulatory Relief Coalition

Protecting Patients' Timely Access To 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 (the electronic prior authorization (e-PA Proposed Rule)

Dear Administrator Brooks-LaSure,

The undersigned members of the Regulatory Relief Coalition (RRC), representing thousands of physicians throughout the United States, write to thank you for proposing the e-PA Proposed Rule and provide our thoughts regarding how the laudatory provisions of this proposal could be further improved. The RRC is a group of national physician specialty organizations advocating for regulatory burden reduction to ensure that utilization review policies are not a barrier to timely and equitable access to care for the patients we serve.

The RRC strongly supports the regulatory changes set forth in the e-PA Proposed Rule. When finalized, these regulations will significantly reduce the barriers to care and lessen provider burden associated with payers'[1] PA requirements. The e-PA Proposed Rule, in conjunction with

[1] For the purposes of these comments, unless otherwise noted, the term payers will be used to refer to Medicare Advantage Organizations, 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.

the 2024 Medicare Advantage (MA) and Part D Proposed Rule (CMS-4201-P)(MA PA Proposed Rule), will significantly reduce unnecessary delays in the provision of patient care and increase the time that providers have to spend with patients.

In this regard, the comments and suggestions below should be viewed as our attempt to help further improve an already praiseworthy proposal, identify potential gaps in the e-PA Proposed Rule's patient and provider protections, and point to possible future directions.

Preliminary Comments

As stated above, when adopted, the above-mentioned proposed rules have the potential to substantially reduce the administrative delay associated with PA and expedite the provision of medically necessary care.

> **Recommendation**: The RRC urges CMS to finalize the e-PA and MA PA Proposed Rules to becomce effective in 2024 or as expeditiously as possible. In addition, we encourage the agency to clearly explain how it will coordinate implementation so physicians and other stakeholders can adopt the new policies.
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> **Recommendation:** While implementing the reforms described in the e-PA Proposed Rule will significantly expedite the PA process, the proposal does not in any way ensure that PA criteria are supported by clinical evidence. By contrast, the MA PA Proposed Rule includes numerous safeguards intended to ensure that PA criteria are reasonably well supported by clinical literature and expert opinion. For example, the MA PA Proposed Rule requires PA criteria are:
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> - Made public before they go into effect;
> - Accompanied by references to the clinical literature or other data that support them; and
> - Reviewed and approved by a Utilization Management Committee.
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> The RRC strongly urges CMS to include in the e-PA Final Rule parallel requirements intended to ensure that the PA criteria of all payers are supported by clinical literature, that they are made public in advance of adoption, and that they are reviewed by physicians with expertise in the services involved prior to implementation. Further, we urge CMS to incorporate the other patient and provider safeguards outlined in the RRC's comments on the MA PA Proposed Rule (Attachment A) into the e-PA Final Rule to ensure that these protections are available to all Payers' enrollees and beneficiaries.

Advancing Interoperability

We strongly support CMS' proposal to require payers to make available data exchange between payers and patients (through the Patient Access Application Programming Interface, or API),

providers (through the Provider Access API) and payers to which a patient may switch enrollment ("successor payers") (through the Payer-to-Payer Information Exchange). The information required to be made available through these APIs includes claims and encounter data, certain clinical data elements, as described in the USCDI v.1 (if the payer maintains this information) and certain information related to PA requests and determinations.

Recommendation: The RRC strongly supports CMS' proposal to require payers to make Provider Access API available. We believe that the availability of this API has the potential to improve care coordination and minimize unnecessary duplication of services. Including information regarding which PA requests have been submitted and approved will significantly reduce delays in providing medically necessary care and relieving provider burden.

Recommendation: The RRC supports using APIs to improve patient access to their health information and facilitate secure information exchange across a patient's care team. However, the RRC believes any standards for such APIs must undergo robust real-world testing in a variety of clinical settings, including small, independent, and rural physician practices, and with all end-users, including physicians, to ensure standards are effective, adoptable, and efficient.

Recommendation: In light of the efficiencies that may result from using the Provider Access API, the RRC requests that CMS make this API available to out-of-network and in-network providers.

Recommendation: The e-PA Proposed Rule does not require any of the three APIs to include information regarding PA requests and decisions for drugs. The RRC believes it is imperative that patients, providers, and successor payers have this information. Patients need access to this information to facilitate patient-provider joint decision-making, and providers need it to ensure that patients receive medically appropriate medication. Furthermore, successor payers need this information to ensure continuity of care. For these reasons, the RRC urges CMS to ensure that the e-PA request and decision history for all drugs be included in all three APIs.

Recommendation: The RRC requests that payers be required to make PA requests and decision information available on all three APIs for as long as the authorization is active for more than one year after the last status change, as proposed in the e-PA Proposed Rule, since a patient's PA history may be relevant to the patient's ongoing care.

Recommendation: The e-PA Proposed Rule requires that payers make claims and encounter data available within one business day of this request. To ensure that this requirement does not put inappropriate pressure on providers to submit claims immediately after providing an item or service, we request that this requirement be

clarified so that it applies only to the claims and encounter information available at the time of the request.

Recommendation: The RRC requests that CMS clarify that payers are considered "actors" in the context of the data blocking rules. The Office of the National Coordinator for Health Information Technology (ONC) website indicates that a payer may be considered an "actor" for the purposes of the information blocking regulations if it meets the definition of a Health Information Network (HIN) or Health Information Exchange (HIE), stating that the definition of these terms "is a functional definition and should be reviewed for potential applicability to a health plan's activities."[2] The ONC website further states:[3]

> Health information network or health information exchange means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information…:
>
> > 2. That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.

The Patient Access, Provider Access, and Payer-to-Payer Information Exchange APIs that payers must make available under the e-PA Proposed Rule include PA information as well as claims and clinical information exchange, all of which constitute electronic health information "[t]hat is for a treatment, payment, or health care operations purpose" within the meaning of this definition of HIN/HIE. Therefore, we believe that the e-PA Proposed Rule, if finalized as proposed, would essentially subject a payer to the information blocking regulations. We would appreciate CMS confirming our understanding of this issue in the e-PA Final Rule.

Recommendation: As an "actor" within the meaning of the information blocking regulations, a payer that makes health-related information available through an API must comply with certain requirements, including, for example, deadlines for complying with a request for information and specific limits on when a fee can be charged for data access. The RRC requests that CMS clearly delineate in the e-PA Final Rule which data information blocking requirements apply within each API and resolve any inconsistencies between the e-PA Proposed Rule and the information blocking

[2] https://www.healthit.gov/faq/are-health-plans-or-other-payers-subject-information-blocking-regulation.
[3] https://www.healthit.gov/sites/default/files/2022-07/InformationBlockingActors.pdf.

requirements. For example, the e-PA Proposed Rule requires that a payer make a patient's information available to the patient within a day. In contrast, the information-blocking requirements reflect a more flexible deadline.

Improving Prior Authorization Practices

The e-PA Proposed Rule would require payers to do the following:

- Implement and maintain an API to support and streamline the PA process;
- Respond to PA requests within certain timeframes;
- Provide a clear reason for PA denials; and
- Publicly report on PA approvals, denials, and appeals.

The RRC strongly supports these proposals. More specifically, CMS proposes that beginning January 1, 2026, payers would be required to implement a standards-based API (referred to as the FHIR PARDD API) that:

- Includes a list of covered items and services (other than drugs) subject to PA;
- Links to any other data, forms, or medical record documentation required by the payer for PA; and
- Facilitates communication of PA determinations.

Most importantly, the PARDD API is required to facilitate an electronic HIPAA-compliant request and response.

While the RRC applauds CMS' initiative to streamline PA processes used by payers, we are concerned that the preamble to the e-PA Proposed Rule solicits input on whether and to what extent the approach to PA reflected in the proposal may be applicable under Medicare Fee-for-Service (FFS). The RRC strenuously opposes using PA in Medicare FFS and urges CMS to suspend any existing FFS PA policies not otherwise mandated by law. We believe that expanding PA in Medicare FFS has the potential to significantly limit Medicare patients' access to medically necessary care and should not be adopted in the absence of a specific legislative mandate.

That said, we offer the following recommendations concerning CMS' proposal to require payers to implement a PARDD API.

Recommendation: The RRC urges CMS to include drugs in the PA policies and payer requirements set forth in the e-PA Proposed Rule. While there are specific PA requirements (including electronic-PA requirements) for Medicare Part D drugs, these requirements do not apply to other payers that fall within the scope of the e-PA Proposed Rule. PA requirements for drugs vary widely across payers, are extremely burdensome for physicians and other providers, and significantly impact patients' timely

access to medically necessary therapeutics. We believe it is critical that payers be required to include medical benefit drug related PA requirements in the PARDD API, and that current pharmacy drug electronic prior authorization standards adopted at 42 CFR § 423.160 be required for all plans impacted under this rule. These changes will help ensure that prescribing providers have ready access to these Payers' PA policies and criteria.

Recommendation: The e-PA Proposed Rule does not explicitly require the PARDD API to facilitate the transmittal of attachments. While we presume that CMS anticipates that payers' PARDD APIs will have this capability, we would appreciate CMS' including this requirement in the regulatory language. If CMS does not anticipate that PARDD API will facilitate the transmittal of attachments, we request that the ePA Final Rule explain clearly what requirements payers will need to meet to facilitate electronic submission of attachments and how PA requests submitted using PARDD and electronically submitted attachments will be linked.

Recommendation: The RRC supports CMS' proposal to refrain from allowing piecemeal or transitional implementation of the PARDD API requirements but rather to require payers to include in the PARDD all items and services subject to PA by the deadline. We believe that any attempt to implement the API on a piecemeal basis is likely to result in significant provider confusion, especially in light of the considerable variation among payers' PA lists.

Recommendation: The RRC urges CMS to coordinate with ONC to facilitate the inclusion of e-PA standards and certification criteria under ONC's HIT Certification Program. We again reiterate that standards must undergo real-world testing to ensure they are adoptable. The RRC also urges CMS to be mindful of the cost to physician practices, particularly small, independent, and rural practices, of updating and implementing standards and how this may lead to varied timelines of adoption and use across all clinical settings. Until electronic health record (EHR) technology includes PA functionality, the full potential of the changes delineated in the e-PA Proposed Rule will not be realized.

Recommendation: The RRC supports CMS' proposal to require PARDD APIs to provide responses from the payer to the provider that include critical information, such as information regarding the duration of payer approval and the specific reason(s) for denial. The RRC also strongly supports those provisions of the e-PA Proposed Rule that require payers to provide a basis for denial, regardless of the method used to request a PA determination.

Requirements related to PA Deadlines

To address PA decision timeframes, CMS proposes that impacted payers must provide notice of PA 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.

> **Recommendation**: The RRC urges CMS to modify the timeframe for organization determinations to require payers to respond to a PA request by no later than 48 hours for a standard request and no later than 24 hours for an expedited request. Allowing payers up to three days to respond to a PA request for emergency situations endangers patient health and safety, and implementation of the PARDD API and other reforms described in the PA Proposed Rule should facilitate payer responses to standard requests within 48 hours.
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> The RRC further believes that CMS should require payers to implement a mechanism for real-time PA decisions for frequently approved services, as described in the *Improving Seniors' Timely Access to Care Act* (S. 3018/H.R. 3173) (the "*Improving Seniors' Access* bill" or "the Bill"). Implementing such a program has the potential to virtually eliminate the delay associated with many PA requirements and facilitate seamless patient care.
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> **Recommendation**: Under the e-PA Proposed Rules, a payer's "determination" with respect to a PA request may consist of a request for additional information. Since the e-PA Proposed Rule requires the PARDD API to include functionality that directs providers to any additional forms or other information that must be included with the request, we believe it is inappropriate to allow the payer up to seven days to determine if all necessary information has been submitted. In fact, we believe that the payer should be required to advise the provider in real time regarding whether or not a PA request is complete and that this functionality should be included in the PARDD API requirements.

Regardless of which deadlines are adopted, the RRC is extremely concerned that the e-PA Proposed Rule does not include a workable enforcement mechanism to ensure the PA deadlines are met. The preamble to the e-PA Proposed Rule indicates that if a payer fails to comply with a deadline, it is up to the provider to follow up with the payer or, alternatively, appeal the payer's failure to adhere to the deadline.

> **Recommendation**: The RRC strongly believes that unless failure to comply with a PA deadline is deemed to constitute an approval of the PA request, payers have little incentive to treat PA deadlines seriously. The RRC strongly recommends against placing the burden of unfulfilled PA requests on the physician and patient instead of the plan that has failed to respond. We urge CMS to allow providers to treat a failure to respond

within the required timeframes as a PA approval, thereby incentivizing payers to comply with PA requests as required by regulation.

Public Reporting of Prior Authorization Metrics

The e-PA Proposed Rule would require payers to publicly report certain aggregated PA metrics. The RRC strongly supports public reporting, which has the potential to make the PA process more transparent.

Recommendation: The RRC urges CMS to align the public reporting requirements applicable under the e-PA Final Rule as outlined in the Bill. We are especially concerned that the e-PA Proposed Rule's public reporting requirements would allow data to be reported on an aggregate basis, which is likely to be meaningless to both patients and providers. In contrast, the Bill would require reporting on an *individual service* basis, thereby facilitating patients' and providers' understanding of whether PA requests for particular services are likely to be approved.

"Gold-Carding" Programs

The e-PA Proposed Rule indicates that CMS is considering for future rulemaking the inclusion of 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' PA policies.

Recommendation: The RRC strongly supports including a gold-carding (or similar process for bypassing PA) measure as a factor in quality ratings for MA organizations and QHPs and requiring gold-carding as a requirement in payers' PA policies. However, experiences from states that have passed gold-carding legislation have demonstrated that several implementation considerations are critical to ensuring that the programs meaningfully reduce burden for physicians across practice settings. The RRC looks forward to working with CMS to ensure that gold-carding programs effectively reduce the burden of PA for all physicians.

Recommendation:. When providers bear the financialrisk of inappropriate utilization, we do not believe that the imposition of PA requirements is appropriate. For this reason, we urge CMS to consider precluding payers from imposing PA requirements altogether for risk-based payment arrangements.

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

The e-PA Proposed Rule would add a new "Electronic Prior Authorization" measure in the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category, beginning in 2026.

> **Recommendation:** While the RRC understands CMS' interest in ensuring that electronic PA mechanisms are utilized, we believe that unless and until ONC's Health IT Certification Program requires certified EHR technology (CEHRT) to include the functionality necessary to communicate through a PARDD API, it is unreasonable to measure physicians' utilization of e-PA for MIPS payment purposes. The key objective of these APIs — particularly the PARDD API — is to provide value to physicians by making patient data more readily available and reducing administrative burden. If these APIs achieve those goals when implemented, and e-PA decreases physician burden, physicians and other clinicians will not need additional incentives to adopt them. They should not be subject to punitive action if they do not implement the requirements in time. Until CEHRT that includes this functionality is available, the full potential of the e-PA Proposed Rule's reforms will not be realized.
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> Currently, there is no HIPAA-compliant standard for the clinical information necessary to support PA requests (in HIPAA parlance, "Attachments"), and the Attachments Proposed Rule[4] (which we have concerns about) with such a standard is not scheduled to go into effect until January 1, 2026. The systems generally available to providers currently do not comply with the proposed Attachments standard. Under these circumstances, we do not believe it is reasonable to measure providers' utilization of e-PA beginning in the 2026 performance year.

Enforcement

The RRC is very much encouraged by CMS' response to our requests for PA reform and believes that finalization of the e-PA Proposed Rule, along with the finalization of the requirements set forth in the MA PA Proposed Rule, is likely to significantly improve timely access to health care services provided through a broad range of government-funded health plans. However, we are concerned about how these requirements will be enforced, especially for payers not under CMS's direct regulatory authority.

> **Recommendation**: The RRC recommends that CMS include in the e-PA Final Rule the enforcement mechanisms that will be used to ensure compliance with the PA requirements for both those payers that are under CMS' direct jurisdiction (such as MA plans) and those that are not, such as Medicaid managed care and other Medicaid programs overseen by State Medicaid Agencies. The RRC strongly recommends against

[4] "Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard (CMS-0053-P). 78438 Federal Register / Vol. 87, No. 244 / Wednesday, December 21, 2022.

relying on physicians or patients to raise complaints about accessing data through APIs or plan adherence to transparency requirements, including status updates, reasons for denials and timeframes for fulfilling prior authorization requests.

We appreciate the opportunity to provide feedback on this critical step forward in making medically necessary services available on a timely basis to patients enrolled in a broad range of health plans.

Respectfully,

American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Osteopathic Association
Association for Clinical Oncology
Congress of Neurological Surgeons
Medical Group Management Association
North American Spine Society

Attachment A

RRC Final Comments on 2024 Medicare Advantage Proposed Rule

RRC

Regulatory Relief Coalition

Protecting Patients' Timely Access To Care

Filed Electronically

February 13, 2023

Chiquita Brooks-LaSure
CMS Administrator
200 Independence Avenue, SW
Washington DC

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 ("2024 MA Proposed Rule" or "Proposed Rule")

Dear Administrator Chiquita Brooks-LaSure:

The undersigned members of the Regulatory Relief Coalition (RRC), representing thousands of physicians throughout the United States, write to thank you for the comprehensive prior authorization (PA) requirements in the contract year (CY) 2024 MA and Part D Proposed Rule. The RRC is a group of national physician specialty organizations advocating for regulatory burden reduction to ensure that utilization review policies are not a barrier to timely and equitable access to care for the patients we serve.

The RRC strongly supports the regulatory changes set forth in the Proposed Rule. We applaud CMS for its thorough and comprehensive proposed regulations, which, when finalized, will limit MA plans' overuse and abuse of PA, reduce barriers to care and lessen provider burden. Finalizing the provisions in this Proposed Rule will help ensure that Medicare beneficiaries who enroll in MA Plans have the same access to Medicare-covered items and services as beneficiaries who opt for Medicare Fee-for-Service (FFS). Additionally, the issuance of this Proposed Rule in conjunction with the electronic PA (e-PA)

proposed rule (which includes MA plans)[5] will improve the efficiency of PA processes, reduce delays in care and alleviate the burden associated with PA.

The comments and suggestions set forth below should be viewed as our attempt to help to further improve an already praiseworthy proposal, identify potential gaps in the Proposed Rule's patient protections and point to possible future directions.

I. Consistency of Regulatory and Potential Legislative PA Requirements

Over the past several years, members of Congress have become increasingly concerned about the barriers to patient access resulting from MA plans' use of PA. To address many of the same deficiencies in MA plans' use of PA as those identified by CMS in the 2024 MA and e-PA Proposed Rules, the House of Representatives **unanimously passed** the *Improving Seniors' Timely Access to Care Act* (S. 3018/H.R. 3173) (the "*Improving Seniors' Access* bill" or "the Bill") by voice vote in September 2022. This bipartisan legislation, developed with input from the RRC, finished the 117th Congress with 380 combined co-sponsors — 53 senators and 327 representatives — supporting the legislation. Importantly, more than 500 organizations representing patients, health care providers, the medical technology and biopharmaceutical industry, health plans, and others endorsed the legislation.

We note that the purposes of the PA provisions of the MA and e-PA Proposed Rules and the Bill closely align. Both the Proposed Rules and legislation acknowledge that PA:

- Plays an important role in utilization management, but it can be misused or overused, creating considerable challenges for patients, providers, and payers;
- Presents a serious health risk for patients when care is delayed;
- Increases provider and payer burden due to inconsistent payer policies, provider workflow challenges, and unpredictable use of electronic standards; and
- Contributes to significant provider burnout.

We also note that the Bill and the approach to PA taken by CMS in the MA and the e-PA Proposed Rules include many similar elements. The e-PA Proposed Rule and the legislation both:

- Require MA plans to adopt e-PA;
- Ensure that MA plans respond to PA requests within specific timeframes;
- Require public reporting on the use of PA;
- Support waiver or modification of PA requirements based on provider performance; and
- Recognize that health plans' proprietary interfaces and web portals through which providers submit their requests remain inefficient and burdensome.

We recognize that several areas of divergence between the CMS regulatory approach and the approach reflected in the bill relate to PA issues addressed in the e-PA Proposed Rule rather than in the 2024 MA Proposed Rule. However, to expedite adoption, we strongly urge CMS to include in the 2024 MA Final

[5] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; 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, etc. [CMS–0057–P] RIN 0938–AU87. 87 Federal Register 238 at 76238 (December 13, 2022).

Rule provisions that address several concerns addressed by both the Bill and the e-PA Proposed Rule. Specifically, the RRC urges CMS to adopt in the 2024 MA Plan Final Rule regulations and policy changes that mirror provisions in the *Improving Seniors' Access* bill and that can be implemented by MA Plans in their 2024 Contract Year.

- **Recommendation One: Deadlines for PA Decisions.** The RRC urges CMS to require MA Plans to respond to PA requests within the timelines set forth in the *Improving Seniors' Access* bill. While the Proposed Rule does not explicitly address PA deadlines, this issue is addressed — for MA plans and other health plans — in the e-PA Proposed Rule. While both the Bill and the e-PA Proposed Rule allow 7 days for a standard determination, the Bill requires MA plans to respond to an urgent PA request within 24 hours and the e-PA Proposed Rule establishes a longer deadline. To ensure that MA enrollees receive timely care in emergent situations and to ensure consistency between regulatory and potential legislative requirements, the RRC supports the 24-hour deadline for PA decisions in urgent situations. We also believe that MA plans have the technological capability to implement these deadlines in 2024, and that the MA Final Rule should require them to do so.

- **Recommendation Two: Transparency**. Both the Bill and the e-PA Proposed Rule would require MA plans to make available to the public certain data regarding their PA decisions, including, for example, the proportion of PA requests approved and denied, both initially and on appeal. The Bill and the e-PA Proposed Rule differ with respect to the data elements that must be disclosed, whether the data must be disclosed on an individual service basis and the manner of disclosure. For example, the Bill requires plans to disclose this information to CMS for public display and the e-PA Proposed Rule requires MA plans to self-disclose on their websites.

  The RRC believes that it is critical that PA data be disclosed on an individual service basis, as disclosure on an aggregate basis will likely be virtually meaningless to both providers and patients. Further, in order to facilitate access to this data during the open enrollment period, this data should be accessible, along with other MA plan data, on CMS' website. Health plans have the capability to provide this data (and, in fact, already do so on an individual service basis). We do not believe that transparency of PA decision making should be delayed until enactment of the Bill or until January 1, 2026, as proposed in the e-PA Proposed Rule. For this reason, we request that CMS include in the 2024 MA Final Rule transparency requirements that fully parallel those in the Bill.

- **Recommendation Three: E-Prior Authorization.** While the Bill would require MA plans to institute a real-time electronic prior authorization program for items and services that are frequently approved, the e-PA Proposed Rule does not include this requirement. We recognize that MA plans may not be able to institute such a program in their 2024 Contract Year, and the Bill itself would not require implementation until three years after enactment. However, we urge CMS to include in the 2024 MA Final Rule a provision that requires MA Plan 2024 Contract bids to include a plan for the implementation of real time decision making and a proposed timeframe.

II. Application of PA Requirements to Step Therapy and Drugs Covered under Part D

Together, payers, manufacturers, physicians and patients incur approximately $93.3 billion in costs annually to implement, contest and navigate utilization management.[6] We recognize that the statutory and regulatory requirements applicable to PA under Medicare Part D differ from, and in many respects are more comprehensive than, the PA requirements that historically have been applicable to other items and services provided by MA plans to enrolled beneficiaries. For example, PA restrictions imposed by Part D plans and MA plans offering Part D coverage require CMS approval, e-PA requirements already have been adopted for Part D prescription drugs, and an e-PA program is already required for Part D drugs.

Nonetheless, recent research suggests that there are significant disparities in access to drugs for minority populations covered by Medicare.[7] In addition, a recent study indicates substantial variation in step therapy protocols, and many step therapy restrictions are not supported by published clinical literature or practice guidelines.[8] Specifically, using data from seventeen of the largest US commercial health plans, the authors examined step therapy protocols that determined patients' eligibility for specialty drugs and identified ten diseases that are often subject to that requirement. Overall, plans applied step therapy in 38.9 percent of drug coverage policies, with varying frequency across plans (20.6–57.5 percent). Of the protocols for the ten diseases, 34.0 percent were consistent with corresponding clinical guidelines, 55.6 percent were more stringent, and 6.1 percent were less stringent. Trials of alternatives not included in the clinical guidelines were required in 4.2 percent of protocols, and the consistency of protocols varied within and across plans. The authors concluded that these findings raise questions about potentially overly restrictive step therapy protocols, as well as concerns that variability across health plans makes protocols onerous for patients and practitioners alike. Under these circumstances.

- **Recommendation Four: Part D Drug Step Therapy**. We do not believe that step therapy requirements are ever appropriate in situations where the patient has a terminal illness, such as cancer. We also request that CMS extend the transparency and other coverage requirements described in the Proposed Rule to Part D step therapy, formulary limitations, and other Part D drug coverage restrictions imposed by Part D sponsors, including MA plans. In particular, we believe that sponsors of Part D drug plans should be required to base PA criteria for drugs (as well as for other items and services provided to Medicare enrollees) on treatment guidelines or clinical literature that is made publicly available to CMS, enrollees and providers, and that Part D plan sponsors should be required to post a public summary of evidence that was considered in establishing PA drug criteria. Part D coverage should not be

[6] Payers spend approximately $6.0 billion annually administering drug utilization management, and manufacturers spend approximately $24.8 billion supporting patient access in response. Physicians devote approximately $26.7 billion in time spent navigating utilization management, whereas patients spend approximately $35.8 billion annually in drug cost sharing, even after taking advantage of manufacturer and philanthropic sources of financial support. https://www.healthaffairs.org/author/Howell%2C+Scott.

[7] Health Disparities and Patient Access Report. December 2022. Institute for Patient Access.

[8] Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler, James D. Chambers. Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans. Health Affairs (November 2021) https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.00822.

limited based on internal, proprietary, or external clinical criteria that are not disclosed both to the public and to the Medicare Program.

Furthermore, we are concerned that CMS asserts in this proposed rule that, "The requirements in the 2019 rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care." We respectfully disagree that the current allowances made for MA plan step therapy Part B drug protocols meet this standard, instead creating unnecessary burdens and irreparable consequences when it comes to the health and wellness of patients.

Numerous cases of patient harm due to the utilization of step therapy protocols have been documented and the beneficiaries receiving Part B covered drugs include some of the most vulnerable in the program.[9] As enrollment in MA plans rapidly grows, including Special Needs Plans,[10] addressing this barrier to care becomes increasingly urgent. The 2024 MA Final Rule presents an opportunity to reconsider the agency's position on step therapy of Part B drugs and ensure equitable access to care for MA beneficiaries.

- **Recommendation Five: Part B Drug Step Therapy.** We urge the Administration to protect patients' access to care and expeditiously reverse the harmful decision to allow MA plans to implement step therapy of Part B drugs through the 2024 MA Plan Final Rule. If that is not possible, we urge the Agency to reconsider the policy through e-PA rulemaking.

III. Continuity of Care

The Proposed Rule provides that MA plans must provide a minimum 90-day transition period when an enrollee switches plans. In addition, the MA Proposed Rule solicits comments on whether PA should be required to be valid for the duration of the prescribed order or ordered course of treatment.

The RRC strongly believes that approval should be valid for the duration of the prescribed order or ordered course of treatment. In this regard, we note that the payer-to-payer application programming interfaces that would be required under the e-PA Proposed Rule would facilitate implementation of this policy.

- **Recommendation Six: Continuity of Care.** The RRC recommends that when a Medicare beneficiary switches MA Plans, the predecessor plan's approval of a course of therapy should be valid for the duration of the prescribed order or ordered course of treatment.

IV. MA Plans' Use of Internal Coverage Criteria in addition to Requirements in Current Regulations.

[9] Boytsov, Natalie et al. "Impact of Plan-Level Access Restrictions on Effectiveness of Biologics Among Patients with Rheumatoid or Psoriatic Arthritis." PharmacoEconomics - open vol. 4,1 (2020): 105-117. doi:10.1007/s41669-019-0152-1.

[10] From 2000 to 2021 enrollment in Medicare Advantage Plans grew from 7 million to 26 million enrollees (73% increase). Special Needs Plans accounted for about 15% of total Medicare Advantage enrollment in 2021. Kaiser Family Foundation. (2021, June 21). *Medicare Advantage in 2021: Enrollment Update and Key Trends*. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2021-enrollment-update-and-key-trends/

MA plans require PA to ensure that items or services to be provided to enrollees are medically necessary. The Medicare Program Integrity Manual (at Section 13.5.4) defines the criteria to be used by Medicare Administrative Contractors (MACs) in determining whether an item or service is medically necessary for the purposes of Local Coverage Determinations. In making this determination, a MAC is required to consider whether the item or service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials National Coverage Determination (NCD) are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

We believe that the criteria used by MA plans in establishing coverage criteria for items and services for which there is no applicable NCD or Local Coverage Determination (LCD) should be limited to the three criteria that may be considered by a MAC in making an LCD and that MA plans should not be authorized to apply criteria other than those set forth above. To allow MA plans to utilize internal coverage criteria other than those used by MACs under the applicable Manual is inconsistent with the governing statute.

- **Recommendation Seven: No internal coverage criteria.** The RRC recommends that CMS limit the medical necessity criteria that may be used by MA plans to the criteria set forth in the Medicare Integrity Manual Section 13.5.4., as cited above.

V. Opportunity for Public Comment on MA Plan Coverage Determinations

The RRC strongly supports those provisions of the Proposed Rule that require MA plans to post public summaries of the evidence used in determining coverage and that preclude MA plans from relying on internal data or other sources not available to the public. We believe that requiring transparency with respect to the establishment of MA plans' coverage determinations has the potential to dissuade MA plans from establishing coverage restrictions that are clearly unsupported by any clinical evidence. However, we believe that making these summaries subject to public comment would enable MA plans to consider the views of experts in the field and would help ensure that coverage determinations are balanced.

- **Recommendation Eight: Public Comment on Coverage Criteria**. We recommend that MA plans' coverage determinations and supporting documentation summaries be subject to public comment utilizing the same procedural safeguards applicable to MACs' LCDs.

- **Recommendation Nine: Inclusion of any Applicable PA Requirements in MA Plan Coverage Policies.** The Proposed Rule requires that an MA plan's coverage policy with respect to an item or service not subject to an NCD or LCD must be made public, along with supporting medical documentation. However, it does not appear to require that the coverage document disclose whether PA is required. We recommend that coverage policies issued by an MA Plan be required to include disclosure of any applicable PA requirements, the effective date of any such requirements, and a list of the specific medical documentation that will be required for PA approval.

VI. Utilization Management (UM) Committee

In the Proposed Rule, CMS solicits comments on whether an MA plan's UM committee should be charged with ensuring that the UM policies and procedures are developed in consultation with contracted providers; whether the UM committee should ensure, as required by § 422.202(b)(2), that MA organization communicates information about practice guidelines and UM policies to providers and, when appropriate, to enrollees; and whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies.

- **Recommendation Ten: UM Composition**. We strongly believe that physicians participating in an MA plan's network should be well represented on the plan's UM Committee. In fact, the governing statute requires such participation.

- **Recommendation Eleven: UM Composition – Specialist Representation.** We appreciate CMS soliciting feedback on recommendations for other types of providers that should also be included on the UM committee. To ensure coverage policies reflect current practice patterns and the real-world experiences of clinicians and their patients, we believe it is critical that the plan's UM committee include at least one clinician, who is free from conflicts of interest, not employed by the plan, and who has current expertise in the use or medical need for that specific item or service.

- **Recommendation Twelve: Revision of UM Policies.** The Proposed Rule requires an MA plan to revise UM policies and procedures as necessary, at least annually. Please note, however, that the governing statute requires that an MA plan discloses to potential enrollees the services subject to PA "at the time of enrollment." Allowing MA plans to add PA requirements to additional services during the plan year would undermine the intent of this statutory provision. For this reason, we urge CMS to clarify that only new services not available at the time of enrollment can be added to the list of services that require PA.

- **Recommendation Thirteen: Pre-Existing MA Plan Coverage Policies.** The Proposed Rule indicates that an MA plan's UM committee must ensure that all coverage policies are approved prior to 2024. However, the Proposed Rule does not appear to specifically address the question of whether coverage policies that are currently in effect can be approved by the UM Committee if the coverage policy (along with clinical support) has not been publicly disclosed, as required elsewhere in the Proposed Rule. We recommend that the 2024 MA final rule clarify that MA coverage policies must be publicly disclosed, along with the supporting clinical literature, before the MA plan submits its 2024 bid. In addition, 2024 MA plan bids should include a certification signed by the plan's medical director (the

UM committee chair) that all the MA plan's coverage policies, including clinical support for those policies, have been disclosed.

VII. Peer-to-Peer Determinations

The Proposed Rule would require that physician or other appropriate health care professional who reviews a PA decision must "have expertise" in the relevant field of medicine before a PA request is denied. In this regard, the Proposed Rule requires the reviewing physician for a PA determination to have the same level of qualifications currently required for peer-to-peer reconsideration requests. However, for both PA decisions and reconsideration determinations, the Proposed Rule explicitly does not require the reviewing physician to be in the same specialty as the performing physician.

While we understand the scarcity of physicians available to conduct PA and reconsideration determinations, we are concerned that physicians utilized by MA plans to engage in peer-to-peer interactions are all too often unfamiliar with the services involved, and treating physicians spend altogether too much time providing health plan clinicians (who are not always even physicians) with basic clinical background.

- **Recommendation Fourteen: Specialty Qualifications of Reviewing Physicians**. The RRC recommends that CMS modify the Proposed Rule to require that reviewing physicians be in the same specialty as the treating physician for both all initial medical necessity determinations (including PA decisions) and reconsideration determinations.

- **Recommendation Fifteen: Scheduling Peer-to-Peer Consultations.** We also note that peer-to-peer consultations are typically scheduled at the convenience of the reviewing physician, resulting in significant inconvenience for treating physicians and their patients. We urge CMS to encourage MA plans to utilize modern telecommunications technologies to schedule and conduct peer-to-peer meetings and that these scheduled conversations occur when it is mutually convenient for the treating physician and the plan representative.

VIII. Payment for Approved Services

All too often, a physician obtains PA for a service only to find that the MA plan ultimately denies payment. The RRC firmly believes that if an MA plan provides PA for a service, the physician should be paid — no further questions asked. Any question related to the medical necessity of the service should be considered resolved once prior approval is obtained.

- **Recommendation Sixteen: Payment for Approved Services.** The RRC requests that CMS modify the applicable regulations to specifically state that the approval of a PA requests constitutes and "organization determination" which is considered final.

Issues also frequently arise when a physician obtains prior approval for a surgical or other procedure/service only to find during the surgery or procedure/service that, due to the patient's particular anatomy or other unforeseen circumstances, an additional medically related procedure(s) is required. In these cases, MA plans often deny these additional, medically necessary procedures or services. For example, a gastroenterologist may discover a polyp in a patient undergoing a routine colonoscopy that needs removal. It is unreasonable for the physician to contact the health plan while the patient is anesthetized to gain additional authorization. It is also inefficient, unreasonable, and

ultimately more expensive for the patient to schedule another appointment to remove the polyp.

- **Recommendation Seventeen: Incidental Surgical or other Procedures/Services.** The RRC requests that CMS make it clear that surgical or other procedures/services performed incident to a procedure that has received prior approval and that are medically related and necessary to furnish the approved procedure may not be denied for failure to obtain prior approval. The MA plan may subsequently choose to challenge the medical necessity of such incidental procedures but cannot peremptorily deny them for failure to obtain prior approval. In addition, the MA plan must cover and pay for the authorized services.

IX. Enforcement and Oversight

We very much appreciate the comprehensive, in-depth approach reflected in the Proposed Rule concerning the MA plans' establishment of coverage criteria and PA requirements. We believe that it may also be important for CMS to address in the final rule or in subregulatory guidance an explanation of how the agency intends to ensure that the MA plans implement the new requirements in a timely manner. For example, it is unclear what recourse will be available to patients and providers if an MA plan establishes a coverage policy that is more restrictive than the policy set forth in a NCD or applicable LCD, thereby effectively denying MA enrollees access to services that are covered for Medicare FFS beneficiaries in the same area.

- **Recommendation Eighteen: Oversight and Enforcement.** The RRC urges CMS to establish a plan for overseeing the implementation of the new requirements and to describe that plan in the preamble to the 2024 MA final rule. In this regard, we urge CMS to consider establishing a patient portal for patient and provider complaints about MA plan coverage policies and PA processes.

X. Need for Limit on Number of Procedures Subject to PA

We ask CMS to consider adopting policies that reduce the overall volume of PA requirements MA plans can impose on certain benefit categories, like basic Medicare benefits. We also ask CMS to address the increased use of peer-to-peer consultations and put in place guardrails to reduce the volume of these requirements. PA requirements inherently delay care — particularly since so few PA decisions are provided in real-time — and the only way to truly address care delays is to reduce the overall volume of PA requirements. A cornerstone of the *Improving Seniors' Access* bill is its provisions requiring CMS to establish a real-time decision-making process for routinely approved services. Such an approach would significantly reduce PA burden and care delays. Additionally, such standards would ensure that PA requirements are only imposed when there is a genuine risk of overutilization of an item or service that Medicare FFS would otherwise cover.

- **Recommendation Nineteen: Real-Time PA Decisions.** The RRC urges CMS to establish standards for real-time e-PA for routinely approved services consistent with the process outlined in the *Improving Seniors' Access* bill.

- **Recommendation Twenty: Exempting Physicians from PA.** We encourage CMS to require MA plans to implement processes that allow high-performing physicians to bypass PA altogether. For example, the GOLD CARD Act of 2022 (H.R. 7995) would exempt providers who received approval for 90% of their requests in the last 12 months from PA.

XI. Conclusion

The RRC appreciates the opportunity to comment on the Proposed Rule and looks forward to working closely with CMS to further refine regulatory requirements to ensure that all Medicare beneficiaries — whether enrolled in MA or covered under Medicare FFS — obtain equal access to covered benefits. If you have any questions or need additional information, do not hesitate to contact us.

Sincerely,

American Academy of Family Physicians
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Medical Rehabilitation Providers Association
American Osteopathic Association
Association for Clinical Oncology
Congress of Neurological Surgeons
Medical Group Management Association
North American Spine Society
Society for Cardiovascular Angiography and Interventions
The National Association for Proton Therapy