

March 13, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445–G  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: File Code CMS–0057–P. 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 Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program**

Dear Administrator Brooks-LaSure:

The Massachusetts Medical Society (MMS), appreciates this opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) on the Notice of Proposed Rule Making (NPRM) that outlines proposals to advance interoperability and improve prior authorization (PA) in Medicare Advantage (MA) plans, state Medicaid agencies and Medicaid managed care plans, Children's Health Insurance Program (CHIP) agencies and CHIP managed care entities, and issuers of Qualified Health Plans (QHPs) on the Federally-Facilitated Exchanges (FfEs) published in the *Federal Register* on December 13, 2022 (87 Fed. Reg. 76238).

The MMS largely supports the comments submitted by the American Medical Association (AMA), as detailed below. We further support the underlying goals in the AMA's [Recovery Plan for America's Physicians](#), which aims to address pivotal issues that hinder physicians' ability to provide optimal care and to seek fundamental changes to create a health system that better supports patients and the physicians who care for them. The plan outlines five pillars that strengthen our physician workforce, recover from the trauma of the pandemic, and improve health care delivery by eliminating some of the most common burdens that threaten to drive physicians from practice. These include:

- Fixing PA to reduce the burden on practices and minimize dangerous care delays for patients.
- Reforming Medicare payment to promote thriving physician practices and innovation.
- Fighting scope creep that threatens patient safety.
- Supporting telehealth to maintain gains in coverage and payment.
- Reducing physician burnout and addressing the stigma around mental health.

The MMS thanks CMS for acknowledging the concerns of physicians, as well as those of our patients, in this NPRM. As CMS notes, “[every] reader of this proposed rule is a patient and has received, or will receive, medical care at some point in their life,” and we commend CMS for the patient-centric focus of this rule. Specifically, we appreciate several meaningful proposals addressing significant PA reforms. As commented in greater detail below, the policy changes outlined in the proposed rule align with MMS policy and will significantly improve PA in MA and other impacted programs. **We appreciate that CMS recognizes the burdens associated with PA programs and urge you to adopt these policies as written,**

**or with the strengthening recommendations detailed below, to support judicious, transparent, and clinically appropriate use of PA that protects patients' access to treatment.**

The following outlines our principal recommendations on this proposed rule:

- The MMS strongly supports inclusion of MA plans in the scope of this rule but urges CMS to leverage a regulatory pathway that will apply to all health plans when mandating PA-related implementation guides and transaction standards in any future rulemaking.
- The MMS encourages CMS to further explore the need to designate an electronic transaction standard for drugs covered under a medical benefit.
- MMS supports the requirement for health plans to provide a specific reason for a PA denial but recommend that CMS strengthen this provision to ensure that the information is understandable and outlines clear, actionable next steps.
- The MMS recommends that CMS shorten the required PA processing timeframes to 48 hours for standard PAs and 24 hours for expedited PAs to protect patient safety.
- We strongly support the public reporting of PA program metrics but urge CMS to require plans to report these data at a more granular level and to require posting of the information on a centralized website (e.g., CMS webpage) to enable easy retrieval by physicians and patients.
- The MMS supports encouragement and exploration of gold-carding programs and urges CMS to include offering of these programs as a measure in star quality rating programs.
- The MMS recommends that CMS create a formal oversight, audit, and enforcement process to promote accountability and ensure appropriate implementation of the rule's provisions, when finalized.
- The MMS supports CMS' efforts to increase patient access to their medical information through health plan-enabled and maintained application programming interfaces (APIs). The MMS urges CMS to consider how its policies can better strengthen patients' data privacy while limiting physician burden.
- The MMS supports CMS including requirements on health plans to exchange data with physicians using APIs. The MMS suggests that CMS consider how its health plan API requirements align with 21st Century Cures Act requirements around information sharing.
- The MMS supports CMS' policy to require that health plans implement information exchange over APIs to support better-coordinated care as patients transition between plans. The MMS supports requiring health plans to honor the PA approvals from patients' previous health plans to support continuity of care and protect patients from potentially dangerous disruptions in ongoing therapy.
- Importantly, the MMS strongly opposes adding burden to physicians and their staff, including by linking electronic PA (ePA) requirements to CMS' Quality Payment Program (QPP). It is unclear why CMS would tie a physician's success in the QPP to untested ePA technology when CMS' stated goal is to reduce physician burden, minimize PA-related costs, and lessen medical staff time requirements.

## **Improving PA Processes: Response to NPRM Scope and PA Policy Proposals**

### *Scope of NPRM*

The MMS advocates for a holistic, cross-program approach to PA reform. While we support automation of the PA process, as proposed in this NPRM, any successful solution must address *both the PA process and underlying decision-making*. Indeed, without addressing the underlying clinical criteria and PA program policies, even the most streamlined electronic PA system will fail both patients and physicians while simply delivering a faster, but inappropriate, denial. **We therefore urge CMS to finalize the critical policy reforms that will ensure the clinical validity of PA programs and protections for continuity of care**

**proposed in the CY2024 Part C and Part D NPRM, as detailed in the sign-on letter of support led by the AMA and signed by the MMS and 118 other state medical associations and national medical specialty societies.<sup>1</sup>**

**We strongly support CMS’ proposal to extend the provisions of this rule to MA plans.** The growing number of seniors enrolled in MA plans—with the most recent number totaling over 31.2 million patients<sup>2</sup>—reinforces the need to include this population in CMS’ PA improvement efforts. Beyond the sheer volume of patients in the MA program, several recent analyses flag major concerns with MA PA programs, further strengthening the case for including these plans in rulemaking. An HHS Office of Inspector General 2022 report found that 13 percent of PA requests denied by MA plans met Medicare coverage rules, and 18 percent of payment request denials met Medicare and MA billing rules.<sup>3</sup> More recently, a Kaiser Family Foundation (KFF) analysis found that MA plans denied two million PA requests in whole or in part in 2021, representing about six percent of the 35 million requests submitted that year.<sup>4</sup> While only about 11 percent of PA denials were appealed, the vast majority (82 percent) of appealed denials were fully or partially overturned, raising serious concerns about the appropriateness of many of the initial denials. Finally, beneficiary disenrollment in MA plans averaged 17 percent in 2021, increasing from an average of 10 percent in 2017;<sup>5</sup> this high voluntary disenrollment rate suggests that MA plans may not be meeting patient’s needs due to PA requirements or other coverage limitations. **Taken in sum, these data support the need to include MA plans in the scope of this NPRM, as well as to finalize the provisions related to clinical criteria and care continuity proposed in the CY 2024 Part C/Part D NPRM.**

While we appreciate that CMS has extended the scope of this NPRM to include MA organizations, we note that a large number of Americans are covered by health plans outside the purview of the rule. We are specifically concerned regarding provisions that would create requirements for electronic data exchange for PA for just the impacted plans. While CMS only recommends (vs. requires) adoption of certain HL7 Fast Healthcare Interoperability Resources (FHIR) implementation guides to meet these requirements, we are concerned that this lays the foundation for insurers to utilize different electronic transaction standards to support PA, based on plan type. As noted by a recent KFF analysis, “the promise of a more connected health system will likely require similar standards across plans, but the proposal does not reach the more than 150 million Americans in employer-sponsored coverage.”<sup>6</sup> While CMS encourages plans not in scope of the NPRM to voluntarily adopt the same electronic PA technology, the MMS is concerned that mandating electronic standards via regulation other than the traditional Health Insurance Portability and Accountability Act (HIPAA) administrative simplification pathway will lead to an untenable, fragmented approach to PA automation across payers, which will increase, rather than reduce, physician practice burdens. The recent release of another NPRM addressing electronic attachment transaction standards for both claims and PA

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<sup>1</sup> February 13, 2023, sign-on letter to CMS Administrator. Available at: <https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FPA-sign-on-letter-Part-C-and-D-rule.zip%2FPA-sign-on-letter-Part-C-and-D-rule.pdf>.

<sup>2</sup> CMS Contract Summary February 2023. Available at: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldata/monthly/contract-summary-2023-02>.

<sup>3</sup> Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>.

<sup>4</sup> Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021. <https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021>.

<sup>5</sup> Commonwealth Fund. Medicare Advantage Disenrollment Rates Can Help Beneficiaries Make Informed Decisions. Available at: <https://www.commonwealthfund.org/blog/2023/medicare-advantage-disenrollment-rates-can-help-beneficiaries-make-informed-decisions>.

<sup>6</sup> Kaiser Family Foundation. CMS Prior Authorization Proposal Aims to Streamline the Process and Improve Transparency. Available at: <https://www.kff.org/health-reform/issue-brief/cms-prior-authorization-proposal-aims-to-streamline-the-process-and-improve-transparency/>.

under HIPAA administrative simplification provisions elevates these issues,<sup>7</sup> as health plans may elect to adopt the standards proposed in the attachments NPRM instead of the FHIR-based technology proposed under the current rule. **For these reasons, the MMS urges CMS to leverage a regulatory pathway that will apply to all health plans when mandating PA-related implementation guides and transaction standards in any future rulemaking.**

The MMS strongly believes in the “right-sizing” of PA and the critical need for a reduction in the overall volume of items and services requiring authorization. Indeed, increasing PA in Medicare FFS would be out of alignment with industry-wide agreement on the need to selectively apply PA to only outlier physicians or services showing a consistent variation in ordering patterns or low approval rates. **To protect timely access to care for Medicare FFS beneficiaries, we urge CMS not to proceed with any expansion of PA in traditional Medicare.**

Of note, CMS excludes drugs of any type from the PA-related provisions of this NPRM because “processes and standards for [PA] applicable to drugs differ from the other ‘items and services’” addressed. While we agree that the workflow for ordering medical services differs from the prescribing process for outpatient drugs, our understanding is that the NCPDP SCRIPT ePA standard is not being used to exchange data for drugs covered under a medical benefit. As such, excluding all drugs from the provisions of this NPRM leaves a sizable gap, as many medications administered by physicians or covered under a medical benefit are subject to PA requirements. Indeed, 99% of MA beneficiaries were enrolled in a plan that required PA for Part B drugs in 2022.<sup>8</sup> The steady introduction of life-saving—but costly—specialty medications for conditions such as cancer and autoimmune diseases underscores the need for an automated, efficient electronic PA process for drugs covered under a medical benefit. Similarities in the process for ordering these office-administered drugs and other items and services suggest that the FHIR-based technology referenced in this NPRM may be an appropriate electronic PA solution for these medications. **We urge CMS to further research this issue by engaging with EHR vendors and the relevant standards development organizations (i.e., NCPDP and HL7) to determine the appropriate PA automation solution for drugs covered under a medical benefit.**

#### *Feedback on CMS’ PA Policy Proposals*

**The MMS applauds CMS for recognizing the need for important guardrails in PA programs to protect beneficiaries from unreasonable barriers to medically necessary care.** The policy changes outlined in the proposed rule address several of the reforms contained in the PA Principles and Consensus Statement mentioned above and have the potential to significantly improve PA in the impacted plans. **We urge CMS to adopt these policies with the strengthening recommendations detailed in the AMA’s comments, and highlighted below, in order to improve the transparency of PA programs and ensure that PA does not create a barrier to medically necessary care for patients.**

a) Reason for denial of PA

To prevent care delays and subsequent patient harms, we urge CMS to strengthen this provision and specify that impacted health plans must provide all the information detailed in AMA PA Principle

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<sup>7</sup>Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard. Available at: <https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and>.

<sup>8</sup>Kaiser Family Foundation. Medicare Advantage in 2022: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. Available at: <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/>.

#11 to ensure that the information included in PA denials is understandable and outlines clear, actionable next steps.

b) Requirements for PA Decision Timeframes and Communications

We urge CMS to require standard PAs be processed within 48 hours and expedited PAs within 24 hours, and we call special attention to the urgent PA processing timeframe: when care is urgent, 72 hours is simply not a safe amount of time to wait to receive approval for coverage. We also note that by requiring shortened timeframes for PA decisions, CMS will incentivize physicians to adopt electronic PA technology. We further urge CMS to strengthen this provision by requiring plans to provide a final PA determination within the mandated timelines. We also request that CMS set the PA processing timeframe for QHPs on the FFEs to 48 hours for standard PAs and 24 hours for expedited cases.

c) Public Reporting of PA Metrics

We commend CMS for proposing improved transparency in health plans' PA programs through public reporting of metrics and agree that this will both encourage improvement in PA processes as well as support informed decision-making for patients selecting a plan. The utility and value of this public reporting could be strengthened with the following enhancements:

- Along with publishing a list of the items and services that require PA, impacted plans should also be required to **disclose their PA clinical criteria**.
- While we agree that aggregated PA data can be useful, we urge CMS to require reporting of this information at a **more granular level**, such as by item or service, or at least by category of service (e.g., imaging, physical therapy, etc.), which would allow physicians to evaluate a plan's PA performance for services relevant in their specialty and prospective patients to assess the plan based on PA metrics related to their clinical condition prior to enrollment.
- We are concerned that both physicians and patients will struggle to locate PA program metrics on payers' websites. Accordingly, we recommend that these data be **published on a centralized, public website**—such as a CMS webpage—to ensure easy access to the information, as well as facilitate comparison between plans. We also note that requiring submission of these PA program metrics to CMS for collation and publication would also support the enforcement of this NPRM's provisions, as we recommend later in this correspondence.
- **Finally, we strongly urge CMS to make payer public reporting requirements effective immediately upon finalization of this rule.** Waiting until 2026, as proposed, would unnecessarily delay CMS' efforts to promote transparency. Immediate availability of these metrics will be invaluable in establishing a baseline to evaluate improvements in PA after the other requirements outlined in this rule become effective. In particular, this benchmarking will allow the industry to assess the value and impact of electronic PA technology.

d. Gold-carding Programs for PA

The MMS supports CMS' encouragement of gold-carding programs, which would exempt physicians with track records of high approval rates from a health plan's PA requirements, limiting administrative burden in effective and measured fashion. The MMS looks forward to working with CMS to develop meaningful guidelines for gold-carding programs that would reduce the volume of PAs to the benefit of patients, physicians, and health plans. We welcome the opportunity to

work with CMS on ensuring that gold-carding programs benefit the diverse patient populations served by the impacted health plans.

#### *Additional program enhancements*

**The AMA sincerely appreciates CMS' efforts to address the significant challenges that PA poses for both patients and physician practices.** We hope that CMS continues to evaluate additional opportunities for PA reform when finalizing this rule and in future rulemaking. Specifically, we request that CMS adopt the following changes to further improve PA programs in impacted health plans:

- PA-related care delays can be especially devastating for patients with substance use disorders. For this reason, we urge CMS to require health plans to provide all forms of medications for opioid use disorders without PA or other UM requirements that create care barriers and delays.
- We reiterate that CMS should strongly encourage harmonization in PA data sets across payers to make the technology proposed in this rule scalable across a large number of health plans, medical services, and PA criteria.
- To ensure full realization of the value of these proposed improvements to PA programs, we urge CMS to create a formal oversight, audit, and enforcement process to promote accountability and ensure that these provisions, when finalized, are appropriately implemented.

Thank you for the opportunity to provide input on this proposed rule and addressing the challenges that PA poses for both patients and our physician members. The MMS stands behind the detailed recommendations withing the AMA's comments on PA and welcomes the opportunity to discuss additional changes that CMS could consider to further improve PA programs to ensure patients' access to timely care.

With regard to the Requests for Information relating to interoperability, the MMS supports expediting standardization and implementation of interoperability of electronic systems while improving usability. We thank CMS for soliciting input and encourage continued collaboration with physician organizations to ensure that regulations promoting interoperability are developed in cooperative fashion. To the extent that the AMA's comments align in this regard, specifically in Appendix B of their comments, the MMS supports those comments. Specifically, MMS supports the following:

#### **Request for Information: Improving the Electronic Exchange of Information in Medicare Fee-for-Service (FFS)**

- We urge CMS to work across HHS, especially with ONC, on a broader education program about the United States Core Data for Interoperability (USCDI) and how all health system participants are leveraging USCDI data classes and elements to better exchange patient health information.
- CMS should explore applying the proposed requirements for the Patient Access API and Provider Access API to the Medicare FFS Program. These steps would be hugely impactful for coordination of patient care and exchange of medical information for all Medicare Beneficiaries.

#### **Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health**

##### Improving Prior Authorization for Maternal Health

- Given our mutual goal to enact meaningful reforms that are health equity centered, taking an aggressive stance on PA reform to help improve maternal outcomes is paramount. The time-

sensitive nature of pregnancy means that any delay in obtaining necessary care can have devastating consequences for maternal health.

#### PA Processing

- In the context of utilization management, we urge CMS to treat services related to pregnancy care as urgent and mandate that the PA processing timeframe for a final determination for this care be 24 hours.

#### Continuity of Care

- We encourage CMS to adopt a continuity of care provision that would protect pregnant women from harms resulting from disruptions in ongoing care, treatment delays, and unanticipated medical costs. Furthermore, we urge CMS to require any and all PA approvals to remain valid for the duration of the pregnancy, regardless of a plan change.

#### Benefits

- It is critical to include postpartum care in all reforms related to maternal health PA policy. Given that Medicaid and CHIP now require coverage for 12 months after pregnancy,<sup>9</sup> we urge CMS to require PA approvals for postpartum care to extend 12 months after pregnancy, regardless of a plan change.
- The MMS strongly supports preserving access to evidence-based reproductive health care services and opposes any effort to undermine the basic medical principle that clinical assessments, such as viability of the pregnancy and safety of the pregnant person, are determinations to be made only by health care professionals with their patients. Considering the crisis to abortion access following the United States Supreme Court's decision in the *Dobbs v. Jackson Women's Health Organization* case, we strongly urge you to consider how PA can impede access to abortion services.
- The MMS recognizes that health care, including reproductive health services like abortion, is a human right. As such, the MMS recommends that CMS lift PA requirements for abortion care/medical management related to termination.

#### Advancing Interoperability for Maternal Health

- Standardization is the first step in forming robust research datasets and is especially important for studies on maternal health. The MMS supports the collection of data related to maternal health. Yet, the current lack of data availability and standardization, limited research on data collection practices, and piecemeal implementation of sources and tools should be addressed. While progress has been made, there remain opportunities to improve the collection, linkage, and analysis of data collected at the point of care.
- Data must also be of high quality to improve maternal health outcomes and support research on the effectiveness of maternal health care services and interventions. These data are necessary to develop strategies and evidence-based practices to prevent disease conditions that contribute to poor obstetric outcomes, maternal morbidity, and maternal mortality.
- Maternal health and child health are inextricably linked, but relevant data is often held in separate, unconnected health records. Models are being developed to support data exchange for predictive analysis, risk assessment, and retrospective maternal health research. CMS should work with data

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<sup>9</sup> <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-announces-more-half-all-states-have-expanded-access-12-months-medicaid>.



model developers to identify risk factors for maternal mortality and poor maternal and infant health outcomes. Data standards must facilitate data linkages between individuals and their infants' health.

- Federal policies should support the development and implementation of a maternal mortality surveillance system.
- Standards are also needed to support physician collection of patient-identified race and ethnicity information to better identify inequities. Better EHR data in clinical settings and standardized across health systems is essential for meaningful and unbiased research.

#### Data Standardization, Harmonization, and Gaps

- It is essential that maternal mortality and maternal morbidity have a standard definition across all federal, state, local, and private organizations. This way, data that is collected at the local, state, federal, and even international level can be integrated, and a more complete picture of maternal health can be discovered.

#### Data Standardization and the United States Core Data for Interoperability (USCDI)

- We urge CMS to set a goal of standardizing data capture for comparative analysis over time to improve health outcomes.

#### Data governance and privacy

- As more data are collected, data protection and security must also be considered. Prior to initiating a data collection effort or expanding the type of data collected, CMS must first evaluate if the necessary technical, governance, and legal protections are in place to maintain an individual's privacy and trust.
- An effective data governance infrastructure is needed to ensure maternal health data are consistent, trustworthy, and not misused. CMS must consider what steps it can take to reassure individuals that their personal information, including maternal and infant health information, remains private and secure.
- CMS' efforts to increase maternity health information exchange should ensure patient data are protected, safe, and secure.
- Data privacy and data information exchange are not mutually exclusive. CMS' data collection efforts must be grounded by patient data protection and policies must guard against data misuse. Therefore, we urge CMS to encourage both data privacy and data information exchange with equal emphasis.

Thank you for the opportunity to provide input on these Requests for Information. The MMS welcomes the opportunity to partake in discussions with CMS to consider ways to further improve interoperability and PA programs in order to ensure patients' access to timely care. Please do not hesitate to reach out with any questions or for more information on the MMS' perspectives on these issues. You can reach MMS' Federal Relations & Health Equity Manager, Casey Rojas, at [CRojas@mms.org](mailto:CRojas@mms.org).

Thank you.