



NATIONAL HEALTH COUNCIL

March 13, 2023

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue S.W.  
Washington, D.C., 20201

Re: CMS-0057. 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, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Dear Secretary Becerra:

The National Health Council (NHC) is pleased to provide the following comments in response to the proposed rule on interoperability and prior authorization in federal health plans. We appreciate that CMS is undertaking this rulemaking process to address issues that can pose barriers to timely access to care for patients. Both increasing the interoperability of health information and streamlining the prior authorization process are of great importance to patients. We encourage you to work with patients, providers, and insurers to build an infrastructure that achieves the goals set out in the proposed rule.

Created by and for patient organizations more than 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 150 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

Increased use of electronic health records, combined with interoperability initiatives, can improve the quality and efficiency of care for all patients and facilitate continuity of care, giving individuals with chronic diseases and disabilities the ability to drive their care plan to best achieve their health care goals. These benefits, however, are not without potential risk to an individual's privacy with respect to their health status and care; such risks must be properly monitored and mitigated with well-crafted guardrails.

The NHC shares CMS's goal of removing inappropriate barriers to care by streamlining prior authorization and other utilization management processes. While some utilization management protocols may be grounded in sound clinical decision making, such as prior authorization to limit drug-to-drug interactions or to prevent overprescribing of potentially addictive medication, the development of such protocols is typically done without much or any patient input, and the rationale for such decisions is not typically made public. As a result, the chronic disease and disability community has become greatly frustrated by the additional burden placed on patients, families, and health care providers. We support oversight and transparency of such practices to inform the patient community as to how decisions are made that have such a direct impact on patients.

### **Need to Address Utilization Management Broadly**

While we believe this proposed rule represents an important step forward, it is important to frame this initiative in the broader context of the challenges patients face from utilization management. Prior authorization is but one method of utilization management, and increasing use of electronic prior authorization is only one needed element of improving prior authorization for patients. For example, it is our hope that the infrastructure built to support electronic prior authorization will eventually also allow for the flow of information about step therapy so that if a patient changes providers or payers they will not have to repeat a step therapy protocol once stabilized on a treatment.

We also note this rule specifically does not apply to prescription drugs. The NHC encourages CMS to address barriers to access that prior authorization and other utilization management practices present for patients who need access to necessary prescription drugs. As we implement this rule, CMS should consider how the new infrastructure can support further expansion to reduce barriers to access to needed medicines.

In previous comments<sup>1</sup>, the NHC has requested that CMS consider the following recommendations to lead to more transparent and consistent utilization management processes by reducing the amount of time and resources providers and patients spend navigating the process and promote quicker patient access to needed therapies. Several are addressed in this rule or the recent CMS rule on prior authorization in Medicare Advantage (MA), and several are still outstanding:

- Addressed in this rule or addressed for the MA population in recent MA Rule:
  - Ensure that utilization management protocols, including step therapy and prior authorization, are aligned with clinical guidelines as well as peer-reviewed clinical studies when updated guidelines are unavailable;
  - Ensure that patients do not have to repeatedly “clear” prior authorization and step-therapy hurdles each year or each time they change plans;

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<sup>1</sup> [NHC Comments on Medicare Advantage RFI - National Health Council](#)

- Retain CMS' current limitation that step therapy cannot be applied to patients that are stable on their treatments;
- Clarify that plans must grant an appeal, authorization, or exceptions request when certain circumstances are met that are in the best interest of the patient and clinically appropriate; and
- Adopt electronic prior authorization standards for clinicians and plans to use to minimize burden and streamline the process.
- Still outstanding or partially addressed:
  - Ensure that plans respond to utilization management appeals, prior authorizations, and step therapy exceptions requests as quickly as possible, with a goal of responding within 24 hours for emergencies, and within 72 hours for all other circumstances;
  - Require plans to get formulary feedback from people with chronic diseases and disabilities and well as clinical experts in geriatrics and care for disabled populations;
  - Increase plan accountability for utilization-management tools by reducing opportunities for PBMs to generate a revenue stream for implementing them; and
  - Ensure that each level of appeal and reconsideration is a meaningful opportunity for the clinician and patient to demonstrate medical necessity.

We appreciate that several of these goals are addressed in this proposed rule, yet there is still work to be done. We support efforts by CMS to continue to achieve these goals.

### **Stakeholder Engagement**

As CMS moves forward in developing interoperability and electronic prior authorization standards, we urge you to continuously engage with stakeholders, including patients with chronic diseases and disabilities, so that the new systems that are created meet patient needs. CMS should also engage with providers to support their ability to quickly provide needed care to their patients and engage providers and payers to help them manage the navigation of new prior authorization systems. This outreach and engagement should afford CMS the opportunity to develop methodology in collaboration with stakeholders and create a feedback loop to identify any unintended barriers that may arise as we transition to new standards.

### **Notification Timetable and Format for Prior Authorization Decisions**

In the proposed rule, CMS requires that prior authorization decisions be delivered within 72 hours for expedited requests and seven calendar days for standard requests. However, CMS also asks about the possibility of creating a standard that requires 48 hours for expedited requests and five calendar days for standard requests. The patient

groups in our membership support a shortened timeframe of 48 hours/five days<sup>2</sup>. When you are in need of urgent treatment three days of waiting for a decision can be excruciating and for some conditions such as cancer or rapidly progressing diseases can lead to irreversible worsening of health. Achieving the shortest timeframe possible should be the goal. If CMS can go further and work with providers and plans to build an infrastructure to achieve a standard of 72 hours for standard requests and 24 hours for expedited requests to align with Medicare Part D standards, we would support that.

The proposed rule also requires that denial notices include a specific reason of why the request was denied. We support efforts to assure that patients and providers have access to clear and actionable information about denials. We urge CMS to be as specific as possible about what information must be included in a notice of denial and that it must be specific, complete, actionable, and communicated to patients in plain language. It would be helpful if CMS were to develop a national consistent set of denial codes. The information about reconsiderations must also be accessible particularly to those with limited English or digital proficiency or access.

### **Patient Privacy Protections**

The NHC supports the goal of increasing interoperability so that patients can more easily move their information from provider to provider and plan to plan as they move through the health care system. Increased interoperability will remove many barriers that patients face including having to restart prior authorization processes and physically moving records from one provider to another such as picking up x-rays and having to deliver them to their various doctors.

The NHC urges CMS to prioritize patient privacy protections as we move towards increased operability. While the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) should protect patients through most of these exchanges, third-party application developers that received data through the Patient Access API should be subject to comparable protections as under HIPAA. While CMS states in the proposed rule that “a payer may ask third-party application developers to attest to certain privacy provisions, such as whether their privacy policy specifies secondary data uses and inform patients about those attestations,”<sup>3</sup> we urge greater privacy protections and transparency about the use of data by third-party applications. These applications have become so entwined in the health care system, it is important that patients trust and know how their data will be used by anyone that will have access to it. CMS should require standards and transparency about data use by third-party apps and create plain language resources for patients and providers to understand their privacy rights.

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<sup>2</sup> We understand payers have expressed concern about the feasibility of the shorter timeframe, given the need to fully transition to electronic prior authorization. As of now, many of these exchanges are still done through fax or other methods. The shorter timeframes will be more achievable once we fully move to electronic prior authorization.

<sup>3</sup> [Interoperability and Patient Access Fact Sheet | CMS](#)

### **Prior Authorization Metrics**

The NHC appreciates CMS efforts to increase access to information about prior authorization practices. We ask that CMS require that this information be publicly available in accessible, plain language formats with enough specificity to be useful to patients in making health care decisions. For example, information about the total number of denials may not be sufficient to help patients make informed decisions. Additional information such as aggregated data about the reasons for denials and the types of services and procedures most often denied might be more useful metrics. Overall, the greater the level of transparency and specificity in these metrics, the more useful the data will be to patients and advocates.

### **RFI on Social Risk Factors**

It is critical that we ensure all plans are collecting demographic data that is comprehensive and consistent including data on things such as sexual orientation, gender identity, race/ethnicity, disability status, language, veteran status, and social needs (potentially through improved and better-utilized medical billing Z codes that document SDOH data such as housing status, food insecurity, transportation access, etc.). It is important this be done in a way that protects patients' privacy and rights.

### **Support for Providers and Patients**

As with any significant change in the health care marketplace, this transition will take an investment from CMS and others in the health care ecosystem to help patients and providers navigate these changes. Providers will need support in transitioning to electronic systems and assuring they have the infrastructure to support this new format. Patients will need education to understand the new formats of information as how they will be delivered. There are significant changes all happening at the same time throughout the health care system due to the end of the public health emergency and the implementation of the Inflation Reduction Act. Patients and providers are navigating these changes, and CMS must provide the needed education to make sure these changes are successful.

### **Need for Data Standards Consistency**

On December 21, 2022, CMS released a proposed rule on Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard<sup>4</sup>. While that proposed rule calls for an X12-based exchange, this proposed rule calls for a FHIR-based exchange. We are concerned that these variations may cause confusion and delay in building an

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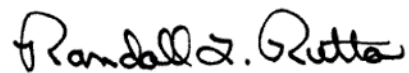
<sup>4</sup> [Federal Register :: Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard](#)

interoperability infrastructure. We encourage CMS to clarify these standards and provide guidance on achieving consistent standards in an efficient and timely way.

### **Conclusion**

Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive style with a large initial 'R'.

Randall L. Rutta  
Chief Executive Officer