NATIONAL HEALTH COUNCIL

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January 4, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: CMS-9123-P Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for 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; Health Information Technology Standards and Implementation Specifications

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule refining prior authorization processes in Medicaid and Children's Health Insurance Program (CHIP), and for issuers of qualified health plans on the Federally facilitated exchanges (the Proposed Rule).

Created by and for patient organizations 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 140 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, and payer organizations.

The NHC appreciates CMS' efforts to reduce longstanding inefficiencies in the health care system, including those associated with limited data sharing, and overly burdensome and opaque prior authorization processes.

Our comments focus on these important areas:

- Reducing provider burden and patient delays associated with prior authorization (PA) processes;
- Exclusion of prescription drugs and covered outpatient drugs;
- Medicare Advantage; and
- Balancing access to health information with patient privacy.

The following is our specific response to the details of the Proposed Rule.

Reducing provider burden and patient delays associated with prior authorization (PA) processes.

The NHC applauds CMS for its proposals to remove inappropriate barriers to care by streamlining prior authorization processes and increasing transparency on 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 [collectively, impacted payer(s)] use of this utilization management tool. We agree with CMS' assessment that, while prior authorization can be a helpful tool for reducing overutilization of inappropriate care, it can also be an overly-burdensome process leading to dangerous delays in treatment, diverting clinician time away from patient care, and general inefficiency. For individuals with chronic diseases and disabilities, onerous prior authorization and step therapy processes can create significant barriers to timely, appropriate care and negatively impact patient health outcomes.

The NHC views CMS' Proposed Rule as an important initial step toward increased transparency and reduced provider burden and encourages the Agency to further refine its proposals prior to finalization. The recommendations below are intended to streamline the prior authorization process and ensure providers and patients quickly get the information and approvals they need to access appropriate care. Specifically, the NHC:

- Supports CMS' proposal to require that impacted payers build and maintain a Fast Healthcare Interoperability Resources (FHIR)-enabled document-requirement lookup-system (DRLS) application programming interface (API) capable of integration with provider electronic health-record (EHR) systems. This requirement would enable providers to electronically locate prior-authorization requirements for each impacted payer and improve efficiencies across the health care system. The NHC agrees that impacted payers must be transparent about

all coverage restrictions and the supporting clinical documentation needed to meet utilization-management requirements.

- Applauds CMS' proposal to require that impacted payers develop and maintain an interoperable electronic Prior Authorization Support API so that payers can send prior authorization requests to providers and receive responses electronically.
- Urges CMS to refine its proposal to require that impacted payers include a specific reason for any prior authorization request denial. The NHC is concerned that the term "specific reason" is subject to varying interpretation. CMS provided examples of payer explanations that would meet the requirement of a "specific reason" for denial, including that documentation was not provided, the patient had exceeded allowable limits, or that the item or service are not determined to be medically necessary. We urge CMS to refine its regulatory language to provide clarity and ensure that the information providers receive from impacted payers is sufficiently granular to inform next steps, including identification of any covered alternative treatments as well as appeal options.
- Encourages CMS to shorten the time period within which impacted payers must send their prior authorization decisions to providers. Prompt access to care is particularly critical for individuals with chronic conditions, as well as those requiring a procedure or other treatment. The 72-hour period for urgent requests and seven days for standard requests does not go far enough to facilitate prompt access to care. We urge CMS to further reduce the allowed time period for payer decisions by, for example, creating three (rather than two) time sensitivity categories and permitting 24 hours for urgent requests, three calendar days for time-sensitive requests, and seven calendar days for standard requests.
- Urges CMS to require impacted payers ensure that an approved prior authorization remain valid for a sufficient time period to allow patient access to care. This is particularly important for patients requiring medical procedures that must be scheduled and approved for coverage well in advance of the treatment date.

Exclusion of prescription drugs and covered outpatient drugs.

CMS specifically determined to exclude prescription drugs and/or covered outpatient drugs from the provisions of the Proposed Rule. The NHC has significant concerns that this decision will substantially reduce the utility of the Proposed Rule in reducing patient and provider burden and care delays associated with impacted payer use of prior authorization. We urge CMS to utilize the time available between promulgation of this proposal and the anticipated 2023 implementation date to assess and address any complicating factors that would substantiate the inclusion of prescription drugs.

Individuals with chronic diseases and disabilities, and their treating providers, often find that the greatest level of burden and uncertainty is associated with payer coverage for prescribed and administered medications. Incorporation of accurate formulary data and prior authorization and step therapy requirements into electronic health records (EHRs)

is absolutely critical to ensure that providers have the information they need at the point of care. When prescription claims are rejected at the pharmacy due to unmet prior authorization requirements, treatments are delayed or completely abandoned. Provider access to after-the-fact data on claims submission is only helpful if it is available in real-time and contains the type of information CMS proposes to require for all other items and services. We strongly urge CMS to apply the prior authorization process requirements in the Proposed Rule to prescription drugs and covered outpatient drugs.

Medicare Advantage.

The NHC urges CMS to include Medicare Advantage plans within its set of impacted payers. CMS has finalized policies through its recent Interoperability and Patient Access final rule[1] requiring Medicare Advantage Organizations to build and maintain APIs that provide the foundation for the requirements of this Proposed Rule. The additional burden to Medicare Advantage organizations, if any, appear to be minimal, particularly in light of CMS' observation that most of these entities maintain lines of business that are subject to the requirements of the Proposed Rule.[2]

As CMS noted, the Proposed Rule, "if finalized, would create misalignments between Medicaid and Medicare that could affect dually eligible individuals enrolled in both a Medicaid managed care plan and an MA plan." The NHC has significant concerns that the identified misalignments are most likely to affect the most vulnerable patients and believes this factor alone is a sufficient rationale for applying the policies in the Proposed Rule to Medicare Advantage organizations.

Balancing access to health information with patient privacy.

The NHC appreciates that CMS recognizes the patient privacy considerations impacted through increased sharing of health care data across multiple entities. CMS has previously noted that a clear, plain-language privacy policy is the primary way to inform patients about how their information will be protected and how it will be used once it is shared with a third-party.[3] We support CMS' proposal requiring impacted payers to request a privacy policy attestation when a third-party application (app) seeks access to patient health care data and agree the attestation should include whether:

- The app maintains a publicly available and accessible privacy policy that is written in plain language. The NHC urges CMS to require the policy be available in language that is short and understandable to the patient. This can be achieved by CMS engaging the patient community to develop template language;
- The third-party app developer has affirmatively shared its privacy policy with the patient prior to gaining authorization to access the health information. This would mean the patient has to take action indicating that he/she was provided and acknowledged receiving the privacy policy; and
- The app's privacy policy includes, at a minimum:

  - How a patient's health information may be accessed, exchanged, used, shared, or sold at any time;
  - Express consent from a patient before the patient's health information is accessed, exchanged, or used, including receiving express consent before a patient's health information is shared or sold and, ideally, the patient should be able to indicate consent level for each use;
  - If an app will access any other information from a patient's device;
  - How a patient can discontinue app access to their data and device; and
  - The policy and processes used for disposing of a patient's data once the patient has withdrawn consent.

Increased use of electronic health records, combined with interoperability initiatives, can improve the quality and efficiency of care for all patients and facilitates 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 risk to an individual's privacy with respect to their health status and care. The NHC appreciates that CMS seeks information that may support future rulemaking or other initiatives on whether patients and providers should have the ability to selectively control the sharing of data in an interoperable landscape. We strongly encourage further investigation into approaches that provide information and flexibility for patient decision making while protecting patient privacy and ensuring informed consent.

We believe that the balancing of the benefits and risks associated with increased sharing of health care data across entities warrants informed consent processes that give patients the opportunity to choose how their data can be used, who can use it, and when it can be accessed. The NHC supports health data sharing informed consent processes that:

- Provide sufficient clarity to enable the patient to fully understand what is being shared, who it is being shared with, how it is used, and how long the consent remains in effect;
- Presented in a language and literacy level that is appropriate for the patient;
- Enables the patient to decline to share data that is not essential to claims for specific services, without having to opt out of receiving care from the provider or coverage through the payer; and
- Provides a clearly defined and easy to implement option for the patient to change or revoke their consent over time.

The NHC strongly encourages CMS to engage stakeholders, particularly the patient community, as it further refines the checks and balances necessary to facilitate efficient health care information exchange while respecting patient privacy interests.

Conclusion

We appreciate the opportunity to provide input on this important Proposed Rule. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Eleanor M. Perfetto, PhD, MS
Interim Chief Executive Officer and
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