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Director's Message

Dear Partners and Colleagues,

Welcome to the December issue of *Burden Reduction News & Highlights,* CMS' quarterly newsletter highlighting our agency's burden reduction efforts. I'd like to start by calling attention to two recent updates related to CMS' work on burden reduction.

Today, CMS released the **Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule**, which aims to improve patient and provider access to health information and streamline processes related to prior

authorization for medical items and services. The proposed rule aligns with CMS' ongoing work to strengthen patient access to care, reduce administrative burden for clinicians so they can focus on direct care, and support interoperability across the health care landscape. For additional information on the rule, please see below. The deadline to submit comments is March 13, 2023.

Also, earlier in November, CMS released an **Administrative Simplification Proposed Rule** on Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and Adoption of a New Pharmacy Subrogation Standard. More information on that proposed rule, and how to comment, can be found below. The deadline to submit comments is January 9, 2023.

In this newsletter, you will also find a reminder on CMS' upcoming **discontinuation of Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)**, which is effective January 1, 2023. The effort to discontinue the use of these forms was a direct result of public feedback that indicated they were burdensome and duplicative of information already available on the claim or in the medical record.

Finally, I would like to thank all the stakeholders who submitted information on CMS' Requests for Information (RFI) seeking public input on the idea of a CMS-established **National Directory of Health Care Providers and Services (NDH)** and our **"Make Your Voice Heard"** RFI. These RFIs are only the beginning of the conversation, and we will let you know about future opportunities for providing input on these and other topics.

I hope you all have a happy holiday season. As always, I invite your feedback on CMS' efforts to reduce burden in the healthcare system. Information on how to contact our office is available at the bottom of this email.

Best wishes for a safe and productive 2023!

Sincerely,
Mary

Mary Greene, MD
Director
CMS Office of Burden Reduction & Health Informatics (OBRHI)

CMS Proposes Rule to Expand Access to Health Information and Improve the Prior Authorization Process

As part of the Biden-Harris Administration's ongoing commitment to increasing health data exchange and investing in interoperability, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would improve patient and provider access to health information and streamline processes related to prior authorization for medical items and services. CMS proposes to modernize the health care system by requiring certain payers to implement an electronic prior authorization process, shorten the time frames for certain payers to respond to prior authorization requests, and establish policies to make the prior authorization process more efficient and transparent. The rule also proposes to require certain payers to implement standards that would enable data exchange from one payer to another payer when a patient changes payers or has concurrent coverage, which is expected to help ensure that complete patient records would be available throughout patient transitions between payers.

"CMS is committed to strengthening access to quality care and making it easier for clinicians to provide that care," said CMS Administrator Chiquita Brooks-LaSure. "The prior authorization and interoperability proposals we are announcing today would streamline the prior authorization process and promote health care data sharing to improve the care experience across providers, patients, and caregivers – helping us to address avoidable delays in patient care and achieve better health outcomes for all."

The proposed rule would address challenges with the prior authorization process faced by providers and patients. Proposals include requiring implementation of a Health Level 7® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) standard Application Programming Interface (API) to support electronic prior authorization. They also include requirements for certain payers to include a specific reason when denying requests, publicly report certain prior authorization metrics, and send decisions within 72 hours for expedited (i.e., urgent) requests and

seven calendar days for standard (i.e., non-urgent) requests, which is twice as fast as the existing Medicare Advantage response time limit. In order to further support a streamlined prior authorization process, this proposed rule would add a new Electronic Prior Authorization measure for eligible hospitals and critical access hospitals under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians under the Promoting Interoperability performance category.

Proposed policies in this rule would also enable improved access to health data, supporting higher-quality care for patients with fewer disruptions. These policies include: expanding the current Patient Access API to include information about prior authorization decisions; allowing providers to access their patients' data by requiring payers to build and maintain a Provider Access FHIR API, to enable data exchange from payers to in-network providers with whom the patient has a treatment relationship; and creating longitudinal patient records by requiring payers to exchange patient data using a Payer-to-Payer FHIR API when a patient moves between payers or has concurrent payers.

These proposed requirements would generally apply to Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) agencies, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs), promoting alignment across coverage types. CMS estimates that efficiencies introduced through these policies would save physician practices and hospitals over $15 billion over a 10-year period.

Finally, the proposed rule includes five requests for information related to standards for social risk factor data, the electronic exchange of behavioral health information among behavioral health providers, improving the exchange of medical documentation between certain providers in the Medicare Fee-for-Service program, advancing the Trusted Exchange Framework and Common Agreement (TEFCA), and the role interoperability can play in improving maternal health outcomes.

The proposed rule is aligned with CMS' ongoing work to strengthen patient access to care, reduce administrative burden for clinicians so they can focus on direct care, and support interoperability across the health care landscape. It withdraws and replaces the previous proposed rule, published in December 2020, and addresses public comments received on that proposed rule.

For additional information, consult this fact sheet.

The proposed rule is available to review here, and the deadline to submit comments is March 13, 2023. CMS encourages comments from all interested members of the public and, in particular, from patients and their families, providers, clinicians, consumer advocates, health care professional associations, individuals serving and

located in underserved communities, and from all other CMS stakeholders serving populations facing disparities in health and health care.

For more information on the CMS proposed rule, please visit: Policies and Technology for Interoperability and Burden Reduction.

Administrative Simplification: Proposed Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and Adoption of a New Pharmacy Subrogation Standard (CMS-0056-P)

The U.S. Department of Health and Human Services (HHS) issued a proposed rule to modify the currently adopted National Council for Prescription Drug Programs (NCPDP) Version D.0 standard to the Telecommunications Standard Implementation Guide Version F6 and the equivalent Batch Standard Implementation Guide Version 15 (hereinafter collectively referred to as Version F6). This rule also proposes to adopt the NCPDP Batch Standard Subrogation Implementation Guide Version 10 (Version 10), to replace the currently adopted Medicaid Pharmacy Subrogation transaction standard and extend the applicability of the pharmacy subrogation transaction beyond state Medicaid agencies to all health plans.

Major Provisions of the Proposed Modifications to the National Council for Prescription Drug Programs Retail Pharmacy Standards and the Adoption of a New Pharmacy Subrogation Standard.

The provisions in this proposed ruled would adopt the NCPDP Telecommunication Standard Implementation Guide, Version F6 (Version F6) and equivalent NCPDP Batch Standard Implementation Guide, Version 15 (Version 15); and NCPDP Batch Standard Pharmacy Subrogation Implementation Guide, Version 10, for non-Medicaid health plans. These updated standards would replace the currently adopted NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) and the equivalent NCPDP Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2); and NCPDP Batch Standard Medicaid Subrogation Implementation Guide, Version 3.0, Release 0.

Industry stakeholders report that Version F6 would bring much needed upgrades over Version D.0, such as improvements to the information attached to controlled

substance claims, including refinement to the quantity prescribed field. This change would enable refills to be distinguished from multiple dispensing events for a single fill, which would increase patient safety. Version F6 provides more specific fields to differentiate various types of fees, including taxes, regulatory fees, and medication administration fees. Finally, Version F6 increases the dollar amount field length and would simplify coverage under prescription benefits of new innovative drug therapies priced at, or in excess of, $1 million. The current adopted Version D.0 does not support this business need.

The current Medicaid Subrogation Implementation Guide Version 3.0 (Version 3.0) was adopted to support federal and state requirements for state Medicaid agencies to seek reimbursement from the correct responsible health plan. However, industry stakeholders reported that there is a need to expand the use of the subrogation transaction beyond Medicaid agencies, and noted that the use of a subrogation standard that would apply to other payers would be a positive step for the industry. Whereas HIPAA regulations currently require only Medicaid agencies to use Version 3.0 in conducting the Medicaid pharmacy subrogation transaction, all health plans would be required to use the Pharmacy Subrogation Implementation Guide for Batch Standard, Version 10, to transmit pharmacy subrogation transactions, which would allow better tracking of subrogation efforts and results across all health plans, and support cost containment efforts.

Should these proposals be adopted as proposed, they would require covered entities to comply 24 months after the effective date of the final rule.

For more information on the proposed rule, please visit:
https://www.cms.gov/files/document/fact-sheet-11-2022.pdf

To view the proposed rule in the Federal Register, please visit:
https://www.federalregister.gov/documents/2022/11/09/2022-24114/administrative-simplification-modifications-of-health-insurance-portability-and-accountability-act

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CMS News

Reminder: Elimination of Certificates of Medical Necessity & Durable Medical Equipment Information Forms

CMS is discontinuing Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs) effective January 1, 2023.

Make sure your billing and IT staff knows about these changes for CMNs and DIFs:

- For services on or after January 1, 2023: Don’t submit CMN or DIF forms or their electronic claim data elements with the claims or we’ll reject your claims and return them to you
- For services before January 1, 2023: Submit CMN and DIF forms or their electronic claim data elements with the claims if required

For more information, see MLN Matters Article SE22002 (PDF).

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