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Submitted electronically via: www.regulations.gov

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

The Honorable Dr. Thomas Keane
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20024

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P)

Dear Administrator Oz and National Coordinator Keane,

Vizient, Inc. appreciates the opportunity to respond to the proposed rule entitled Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P) (hereinafter "Proposed Rule"). Vizient appreciates CMS for building on feedback received on the 2024 CMS Interoperability and Prior Authorization (PA) final rule[1] (2024 PA Final Rule) and proposing to extend several of those finalized policies to drugs, which should help streamline care. In addition, Vizient appreciates the Office of the National Coordinator for Health Information Technology (ONC) considering changes to certain standards to help streamline PA, and offers the following suggestions for consideration.

[1] https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, provides solutions and services to more than two-thirds of the nation's acute care providers and more than one-third of ambulatory providers. Vizient offers proprietary data and analytics to deliver unique clinical and operational insights and a contract portfolio representing $156 billion in annual purchasing volume enabling the delivery of cost-effective care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at www.vizientinc.com.

Recommendations

Vizient appreciates CMS's efforts to strengthen patient protections, improve access to medications and increase transparency regarding impacted payers' PA decisions. Vizient offers the following recommendations to improve PA processes and enhance transparency.

Prior Authorization

Electronic Prior Authorization (ePA) for Drugs

In the Proposed Rule, CMS proposes to require impacted payers to support standardized electronic PA for all drugs that require PA. For drugs covered under a medical benefit (e.g., provider-administered drugs, drugs furnished incident to a physician's service and drugs associated with durable medical equipment), CMS proposes to require impacted payers to incorporate those drugs into the existing PA Application Programming Interface (API). For drugs covered under a pharmacy benefit (e.g., self-administered outpatient prescription drugs), CMS proposes to require impacted payers to support applicable National Council for Prescription Drug Programs (NCPDP) standards.[2] As CMS is aware, and consistent with Vizient's prior comments, existing PA processes can significantly delay care and impose substantial administrative burden, especially where providers are expected to log-in to additional portals or wait on the phone with payers. PA has become a highly variable, administratively complex and often duplicative process that can delay medically necessary care even when treatment is supported by evidence-based clinical pathways. Requiring payers to support ePA through specific standards will help ease provider burden reducing some variability in the PA process. Vizient appreciates the agency's proposal and encourages CMS to finalize these requirements with certain modifications.

In the Proposed Rule, CMS anticipates that impacted payers would determine whether ePA for each drug should be covered under the pharmacy benefit or the medical benefit. CMS also states that these categories are intended to be mutually exclusive and, together, should encompass all drugs covered by an impacted payer. As CMS may be aware, while drugs are generally covered under either a medical benefit or a pharmacy benefit, there are circumstances where a drug typically covered under the pharmacy benefit is covered under the medical benefit. For example,

[2] CMS proposes three NCPDP standards to facilitate ePA: the NCPDP SCRIPT standard, NCPDP Formulary & Benefit Standard Implementation Guide, and the NCPDP Real-Time Prescription Benefit Standard Implementation Guide.

some drugs that are generally dispensed through a pharmacy benefit may be difficult for a patient to self-administer and may need to be administered in a clinical setting under certain circumstances and as a result, would be covered under the medical benefit. In addition, different sites of care may have policies or payer agreements that prevent white bagging,[3] so these drugs may be covered by the medical benefit depending on the site of care. To ensure ePA is streamlined and PA requests are not inappropriately denied, including when requested through the medical benefit, impacted payers should be required to ensure that their ePA pathways account for patient-specific, provider-specific and site-of-care arrangements.

In addition, related to white bagging, Vizient encourages CMS to clarify that the Proposed Rule does not require payers to cover certain products only under either the medical benefit or pharmacy benefit. While many payers may attempt to impose white bagging, this practice causes disruptions to care, increases provider administrative burden and labor costs, and creates operational challenges, among other concerns identified in Vizient's "Survey on the patient care impact and additional expense of white/brown bagging." Further, some states have enacted laws that restrict or prohibit mandatory "white bagging" or "brown bagging" practices.[4] Therefore, to prevent confusion and potentially conflicting requirements, Vizient recommends that CMS clarify that the ePA requirements do not unintentionally restrict coverage design, site-of-care arrangements or how a medication may be dispensed.

Improving Communications and Decision Timeframes for PA

Specific Denial Reason

CMS proposes that, beginning October 1, 2027, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities and QHP issuers on the FFEs must provide a specific reason to providers when denying a PA request for drugs, regardless of the method used to send the request or decision. Providers often face challenges identifying the basis for a denial. Requiring impacted payers to provide specific, actionable denial reasons could reduce follow-up communications and provider administrative burden. Vizient encourages CMS to work with providers to ensure that when a denial reason is provided, that it is sufficiently specific to reduce provider burden.

CMS also proposes that the payer's response include what actions must be taken to resubmit or appeal the decision. However, it is unclear whether this information would be sufficiently detailed to allow the provider to act without contacting the payer for additional information. For example, a generic response stating that a request was denied due to a lack of supporting medical documentation would likely still require the provider to follow up with the payer to identify the specific records or clinical information needed for authorization. Therefore, Vizient suggests CMS ensure payer directions related to resubmissions or appeals are sufficiently detailed so providers do not need to seek additional information from the plan.

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[3] Recent payer-imposed policies (i.e., white bagging policies) have required many physicians and health systems to move from a traditional buy-and-bill model to one in which specialty medications are dispensed by a third-party pharmacy unaffiliated with the prescriber. This change can complicate access, create delivery and dispensing delays that affect time to therapy, and potentially result in negative outcomes and additional financial burden for patients.

[4] https://www.ama-assn.org/system/files/issue-brief-asco-patient-access-to-medication-safety.pdf

PA Decision Timeframes

CMS proposes to standardize drug PA decision timeframes across impacted payers to align with existing drug-specific requirements or decision timeframes for medical items and services (e.g., seven calendar days for standard requests and 72 hours for expedited requests). Consistent with prior comments to CMS, Vizient believes that the timeframes for standard and expedited requests are excessively long and do not adequately reflect the sense of urgency that is needed when care decisions need to be made. While Vizient appreciates the agency's interest in aligning review timeframes, we encourage CMS to adopt shorter timeframes for drugs (e.g., a maximum of 24 hours for expedited requests and 72 hours for standard requests) and to also shorten the timeframes for medical items and services.

Additional Opportunities to Improve PA Communications

Although not addressed in the Proposed Rule, a lack of standardization in other components of the PA process adds provider burden that could be reduced. For example, impacted payers have different documentation requirements, documentation standards and appeal pathways. As a result, to complete different payers' PA requirements, providers may hire additional staff and purchase technology specifically for PA, while PA also consumes additional clinician time. This can delay patient care and strain provider capacity, particularly when peer-to-peer review occurs. While the Proposed Rule is a significant step in the right direction, Vizient encourages CMS to consider additional opportunities to improve other aspects of the PA process.

Proposed Requirements To Publicly Report PA Metrics for Drugs for Impacted Payers

CMS proposes to incorporate drugs into the existing PA metrics framework by requiring impacted payers to annually post certain metrics about PAs for all drugs (excluding covered Part D drugs for MA-PD plans) on their public websites. For most impacted payers, reporting would begin in 2028 using 2027 data. For example, MA organizations would be required to report the total number and percentage of approved and denied standard PA requests for Part B drugs during the calendar year. While aggregated PA metrics help increase transparency, they do not provide sufficiently granular information to identify recurring access challenges or potentially inappropriate PA practices. Therefore, Vizient encourages CMS to require more granular reporting, such as drug-specific metrics.

Proposed Changes to Publicly Reported PA Metrics for Non-Drug Items and Services for Impacted Payers

In the 2024 PA Final Rule, CMS finalized a requirement for impacted payers to report certain PA metrics,[5] aggregated for all non-drug items and services, on their public websites. For certain existing metrics, CMS now proposes to require payers to also report numeric counts, in addition to existing percentage requirements. Numeric counts of PA metrics will help provide additional

[5] Metrics finalized in the CY 2024 PA rule included the percentage of PA requests that were approved, denied, approved after appeal, or approved after the timeframe for review was extended.

context and transparency regarding payer PA decisions. Vizient encourages CMS to finalize this proposal.

While CMS proposes to require numeric counts for existing metrics, CMS does not propose new metrics that would require payers to report more granular information that could help a beneficiary evaluate potential PA challenges for specific items and services. To further enhance PA transparency, Vizient encourages CMS to require impacted payers to report metrics for specific items and services, in addition to aggregated metrics.

Currently, impacted payers report the required metrics on their public websites. However, there is significant variability in how these metrics are reported and the information can be difficult to find. To increase the usability of reported PA metrics, Vizient suggests that CMS provide standardized reporting templates for impacted payers. In addition, CMS should create a centralized repository where stakeholders can more easily find and access payer-reported metrics.

Modifications to Health Insurance Portability and Accountability Act (HIPAA) Standards Related to PA

In the Proposed Rule, ONC proposes replacing the current X12N 278 standard for the PA workflow for dental, professional and institutional transactions with HL7 FHIR-based standards. Vizient supports efforts to shift towards HL7 FHIR-based standards and believes the proposed replacement of the current X12N 278 standard will help streamline communications.

In addition, as proposed, covered entities would be required to adopt the updated interoperability standards within 24 months of the final rule's effective date. Since providers have limited resources and may experience challenges when shifting to certain HL7 FHIR-based standards, 24 months may not be a reasonable time frame for each covered entity to comply. Therefore, while supportive of the proposed shift towards HL7 FHIR-based standards, we suggest that CMS provide covered entities with additional resources and flexibilities to support their compliance, if the proposal is finalized.

ONC also notes that versions of certain proposed standards may be updated between publication of the Proposed Rule and final rule, and requests comment on whether the agency should adopt an updated version if one becomes available by final rulemaking. Although the potential burden associated with any updated standard is unclear, it is important that providers could continue to rely on prior versions to prevent disruptions, should ONC aim to update standards in regulation. To help facilitate this process, Vizient believes ONC should establish a predictable transition process that allows providers and other covered entities to implement updated standards without excessive burden or disruptions to care. For example, ensuring backward compatibility where feasible, providing adequate implementation lead time and coordinating transition timelines across various requirements can help prevent disruptions. In addition, ensuring the transition process allows for provider use of older versions as payers update their systems would help prevent disruptions should ONC use updated standards in rulemaking. Therefore, Vizient encourages the coordination of predictable and seamless transitions as new versions become available to prevent disruptions to care.

Open Payments Civil Monetary Penalties

CMS proposes to add a definition of "failure to report" that would permit CMS to impose a civil monetary penalty (CMP) on an applicable manufacturer or applicable group purchasing organization if the entity fails to provide timely access to records needed for an audit. Under the proposal, timely access would mean access within 30 calendar days of the audit request to books, contracts, records, documents and other evidence sufficient to enable CMS to audit, evaluate and inspect the entity's records. Vizient is concerned that CMS presumes 30 days would be enough time for an entity to respond, particularly as the scope, nature or complexity of the requested information could vary significantly. Depending on the audit request, an entity may need additional time to identify responsive records, coordinate across internal business units, validate the information and prepare a complete and accurate response. To support entities' ability to respond effectively and ensure CMS receives accurate information, Vizient recommends that CMS substantially extend the proposed 30-calendar-day timeframe. Vizient also recommends that CMS establish a clear process for an entity to request an extension when additional time is needed to respond to an audit request.

Conclusion

Vizient thanks CMS and ONC for the opportunity to comment on the Proposed Rule, which would help address PA challenges, particularly for drugs. Vizient's membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS and ONC for providing us the opportunity to comment on this important Proposed Rule. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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