799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

Vizient Office of Public Policy and Government Relations

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and PA 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)

April 22, 2026

Summary

On April 10, the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) issued a proposed rule that builds upon the 2024 CMS Interoperability and PA Final Rule and aims to improve and streamline the prior authorization (PA) process by providing additional interoperability requirements for different types of payers (hereinafter, "Proposed Rule"). CMS proposes requirements related to electronic PA for drugs for Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities and Qualified Health Plan (QHP) issuers on the Federally-facilitated exchanges (FFEs)[1] (hereinafter "Impacted Payers"). In addition, CMS proposes to require impacted payers to report their application programming interface (API) endpoints and related information for various APIs (i.e., Patient Access, Provider Directory, Provider Access, Payer-to-Payer and PA APIs) to CMS.

In addition, CMS proposes changes to the agency's Open Payments Program which would allow CMS to impose a civil monetary penalty on certain non-provider entities (e.g., manufacturers, Group Purchasing Organizations) for failing to provide CMS with timely access to documents under certain circumstances. CMS proposes this change would begin on the effective date of the final rule.

Several portions of the Proposed Rule do not directly pertain to Medicare fee-for-service (FFS). However, CMS indicates it continues to explore electronic PA in Medicare FFS.

Comments are due **June 15, 2026**, with no specific deadline for release of the final rule. In the Proposed Rule, CMS outlines various potential compliance dates, including October 1, 2027, for several provisions. Vizient looks forward to working with members to help inform our letter to the agency.

Background

In May 2020, CMS published a final rule (also known as the CMS Interoperability and Patient Access Final Rule or 2020 Final Rule) to require certain payers[2] to share certain information (e.g.,

[1] In the Proposed Rule, CMS proposes to include QHP issuers that offer small group market QHPs on the Federally-facilitated Small Business Health Options Program (FF-SHOP) Exchanges, among the payer types that must comply with the interoperability requirements. Also, for purposes of the Proposed Rule, FFEs include FFEs in states that perform plan management functions and State-based Exchanges on the Federal Platform (SBE-FPs) are not FFEs.

[2] MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities and issuers that offer individual market QHPs on the FFEs (collectively, "individual market QHP issuers on the FFEs")

patient claims, encounter data, and a subset of clinical data) via Fast Healthcare Interoperability Resources (FHIR) APIs[3].

Building from the May 2020 Final Rule, CMS released another final rule in May 2024 (also known as the CMS Interoperability and PA Final Rule or 2024 Final Rule). The 2024 Final Rule required impacted payers[4] to implement a PA API to enable electronic PA transaction and established decision timelines for responding to PA requests for non-drug items and services (7 calendar days for standard requests and 72 hours for expedited requests, with the possibility of an extension of up to 14 days in certain circumstances).[5,6] The 2024 Final Rule did not include drugs.

For purposes of the Proposed Rule, the "Interoperability APIs" include the Patient Access, Provider Directory, Provider Access, Payer-to-Payer and PA APIs. Alternatively, "Access APIs" are those that are used primarily to access a specific patient's health record (i.e., Patient Access, Provider Access and Payer-to-Payer APIs).

Interoperability Standards for APIs

In the May 2024 Final Rule, CMS finalized requirements for impacted payers to use specific versions of health IT-related standards that were adopted by ONC but also allowed the use of updated standards under certain circumstances. Through ONC rulemaking, some of the required versions now have established expiration dates. As a result, CMS proposes several changes to align with ONC's process to adopt, update and sunset expired health IT standards. Table 2 (pg. 25-27) of the Proposed Rule outlines the proposed updates to required standards for Interoperability Standards and Table 3 (pg. 27-32) lists the required standards finalized in the 2024 CMS Interoperability and Prior Authorization Final Rule and additional FHIR implementation guides (IGs) proposed in this rule by applicable API.

Electronic PA for Drugs

In the May 2024 Final Rule, CMS required impacted payers to implement and maintain a PA API for non-drug items and services beginning in 2027.[7] In the Proposed Rule, CMS proposes to expand the PA API to include drugs covered under both the medical benefit (e.g., provider-administered, furnished incident to a physician's service, associated with durable medical equipment) and pharmacy benefit (e.g., self-administered outpatient prescription drugs).

For drugs covered under the medical benefit, beginning October 1, 2027, CMS proposes that impacted payers enhance their PA APIs by incorporating PA coverage and documentation requirements for drugs covered under a medical benefit. CMS also proposes to require implementation guides (IGs), which include a set of workflow instructions to support PA.

For drugs covered under the pharmacy benefit, CMS proposes to require most impacted payers to utilize certain National Council for Prescription Drug Programs (NCPDP) standards. Table 4 (pg. 41)

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[3] An API is a set of commands, functions, protocols, or tools published by one software developer ("A") that enables other software developers to create programs (applications or "apps") that can interact with A's software without needing to know the internal workings of A's software, while maintaining data security and patient privacy, if properly implemented.
[4] Impacted payers other than QHP issuers.
[5] CMS did not propose PA decision timeframes for QHP issuers on the FFEs because those timeframes align with other non-grandfathered group and individual market plans. For purposes of the Proposed Rule, references to QHP issuers do not include issuers offering stand-alone dental plans on the FFEs.
[6] CMS also finalized policy to allow states to establish shorter timeframes.
[7] The compliance timeline varies slightly by payer type but all align to 2027 plan/rating periods.

of the Proposed Rule clarifies the proposal and standards for each applicable payer, based on existing regulations. In addition, CMS proposes certain exceptions for QHP issuers on the FFEs.

CMS indicates that it does not intend to specify an exhaustive list of drugs covered under a medical benefit, as payers structure their formularies differently. However, the agency does expect that each category of drugs (i.e., medical benefit and pharmacy benefit) would be mutually exclusive and collectively include all drugs covered by any particular payer.

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 PA request or decision. CMS indicates that the content of the response should include a specific reason for denying a PA request that helps a provider understand why the request was denied and what actions must be taken to resubmit or appeal the decision. A specific reason for denial could include information about the specific plan coverage criteria on which the denial is based, why documentation did not support the medication or prescription or why the drug is not deemed necessary. **CMS seeks comment on these proposals, including the October 1, 2027 compliance date.**

PA Decision Timeframes

Currently, there are variable requirements for PA decision timeframes depending on the payer type and product or service. For example, the 2024 Final Rule requires MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans and CHIP managed care entities to make PA decision requests on non-drug items and services as expeditiously as a patient's health condition requires but no later than 7 calendar days after receiving a standard request and no later than 72 hours after receiving an expedited request, effective in 2026.

PA Decision Timeframes for QHP Issuers

QHP issuers are currently subject to different requirements and these requirements vary depending on whether the QHP issuer is on the FFE. CMS proposes that beginning October 1, 2027, in response to a request for PA for non-drug items and services, QHP issuers on the FFEs must notify the requesting provider of their decision as expeditiously as a patient's health condition requires but no later than 7 days after receiving a standard PA request and no later than 72 hours after receiving an expedited PA request.

For a PA request for drugs, CMS proposes that beginning October 1, 2027, QHP issuers on the FFEs must notify a requesting provider of their decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving a standard PA request and no later than 24 hours after receiving an expedited PA request.[8]

[8] CMS also proposes that the QHP issuer on the FFEs may extend the timeframes to notify the requesting provider of a PA decision by up to 14 calendar days under any of the following circumstances: (1) if the provider requests the extension; (2) the extension is justified and in the provider's or enrollee's interest because the QHP issuer on the FFEs needs additional medical evidence from another provider or the enrollee in order to issue a decision; or (3) the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the provider's or enrollee's interest. If extended, the QHP issuer on the FFEs would be required to notify the provider of its determination

PA Decision Timeframes for Drugs That Are Not Covered Outpatient Drugs for State Medicaid Fee-for-Service Programs, Medicaid Managed Care Plans, and CHIP Managed Care Entities

Existing Medicaid law establishes a 24-hour timeframe for state Medicaid FFS programs to respond to requests for PA of covered outpatient drugs for which Federal Financial Participation (FFP) is available.[9] However, that timeframe may not apply to all drugs that are covered by states for which states receive FFP. Therefore, for certain non-covered outpatient drugs[10] CMS believes that the timeframe requirements should align with those of non-drug items and services, which is 7 calendar days for standard requests and 72 hours for expedited requests. **CMS requests comment on whether there are categories of noncovered outpatient drugs for which it would be more appropriate to finalize a decision timeframe that aligns with the statutory requirement for covered outpatient drugs.** CMS proposes an October 1, 2027 compliance date for these proposals.

Also, CMS specifically requests comment on whether there are any drugs payable under Part A that are not included as part of a larger bundle of inpatient services to which the timeframe to make PA decisions should apply for MA organizations. If so, CMS would consider finalizing a policy to ensure that all drugs that require PA have appropriate decision timeframes.

PA Decision Timeframes for Prescription Drugs for State CHIP Fee-for-Service Programs

To align with the existing requirements for state Medicaid FFS programs, Medicaid managed care plans and CHIP managed care entities for covered outpatient drugs, as well as content in the Proposed Rule, CMS proposes to shorten the timeframe for state CHIP FFS programs to make PA decisions on prescription drugs for which the state receives FFP. CMS proposes that state CHIP FFS programs must provide notice to providers and beneficiaries of PA decisions for prescription drugs for which FFP is available in accordance with the beneficiary's medical needs but no later than 24 hours after receiving the PA request. Also, CMS proposes these changes would go into effect October 1, 2027.

Proposed Changes to Reporting Deadlines and Reporting Levels for Publicly Reported PA Metrics for Non-Drug Items and Services for Medicaid Managed Care Plans and CHIP Managed Care Entities

In the 2024 Final Rule, CMS finalized requirements for impacted payers to publicly report PA metrics for non-drug items and services beginning in 2026. CMS indicates that the reporting deadline (March 31 for the prior year's data) does not align with Medicaid and CHIP managed care contract rating periods. CMS proposes to modify these deadlines for Medicaid managed care plans and CHIP managed care entities to be no later than 90 days after the end of their contract rating period. CMS also proposes to require such reporting to be done by program and by plan, and that these changes would become effective on the effective date of the final rule.

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as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension. CMS proposes additional policies related to such extensions.

[9] Section 1927(k)(3) of the Act limits the term ''covered outpatient drug'' to exclude any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, certain services (and for which payment may be made under that subchapter as part of payment for those services and not as direct reimbursement for the drug). The services listed in section 1927(k)(3) of the Act are: inpatient hospital services; hospice services; dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs; physicians' services; outpatient hospital services; nursing facility services and services provided by an intermediate care facility for the mentally retarded; other laboratory and x-ray services; and renal dialysis.

[10] Non-covered outpatient drugs that meet the limiting definition in section 1927(k)(3) of the Social Security Act

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

In the 2024 Final Rule, CMS finalized a requirement for impacted payers to report certain PA metrics (e.g., percentage of PA that were approved, denied, approved after appeal and approved after the timeframe for review was extended) aggregated for all non-drug items and services on their public websites. For certain metrics, CMS proposes to require payers to report a numeric count of PA requests, as well as percentages.

In the Proposed Rule (pg. 51), CMS proposes adding several additional metrics related to PA for non-drug items and services that will provide additional context regarding PA decisions by including information about denials, approvals, extensions and appeals and timelines for some of those decisions.

CMS proposes that if finalized, these additional metrics would be effective beginning on the effective date of the final rule to be reported in the following year.

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

To incorporate drugs into the existing PA metrics, CMS proposes requiring impacted payers to annually report certain metrics about PA for all drugs (excluding covered Part D drugs for MA–PDs)[11] by posting this information on their public website. For most impacted payers, reporting would begin in 2028 using 2027 data.[12] Table 1 outlines the metrics that CMS proposes to be reported. Detailed information regarding the numerator and denominators is in the Proposed Rule (pg. 53-56).

Payer Type	Proposed Metrics
MA orgs.	- A list of all drugs payable under Part B that require PA. - The total number and percentage of: ● Approved standard PA requests for Part B drugs during the calendar year (CY). ● Denied standard PA requests for Part B drugs during the CY. ● Standard PA requests for Part B drugs for which the timeframe for review was extended, and the request was approved during the CY. ● Standard PA requests for Part B drugs for which the timeframe for review was extended, and the request was denied during the CY. ● Standard PA requests for Part B drugs approved after appeal during the CY. ● Standard PA requests for Part B drugs that remain denied after appeal during the CY. ● Approved expedited PA requests for Part B drugs during the CY. ● Denied expedited PA requests for Part B drugs during the CY ● Expedited PA requests for Part B drugs for which the timeframe for review was extended, and the request was approved during the CY ● Expedited PA requests for Part B drugs approved after appeal during the CY. ● Expedited PA requests for Part B drugs that remain denied after appeal during the CY.

[11] CMS indicates Covered Part D drugs and PDPs are not included in this proposal because they are covered in other reporting regulations, and it would be burdensome to add new, duplicative reporting requirements on these plans.
[12] CMS proposes a different timeline for Medicaid managed care plans and CHIP managed care plans.

	- The average and median elapsed time between request submission and decisions for: ● Standard PA for Part B drugs during the CY. ● Expedited PA for Part B drugs during the CY.
State Medicaid and CHIP FFS programs	- A list of all drugs that require PA. - The total number and percentage of PA requests for all drugs that were: ● Approved during the reporting period. ● Denied during the reporting period. ● Approved after appeal during the reporting period. ● Remaining denied after appeal during the reporting period. - The average and median time that elapsed between the submission of requests and decisions for PA for all drugs during the reporting period.
QHP Issuers on the FFEs	- A list of all drugs that require PA. - The total number and percentage of standard PA requests for all drugs that were: ● Approved during the CY. ● Denied during the CY. - The total number and percentage of standard PA requests for all drugs for which the timeframe for review was extended, and the request was: ● Approved during the CY. ● Extended, and the request was denied during the CY. - The total number and percentage of standard PA requests for all drugs: ● Approved after appeal during the CY. ● Remaining denied after appeal during the CY. - The average and median elapsed time between request submission and decisions for: ● Standard PA for all drugs during the CY ● Expedited PA for all drugs during the CY. - The total number and percentage of expedited PA requests for all drugs that were: ● Approved during the CY. ● Denied during the CY. - The total number and percentage of expedited PA requests for all drugs for which the timeframe for review was extended, and the request was: ● Approved during the CY ● Denied during the CY. - The total number and percentage of expedited PA requests for all drugs: ● Approved after appeal during the CY. ● Remaining denied after appeal during the CY.

Table 1: Metrics, by payer, that CMS proposes certain impacted payers report.

Reporting Payer API Endpoints and Associated Information for CMS to Publish

An API's endpoint is the digital location (e.g., URL, IP address) that can accept secure queries to the API. Developers need to know an API's endpoint to configure their apps to interact with the API. Although CMS has required payers to implement multiple APIs, stakeholders raised concerns that there was no centralized way to find API endpoints. Therefore, CMS proposes that impacted payers

report to CMS their API endpoints for each required interoperability API.[13]

CMS proposes reporting requirements for impacted payers, including initial reporting of their API endpoints, no later than 60 days after the effective date of the final rule. Also, impacted payers would be required to report changes to CMS within 1 week of any changes to their API endpoint(s) and verify every 12 months that there have been no changes and their data are accurate. Table 8 of the Proposed Rule (pg. 74-75) outlines the proposals to require impacted payers to report payer API endpoints and associated information.

CMS seeks input on how the agency could collect and publish reporting information in a manner (e.g., machine-readable file, FHIR-enabled registry) that would balance the burden on payers with the benefits to developers, patients, providers and payers.

Updates to Patient Access, Provider Directory, Provider Access and Payer-to-Payer APIs; API Usage Metrics

Information About PA for Drugs in the Patient Access, Provider Access and Payer-to-Payer APIs

In the 2024 Final Rule, CMS required impacted payers to make available certain information about PA for non-drug items and services via a Patient Access API and similarly required additional information via Provider Access and Payer-to-Payer APIs.[14] CMS finalized compliance dates beginning in 2027 for each of these APIs. To help ensure there is access to PA information for drugs, CMS proposes to add information about PA requests and decisions for all drugs to the categories of data impacted payers are required to make available through the Access APIs. CMS proposes an October 1, 2027 compliance date for MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities and QHP issuers on the FFEs to make the proposed information about PA for drugs available via the Access APIs.

Specifically, the information about PA for drugs that CMS proposes be made available via the Patient Access, Provider Access and Payer-to-Payer APIs are listed in Table 2.

API	Metric
Provider Access API and Patient Access	- The PA status. - The date the PA was approved or denied. - The date or circumstance under which the PA ends. - The drug or drugs approved (including the dosage). - If denied, a specific reason why the request was denied. - Related structured administrative and clinical documentation submitted by a provider.

[13] For this proposal, CMS provides the following limited exceptions: unless the impacted payer is a state Medicaid or CHIP FFS program that has been granted an extension or a QHP issuer on the FFEs that has been granted an exception from implementing any or all of the interoperability APIs.

[14] Specifically, impacted payers must make all of the following information available about PA requests and decisions for non-drug items and services via the Patient Access and Provider Access APIs: The PA status; The date the PA was approved or denied; The date or circumstance under which the PA ends; The items and services approved; If denied, a specific reason why the request was denied; and Related structured administrative and clinical documentation submitted by a provider. Impacted payers must make the same PA information available through the Payer-to-Payer API, with some variation. For each of these APIs, CMS required that impacted payers make this information about PAs available no later than 1 business day after the payer receives a PA request and must update that information no later than 1 business day after any status change. This information must be available for the duration that the authorization is active and at least 1 year after the PA's last status change.

Payer-to-Payer API[15]	- The percent of patients who have opted in to the payer to payer data exchange. - The total number of unique patients whose data have been sent to other payers. - The total number of unique patients whose data have been received from other payers.

Table 2. PA for drugs metrics CMS proposes be made available via an API

Also, CMS proposes that the requirement to make available information about PA for drugs would be subject to the same timeframes established for making available PA information for non-drug items and services—no later than 1 business day after the payer receives a PA request—and the payer must update that information no later than 1 business day after any status change. CMS also proposes that information about PA for drugs be required to be available via the Access APIs for as long as the authorization is active and at least 1 year after.

Reporting Usage Metrics for Patient Access, Provider Access, Payer-to-Payer and PA APIs

CMS previously finalized a requirement that, beginning March 31, 2026, impacted payers are required to annually report to CMS certain metrics[16] about patient data requests made via the Patient Access API. However, CMS did not previously propose or finalize requirements for impacted payers to report usage metrics to CMS about Provider Access, Payer-to-Payer or PA APIs.

In the Proposed Rule, CMS proposes changes to the existing usage metric requirements for the Patient Access API related to the reporting timeframes for different types of impacted payers. In addition, CMS proposes requirements for impacted payers to report metrics about usage of the Provider Access, Payer-to-Payer and PA APIs, as outlined in Table 3.

Also, CMS proposes that beginning in 2028[17], MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities and QHP issuers on the FFEs would be required to annually report metrics in the form of aggregated, de-identified data. CMS also indicates that it does not plan to publicly report these metrics at the contract, state, plan and program or issuer level, but may reference or publish aggregated and de-identified data that does not include names of specific payers or plans. **CMS specifically requests comments regarding this position. CMS also requests comment on whether there are different metrics CMS should consider requiring impacted payers to report.**

API	Usage Metric
Provider Access API	- The total number of unique providers who requested patient data via their Provider Access API. - The total number of unique patients whose data were transferred via their Provider Access API to a provider's health IT system (for example, an EHR or health IT system). - The total number of patient data transfers via their Provider Access API.
Payer-to-Payer API	- The percent of patients who have opted in to the payer to payer data exchange. - The total number of unique patients whose data have been sent to other payers. - The total number of unique patients whose data have been received from other payers.
PA API	- The total number of unique providers who request a PA for items, services, or drugs through their PA API.

[15] CMS proposes to exclude denied PA requests because CMS believes they generally would not reflect ongoing treatment, since it does not demonstrate that patients actually received items, services or drugs.
[16] The metrics are: number of unique patients whose data are transferred via the Patient Access API to a health app designated by the patient, total number of patients whose data are transferred more than once via the Patient Access API to a health app designated by the patient.
[17] Table 9 (pg. 85) of the Proposed Rule details the reporting level and reporting deadlines by impacted payer type related to the API usage metrics.

- The number of unique PA requests for items, services and drugs received through their PA API.
- The percentage of all PA requests that were received through their PA API.

Table 3. Usage Metric API Reporting

Removing Drug Formulary Information from the Provider Access and Payer-to-Payer APIs

In the 2020 Final Rule and 2024 Final Rule, CMS required certain impacted payers to make information available about their drug formularies through the Access APIs. However, CMS now believes inclusion of such data in the Provider Access and Payer-to-Payer APIs may be unnecessary and burdensome. As a result, CMS proposes to remove drug formulary information as data required to be made available via the Provider Access and Payer-to-Payer APIs for MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans and CHIP managed care entities. This proposal would become effective beginning on the effective date of the final rule. **CMS seeks examples of use cases where it would be helpful for any party to have access to drug formulary data via those APIs.**

Denial or Discontinuation of Access to the Provider Directory API

In the 2020 Final Rule and 2024 Final Rule, CMS finalized requirements that impacted payers must implement and maintain Patient Access, Provider Access, Payer-to-Payer and PA APIs conformant with certain technical standards, documentation requirements and denial or discontinuation policies.[18] CMS does not currently require the Provider Directory API to comply with the denial or discontinuation policies applicable to the other APIs. To align requirements across all APIs, CMS proposes that MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans and CHIP managed care entities update their Provider Directory API policies to conform with the denial or discontinuation policies that apply to the other APIs. CMS proposes that impacted payers would be required to implement that policy by the effective date of the final rule.

Other Changes to Access API Requirements

In the Proposed Rule, CMS also proposes several other changes related to the Access API requirements. Those changes relate to applicability dates and exceptions for QHP issuers on the FFEs. Also, Table 10 of the Proposed Rule (pg. 88-89) provides an overview of proposed updates to Access API proposals and reporting API Usage Metrics.

Open Payments Civil Monetary Penalties

The Open Payments program is a statutorily mandated program[19] that promotes the transparency of pharmaceutical and medical device industry financial relationships with certain types of health care providers by providing the public with certain payment or transfer of value information. As noted in the Proposed Rule, in 2022, CMS began exercising the Open Payments program audit authority by requiring certain reporting entities (e.g., applicable GPOs, applicable manufacturers) to provide relevant documentation pertaining to their reported records (e.g., copies of checks, written

[18] As noted in the Proposed Rule, impacted payers may only deny or discontinue any third-party app's connection to the API if they (1) reasonably determine, consistent with their security risk analysis required by the HIPAA Security Rule, that allowing an app to connect or remain connected to the API would present an unacceptable level of risk to the security of PHI on their systems; and (2) make this determination using objective, verifiable criteria that are applied fairly and consistently across all apps and developers through which parties seek to access electronic health information (EHI) as defined in 45 CFR 171.102, including but not limited to, criteria that rely on automated monitoring and risk mitigation tools.

[19] Section 1128G of the Social Security Act

agreements, a general ledger) to verify that payments had been reported accurately. However, CMS indicates that in attempting to conduct such audits, it encountered challenges, noting that "certain reporting entities thwarted our efforts by refusing to comply with our audit requests and rendering it impossible for us to evaluate their Open Payments reporting compliance". As a result, CMS proposes to define "failure to report" to refine the effectiveness of the agency's auditing authority.

Modifications to HIPAA Standards Related to PA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the Secretary to adopt standards for electronically conducting certain health care administrative transactions between certain entities. These HIPAA Administrative Simplification transaction standards apply to health plans, health care clearinghouses and health care providers, collectively referred to as HIPAA covered entities, that electronically transmit health information in connection with those transactions. HIPAA's Administrative Simplification framework assumes standards will evolve over time, so it includes authority for HHS to add or modify standards and requires periodic review to keep them updated. In this Proposed Rule, ONC proposes to advance HIPAA Administrative Simplification by adopting Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards related to two HIPAA transactions ("referral certification and authorization" and "eligibility for a health plan") for all HIPAA covered entities.

Based on feedback from multiple stakeholders and project testing initiatives (i.e., HL7 Da Vinci Project) that the current standards are outdated for "referral certification and authorization", ONC proposes replacing the current X12N 278 standard for the PA workflow for dental, professional and institutional transactions with HL7 FHIR-based standards. Specifically, ONC would adopt several specifications as the standard for the ''referral certification and authorization'' transactions within the contours of the agency's proposed definition of PA.[20] This proposal does not apply to the adopted standards for retail pharmacy drugs, which are typically handled under different standards. As noted in the Proposed Rule, this would be the first time that ONC has proposed adopting HL7 FHIR standards as they aim to keep pace with technology.[21] **CMS seeks comment on whether there are any benefits to maintaining the existing X12N 278 transaction standard for referral and certification transmissions.**

Prior to submitting a request for PA, health care providers must first determine whether PA is required, and, if so, the health plan's documentation requirements that are required to obtain an approval. This process falls under the HIPAA **"**eligibility for a health plan**"** transaction, which describes a health care provider's inquiry to a health plan, or a health plan's inquiry to another health plan, for eligibility, coverage or benefits information for a patient. Under current rules, ONC utilizes the X12 270/271 standard for the dental, professional and institutional ''eligibility for a health plan'' transactions. The Proposed Rule would modify the inquiry/response used to determine whether PA is a required subset of the eligibility standard from the existing standard[22] to the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide (built on the HL7 FHIR base standard). All other eligibility inquiries and responses not related to determining whether PA is required would remain under the existing X12 270/271 standard. CMS acknowledges that the

[20] ONC proposes the following definition for PA: "*PA* means transmissions described in § 162.1301(a) used by health care providers to obtain authorization for health care, and transmissions described in § 162.1301(c) used by health plans to respond to such requests." § 162.1301 provides standards for referral certification and authorization transaction.
[21] Based on its testing the HL7 Da Vinci Project reported that a FHIR-based transaction reduced the time required to perform the necessary activities to request a PA to 5 to 6 minutes per transaction, amounting to a 40–60% time savings that clinicians could potentially rededicate to patient care.
[22] The existing standard is X12 270/271

versions of the proposed standards may be updated in the period between publication of the Proposed and Final Rules, should the agency finalize this rule. **CMS requests comment on whether the agency should adopt an updated version of any proposed standard, should one become available by the time of final rulemaking.**

Also, ONC proposes modifications and subsequent maintenance related to specifications. ONC proposes that HIPAA covered entities would be required to comply with the proposed modified standard no later than 24 months from the effective date of a final rule, except for small health plans, for which the compliance date would be 36 months from the effective date of a final rule.

In the Proposed Rule, ONC proposes adopting the HL7 FHIR Da Vinci Clinical Data Exchange (CDex) Implementation Guide (IG) for PA attachments. ONC proposes that HIPAA covered entities would be required to comply with the proposed modified standard no later than 24 months from the effective date of a final rule, except for small health plans, for which the compliance date would be 36 months from the effective date of a final rule.

Table 11 of the Proposed Rule (pg. 111) outlines the various HIPAA administrative simplification proposals related to PA transactions.

ONC seeks comment on several questions, as noted in the Proposed Rule (pg. 109), including whether it would be economical for HIPAA covered entities to implement the CDex IG as the same time as the proposed PA transaction standards.

Also, ONC requests comments related to certain exceptions for "direct data entry". Direct data entry is the process by which data are directly keyed by a health care provider into a health plan's computer (e.g., direct data entry portal used for PA and other transactions). While ONC is not making any proposals related to direct data entry, they seek comments about whether and how the exception should be revisited for possible future rulemaking. A complete list of questions from ONC is in the Proposed Rule (pg. 110).

Requests for Information

The Proposed Rule contains five separate requests for information regarding:
- Electronic Event Notifications for Value-Based Care and Care Coordination (pg. 117-119)
- Increasing Health Care Resiliency (e.g., cybersecurity, standards to promote resiliency, point-to-point connections (pg. 119-122)
- Improving Implementation of Payer API Technology (pg. 122-123)
- Step Therapy (e.g., technology and step therapy, step therapy by previous payer) (pg. 124-125)
- Laboratory Tests and Durable Medical Equipment, Prosthetic, Orthotics and Supplies Items (pg. 125-127)

What's Next?

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. This feedback will help inform our comments to the agency. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, VP Regulatory Affairs and Public Policy in the Washington, D.C. office.