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Public Comment

The Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services (HHS), and the Office of the National Coordinator for Health Information Technology (ONC) encourage the public to review and comment on the proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (CMS-0062-P). The proposed rule was published in the Federal Register on April 14, 2026, and is available for public comment for 60 days, closing on June 15, 2026.

The following is a guide to the proposals intended to assist commenters as they respond to the proposed rule. Only what is in the proposed rule is official, and in the case of any discrepancies, this document should be discounted. Please see the proposals and requests for comments that appear in each section of the proposed rule below.

Section I. Background, Summary of Proposals, Terms, and Severability

Section I.B. Summary of Major Proposals

Request for Comment: We solicit comments on the proposals throughout this rule specifically regarding the proposed compliance dates for small group market Qualified Health Plan (QHP) issuers on the Federally-facilitated Small Business Health Options Program (FF-SHOPs), including regarding whether these plans may need more time to implement these requirements. For instance, how could the prior authorization proposals in section II.B. of this proposed rule (electronic prior authorization proposal applicable to all QHP issuers on the Federally-facilitated Exchanges [FFEs]) and II.C. of this proposed rule (prior authorization processes applicable to all QHP issuers on the FFEs) affect small group market QHP issuers on the FF-SHOPs' ability to meet the requirements proposed in section II.D. of this proposed rule (requirements for small group market QHP issuers on the FF-SHOPs), and vice versa?

Section I.C. Specific Terms Used in This Proposed Rule

Requests for Comment:

- We request comment on whether there are drugs covered by any impacted payer that may not fit into the categories "drugs covered under a medical benefit" and "drugs covered under a pharmacy benefit" and how such drugs can be included in one of those two categories.
- We also solicit comment in this proposed rule on whether to consider future rulemaking to extend these proposals, and those policies finalized in the 2020 CMS Interoperability and Patient Access and the 2024 CMS Interoperability and Prior Authorization final rules, to issuers that offer coverage through State-based Exchanges on the Federal Platform (SBE-FPs), SBEs, or both. In the 2024 CMS Interoperability and Prior Authorization final rule, we encouraged these Exchanges to consider adopting similar requirements, and, in this

proposed rule, we solicit comment on the extent to which they have or may do so, as well as potential feasible deadlines for issuers in those Exchanges to implement interoperability requirements, so their enrollees can benefit from access to their health care data and more efficient and timely prior authorization processes.

- We are not proposing to apply requirements to stand-alone dental plan (SADP) issuers, but we solicit comment on whether the considerations described previously do in fact diminish the need for electronic prior authorization requirements and prior authorization process requirements for SADP issuers. We solicit comments on whether we should consider future rulemaking to apply these proposed requirements and those finalized in the 2024 CMS Interoperability and Prior Authorization final rule to SADP issuers.
- We intend for the Medicare fee-for-service (FFS) program to be a market leader on electronic prior authorization and therefore, seek comment throughout this proposed rule on how these proposals could apply to Medicare FFS.

Section I.D. Severability

Requests for Comment:

- We request comments from the public on severability, particularly which policies could be severable, if finalized, and how the other policies in a final rule would operate absent those particular provisions.

Section II.A. Interoperability Standards for Application Programming Interfaces (APIs)

Section II.A.2. National Council for Prescription Drug Programs (NCPDP) Standards for Prior Authorization of Drugs Covered Under a Pharmacy Benefit

Note: The proposals in this section also appear in Section II.B. Electronic Prior Authorization for Drugs.

Proposals: State Medicaid and Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs would be required to support an unexpired version of the NCPDP SCRIPT standard adopted by the Secretary in 45 CFR 170.205(b) for the electronic prior authorization of drugs covered under a pharmacy benefit using the following transactions: PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and PANotification (currently NCPDP SCRIPT standard version 2023011 only), an unexpired version of the NCPDP Formulary & Benefit (F&B) standard adopted by the Secretary in 45 CFR 170.205(u) to make available formulary and benefits information for drugs covered under a pharmacy benefit, and an unexpired version of the NCPDP Real-Time Prescription Benefit (RTPB) standard adopted by

the Secretary in 45 CFR 170.205(c) for exchanging real-time coverage information regarding drugs covered under a pharmacy benefit by **October 1, 2027**.

Requests for Comment:

- Through what mechanisms do payers make their NCPDP F&B files available today?
- How frequently do payers or their pharmacy benefit managers (PBMs) update their F&B flat file today? How often should payers update their F&B flat file to account for formulary or benefit changes?
- How often do payers update the indicators for whether prior authorization is required within their F&B flat files? How often does that information change and is there typically a lag between policy changes and published F&B flat files?
- How frequently do providers use the NCPDP F&B standard as part of their prior authorization workflow today?
- How well integrated is the NCPDP F&B standard into providers' electronic health records (EHRs) today?
- How accurate is the group-level information included in the NCPDP F&B standard to specific patients?
- How could impacted payers utilize the NCPDP RTPB standard to indicate whether a drug is covered under a medical benefit?
- Through what mechanisms do payers make information available using the NCPDP RTPB standard today?
- How frequently do providers use tools conforming to the NCPDP RTPB standard as part of their prior authorization workflow today?
- How prevalent is implementation of the NCPDP RTPB standard into providers' EHRs today? How automated are current interactions with the NCPDP RTPB standard within providers' EHRs and clinical workflow?
- For electronic prior authorization, would or could requiring impacted payers to make available information using the NCPDP RTPB standard negate the need for impacted payers to make available information using the NCPDP F&B standard? Does the NCPDP RTPB standard include all the necessary formulary and benefits information and functionality that would be available by using the NCPDP F&B standard for electronic prior authorization?
- Would requiring impacted payers to make information available using both standards add value or create additional burden, specifically related to electronic prior authorization of drugs?
- Does the Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide (IG) have the technical capability to return specific coverage information through the "CoverageInformation" extension?

    - How could the "CoverageInformation" extension be best utilized to indicate whether a particular drug is covered under a medical benefit and whether the Prior Authorization API should be used for electronic prior authorization?
- Are there other existing technical solutions or methods that impacted payers could utilize to indicate to providers how a prior authorization request for a drug should be submitted?

Section II.A.3. Required Standards for FHIR APIs

Proposal: Impacted payers (Medicare Advantage [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 implement and maintain API technology conformant with unexpired versions of the standards adopted by the Secretary in 45 CFR 170.215, specifically 45 CFR 170.215(a), (b)(1), and (c), (d), and (e), as applicable, beginning on **the effective date of the final rule.**

Requests for Comment:

- Whether there are opportunities to streamline our regulatory requirements in instances where requiring conformance with the previously recommended IGs proposed in II.A.4.b. of this proposed rule for specific API use cases would achieve the same functional goal as explicitly requiring conformance with both the use case-specific IGs and required IGs or standards. For instance, whether it is necessary to require the base FHIR standard as well as the CRD, HL7 FHIR Da Vinci Documentation Templates and Rules (DTR), and HL7 FHIR Da Vinci Prior Authorization Support (PAS) IGs that we propose to require for the Prior Authorization API, or whether requiring the CRD, DTR, and PAS IGs alone, which are based on the FHIR standard, would provide comparable technical guidance for implementers while reducing regulatory complexity.
    - Scenarios in which independently requiring both the required standards in this section and use case-specific IGs proposed in section II.A.4.b. of the proposed rule could introduce alignment challenges. For instance, where one required standard references a specific version of another required standard, independent adoption of the latter standard could present further alignment challenges.
    - Instances in which requiring conformance with both the required standards in this section and the use case-specific IGs proposed in section II.A.4.b. of the proposed rule are necessary to fully represent necessary technical requirements and should be maintained.
- Comments on whether it would be helpful for payers to more specifically identify capabilities of required IGs relevant to a specific API, to further streamline requirements and reduce unnecessary development. For instance, whether we should specify only those capabilities of the HL7 Substitutable Medical Applications, Reusable Technologies (SMART) Application Launch Framework IG (SMART App Launch IG) relevant to the Patient Access API use case (e.g., the "Patient Access for Standalone Apps" Capability Set as well as the capabilities of "launch-standalone" and "context-standalone-patient," and the capabilities

in subsections “Authorization Methods,” “Client Types,” “Single Sign-on,” and “Permissions” except the “permission-online” and “permission-user”).

Section II.A.4. Requiring Additional Implementation Guides to Support Interoperability APIs

Proposals: Impacted payers would be required to use the following standards adopted by the Secretary by **October 1, 2027**:

- Patient Access API: An unexpired version of
  - HL7 FHIR Consumer Directed Exchange (CARIN) Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG
  - HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG
  - HL7 FHIR Da Vinci PDex US Drug Formulary IG (PDex US Drug Formulary IG)
- Provider Access API: An unexpired version of
  - CARIN IG for Blue Button
  - PDex IG
- Provider Directory API: An unexpired version of
  - HL7 FHIR Da Vinci PDex Plan Net IG (PDex Plan Net IG)
- Payer-to-Payer API: An unexpired version of
  - CARIN IG for Blue Button
  - PDex IG
- Prior Authorization API: An unexpired version of-
  - CRD IG
  - DTR IG

Alternative Proposal: Impacted payers would be required to use an unexpired version of the PDex US Drug Formulary IG adopted by the Secretary, if the drug formulary data requirement is retained, for impacted payers’ Provider Access and Payer-to-Payer APIs.

Section II.A.5. Recommended Implementation Guides to Support Interoperability APIs and Request for Comment

Recommendations: Impacted payers are recommended to use the following standards:

- Patient Access API: FHIR at Scale Taskforce (FAST) Security IG for registration, authentication, and authorization.
- Provider Access API:
  - HL7 FHIR Da Vinci Member Attribution (ATR) List IG (ATR List IG) to document and share attribution lists that identify whose patient data may be shared with a provider through the Provider Access API
  - FHIR at Scale Taskforce (FAST) Security IG for registration, authentication, and authorization
- Prior Authorization API:

- HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG for exchanging attachments related to prior authorization
- FHIR at Scale Taskforce (FAST) Security IG for registration, authentication, and authorization

Requests for Comment:

- Whether any of the IGs recommended are now mature and important enough for CMS to adopt in a final rule.
- How can CMS know whether and when the ATR List, CDex, and FAST Security IGs are ready for us to propose to require their use?
- Should CMS consider recommending or requiring the FAST Security IG "Tiered Open Authorization (Tiered OAuth)" in future rulemaking?
- If CMS proposes, in future rulemaking, to require the FAST Security IG, should we also propose to require impacted payers to use Tiered OAuth for user authentication? If so, to which APIs should that proposal apply? Would this be a useful solution to enable authentication and authorization at scale?
- Are there trust communities that exist today that impacted payers can utilize for business-to-business authentication and authorization? Do such communities exist for other stakeholders in the health care system, such as providers, or in other industries that could be used or expanded for this purpose?
- How much testing is necessary and under what readiness conditions would it be appropriate for us to propose to require use of the FAST Security IG for the Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization APIs?
- Should CMS consider recommending the CARIN Consumer Real-Time Pharmacy Benefit Check (RTPBC) IG?
- Are there differences in scope or use cases between the RTPBC IG and the Da Vinci PDex Drug Formulary IG? Specifically, would RTPBC IG provide additional or distinct benefits compared to the PDex Drug Formulary IG, or do the two largely address overlapping use cases?
- Is there value in providing patients with real-time prescription drug cost and coverage information through the Patient Access API?
- Are there potential technical or operational challenges associated with implementing the RTPBC IG within the Patient Access API?
- Is there enough patient demand via third-party apps to justify the burden of implementing the RTPBC IG?
- Do any third-party apps currently include this functionality (access to real-time prescription drug cost and coverage information), or would developers build it, if recommended?
- Do payers or PBMs currently support the required technical standards to enable third-party apps to use the RTPBC IG and would payers build that functionality, if recommended?

Section II.B. Electronic Prior Authorization for Drugs

Section II.B.3. Proposed Requirement to Incorporate Drugs Covered Under a Medical Benefit Into the Prior Authorization API for All Impacted Payers

Proposal: Impacted payers would be required to incorporate coverage and documentation requirements into the Prior Authorization API to support electronic prior authorization for drugs covered under a medical benefit by **October 1, 2027**.

Requests for Comment:

- Is the scope of the Prior Authorization API, as defined by its implementation guidance and the description of drugs covered under a medical benefit, clear and appropriate for impacted payers?
- For MA organizations, are there drugs other than those payable under Part B, such as supplemental benefits, that should be covered by our proposals to require MA organizations to support electronic prior authorization?
- Is the rubric to categorize drugs as within the scope of the Prior Authorization API (covered under a medical benefit) or within the scope of the NCPDP standards (covered under a pharmacy benefit) based on the system through which the claims are processed applicable to and appropriate for all or most state Medicaid and CHIP FFS programs?
- Is the system through which claims are processed the accurate and appropriate way to differentiate the categories of drugs that are within scope of the Prior Authorization API versus the NCPDP standards for other types of impacted payers?

Section II.B.7.b. Exceptions for Qualified Health Plan Issuers on the Federally-facilitated Exchanges

Proposals:

- The policy finalized in the 2024 CMS Interoperability and Prior Authorization final rule that allows states with small FFS populations to request an exemption from CMS for the non-drug items and services Prior Authorization API requirements would be removed.
- State Medicaid and CHIP FFS programs would be able to request extensions to the finalized compliance date to implement the Prior Authorization API and the proposed compliance date to incorporate drugs covered under a medical benefit into the Prior Authorization API.
- State Medicaid and CHIP FFS programs would be able to request extensions and QHP issuers on the FFEs would be able to request an exception from the proposed requirement to support an unexpired version of the NCPDP standards that the Secretary has adopted in 45 CFR 170.205(b), (c), or (u).
- Language in 45 CFR 156.223(i)(1)(iii) would be amended to require a QHP issuer on the FFEs seeking an exception from the Prior Authorization API requirements and/or proposed requirement to support an unexpired version of the NCPDP standards that the Secretary

has adopted in 45 CFR 170.205(b), (c), or (u) to describe their current or proposed means of conducting prior authorization.

Request for Comment: Flexibilities and options that can be provided to state Medicaid and CHIP FFS programs eligible for an exemption and QHP issuers on the FFEs eligible for an exception that would reduce burden for the reasons outlined previously, while ensuring compliance with the proposed or adopted Health Insurance Portability and Accountability Act of 1996 (hereinafter referred to as "HIPAA") transaction standards.

Section II.C. Improving Communications and Decision Timeframes for Prior Authorizations

Section II.C.2.c. Proposed Requirement to Include a Specific Reason for Denial to Providers When Denying Prior Authorization of All Drugs for State Medicaid and CHIP Fee-for-Service Programs, Medicaid Managed Care Plans, CHIP Managed Care Entities, and Qualified Health Plan Issuers on the Federally-facilitated Exchanges

Proposals:

- State Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs would be required to communicate to providers a specific reason for denying a prior authorization request for any drugs, regardless of the method used to send the prior authorization request or decision, by **October 1, 2027**.
- Structural changes to 42 CFR 438.210(c) and 42 CFR 438.242 to improve readability.

Section II.C.3.b. Prior Authorization Decision Timeframes for Qualified Health Plan Issuers on the Federally-facilitated Exchanges

Proposals:

- QHP issuers on the FFEs would be required to provide notice to the requesting provider of prior authorization decisions as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after receiving a standard prior authorization request for and as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving an expedited request for non-drug items and services and would be required to provide notice to the requesting provider of prior authorization decisions as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving a standard prior authorization request and as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving an expedited request for drugs by **October 1, 2027**.

    - For purposes of this proposal, a standard prior authorization request would have the meaning given in 29 CFR 2560.503-1(m)(2) to a "pre-service claim" and an expedited prior authorization request would have the meaning given in 29 CFR 2560.503-1(m)(1) to a "claim involving urgent care" for QHP issuers on the FFEs.

- QHP issuers on the FFEs would be able to extend the timeframes to notify the requesting provider of a prior authorization decision by up to 14 calendar days under certain circumstances, and would be required to notify the requesting provider in writing of the reasons for the delay and inform the provider of the right to file an expedited grievance if the provider disagrees with the QHP issuer on the FFEs' decision to grant an extension by **October 1, 2027**.

Requests for Comment:

- We are proposing that, in determining what meets the "as expeditiously as the enrollee's health condition requires" standard, QHP issuers on the FFEs must abide by the same requirement to make decisions in accordance with established accepted standards of medical practice in assessing an individual's medical condition, and we solicit comment on whether any other language in regulation or in sub-regulatory guidance is necessary to ensure that QHP issuers on the FFEs adhere to this standard.
- We believe it is appropriate to require QHP issuers on the FFEs to notify the requesting provider of reasons for extension and the right to file a grievance, but solicit comment on whether that is the case or if it should be amended.
- Whether requiring QHP issuers on the FFEs to provide notice to requesting providers of prior authorization decisions in a shorter timeframe than they are currently required to provide notice to patients of prior authorization decisions is sufficient to improve enrollees' care, or if CMS should consider also applying shorter timeframes for notification to patients, as well.
- Whether there would be burden due to the different timeframes for QHP issuers on the FFEs to notify a requesting provider of a prior authorization decision and to notify participants, beneficiaries, and enrollees of prior authorization decisions, and how we could potentially alleviate that burden.
- Whether we should finalize shorter timeframes for QHP issuers on the FFEs to notify the requesting provider of prior authorization requests for drugs, specifically, 24 hours for all requests (standard or expedited), to align with the existing requirements for state Medicaid FFS programs, Medicaid managed care plans, and CHIP managed care entities, and our proposal for state CHIP FFS programs.
- Whether the requirement to make decisions as "expeditiously as the enrollee's health condition requires" is appropriate, or whether additional or alternative language or sub-regulatory guidance is necessary to help ensure impacted payers make timely decisions and for consistency with existing decision timeframes in 45 CFR 147.136(b)(3) and 29 CFR 2560.503-1(f).

- Whether QHP issuers' parent organizations that participate in multiple CMS-regulated programs, such as MA organizations or Medicaid managed care plans, already have experience responding to prior authorization requests more quickly than is currently required by existing market-wide rules that they can leverage to improve processes for their QHPs offered on the FFEs.
- Whether QHP issuers on the FFEs' plan management systems can readily distinguish between a policy applicable to a QHP offered on an FFE, a policy applicable to off-Exchange individual or small group coverage, or a QHP issuer in an SBE.

Section II.C.3.c. Prior Authorization 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

Proposal: If commenters identify gaps in the decision timeframe requirements for drugs, state Medicaid FFS programs, Medicaid managed care plans, and CHIP managed care entities would be required to provide notice of prior authorization decisions for drugs within a timeframe that aligns with the existing 24-hour decision timeframe for covered outpatient drugs requirements by **October 1, 2027.**

Requests for Comment:

- Are there types of drugs covered by Medicaid or CHIP for which we should finalize a requirement that aligns with the 24-hour timeframe established for covered outpatient drugs by section 1927(d)(5)(A) of the Act?
- Whether we should consider future rulemaking to propose a requirement for MA organizations to respond to all prior authorization requests for drugs no later than 24 hours to align with the Medicaid and CHIP requirements for covered outpatient drugs.
- Whether there are any drugs payable under Medicare Part A that are not included as part of a larger bundle of inpatient services to which the timeframe to make prior authorizations decisions should apply for MA organizations.

Section II.C.3.d. Prior Authorization Decision Timeframes for Prescription Drugs for State CHIP Fee-for-Service Programs

Proposal: State CHIP FFS programs would be required to provide notice to providers and patients of prior authorization decisions in accordance with the beneficiary's medical needs, but no later than 24 hours after receiving a prior authorization request for prescription drugs for which Federal Financial Participation (FFP) is available, by **October 1, 2027**.

Section II.C.4. Update to State Medicaid and CHIP Fee-for-Service Programs' Decision Timeframe Terminology

Proposal: Regulatory language for state Medicaid FFS programs would be revised and regulatory language for state CHIP FFS programs would be added to explain that state Medicaid and CHIP FFS

programs must make prior authorization decisions available for non-drug items and services no later than 7 calendar days for standard requests and 72 hours for expedited requests unless a shorter timeframe is established by the state beginning on **the effective date of the final rule**.

Section II.C.5. Proposed Changes to Reporting Deadlines and Reporting Levels for Publicly Reported Prior Authorization Metrics for Non-Drug Items and Services for Medicaid Managed Care Plans and CHIP Managed Care Entities

Proposals: Medicaid managed care plans and CHIP managed care entities would be required to report certain metrics about prior authorizations for non-drug items and services, finalized in the 2024 CMS Interoperability and Prior Authorization final rule, by program, as well as by plan, no later than 90 days after the end of their contract rating period, beginning on **the effective date of the final rule**.

Section II.C.6. Proposed Changes to Publicly Reported Prior Authorization Metrics for Non-Drug Items and Services for Impacted Payers

Proposal: Impacted payers would be required to report new prior authorization metrics regarding non-drug items and services on their public websites beginning on **the effective date of the final rule**.

Section II.C.7. Proposed Requirement to Publicly Report Prior Authorization Metrics for Drugs for Impacted Payers

Proposals:

- MA organizations would be required to report metrics about prior authorization for drugs payable under Part B, and state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs would be required to report metrics about prior authorization metrics for drugs on their public websites by **2028 (to report metrics from the 2027 reporting period)**.
    - Deadlines: MA organizations, state Medicaid and CHIP FFS programs, and QHP issuers on the FFEs would be required to annually report the previous calendar year's metrics on their public websites no later than March 31 following any calendar year that the impacted payer offered that type of plan, and Medicaid managed care plans and CHIP managed care entities would be required to annually report the previous rating period's metrics on their public websites no later than 90 days after the end of their rating period.
    - Reporting Level: MA organizations would be required to report at the contract level (applicable integrated plans would report drugs covered by MA organizations at the MA contract level), state Medicaid and CHIP FFS programs to report at the state level, Medicaid managed care plans and CHIP managed care entities to report at the plan and program level (if coverage of drugs is included in their contract), and QHP issuers on the FFEs to report at the issuer level.

Request for Comment: Whether there are drugs payable under Part A that require prior authorization separate from other non-drug items and services that should be included in the scope of the proposed metrics for MA organizations.

Section II.D. Requirements for Issuers that Offer Small Group Market Qualified Health Plans on the Federally-facilitated Small Business Health Options Program Exchanges

Section II.D.3.b. Patient Access API - Proposals

Proposals: Small group market QHP issuers on the FF-SHOPs would be required to implement and maintain a Patient Access API in conformance with the requirements for QHP issuers on the individual market FFEs by **January 1, 2028**, and to annually report Patient Access API metrics to CMS in a form and manner and within the timeframes specified by the Secretary beginning in **2029 (to report metrics from the 2028 reporting period)**.

Section II.D.4.b. Provider Access API - Proposals

Proposal: Small group market QHP issuers on the FF-SHOPs would be required to implement and maintain a Provider Access API in conformance with the requirements for QHP issuers on the individual market FFEs by **January 1, 2028**.

Request for Comment: We believe that the compliance date for the above proposal provides sufficient time for those issuers to incorporate their small group market QHPs on the FF-SHOPs into their previous API implementation for individual market QHPs on the FFEs given that small group market QHP issuers on the FF-SHOPs also offer individual market QHPs on the FFEs. However, we solicit comment on whether this is the case.

Section II.D.5.b. Payer-to-Payer API - Proposals

Proposal: Small group market QHP issuers on the FF-SHOPs would be required to implement and maintain a Payer-to-Payer API in conformance with the requirements for QHP issuers on the individual market FFEs by **January 1, 2028.**

Request for Comment: We believe that the compliance date for the above proposal provides sufficient time for those issuers to incorporate their small group market QHPs on the FF-SHOPs into their previous API implementation for individual market QHPs on the FFEs given that small group market QHP issuers on the FF-SHOPs also offer individual market QHPs on the FFEs. However, we solicit comment on whether this is the case.

Section II.D.6.b. Prior Authorization API and Prior Authorization Process - Proposals

Proposals: Small group market QHP issuers on the FF-SHOPs would be required to implement and maintain a Prior Authorization API in conformance with the requirements for QHP issuers on the individual market FFEs by **January 1, 2028**, to respond to providers with a reason for denial for non-drug items and services by **October 1, 2027**, and to publicly report prior authorization metrics on non-drug items and services **beginning in 2028 (to report metrics from the 2027 reporting period)**.

Request for Comment: We believe that the proposed compliance dates for the above proposals provide sufficient time for individual market QHP issuers on the FFEs to extend their technology solutions and business processes to their small group market QHPs on the FF-SHOPs given that those issuers have met or are working to meet these proposed requirements for their individual market QHPs on the FFEs. However, we solicit comment on whether this is the case.

Section II.D.7.b. Exceptions

Proposal: The same exceptions process to the proposed requirements would be applied for small group market QHP issuers on the FF-SHOPs as currently applies to individual market QHP issuers on the FFEs per 45 CFR 156.221(h), including as cross referenced in 45 CFR 156.222(c) and 45 CFR 156.223(d).

Section II.E. Reporting Payer API Endpoints and Associated Information for CMS to Publish

Section II.E.6. Summary

Proposals:

- Impacted payers would be required to report all API endpoints to CMS, in the form of an Endpoint Resource, as defined by an unexpired version of the FHIR standard adopted in 45 CFR 170.215(a), including, if multiple, appropriate use cases for each.
- Impacted payers would also be required to report URLs with the required documentation for each of their interoperability APIs, as applicable:
    - A direct URL to the API FHIR capability statement
    - Authorization and authentication protocols and implementation details
    - API registration information
- Impacted payers would be required to report the above information to CMS **no later than 60 days after the effective date of a final rule**, update CMS within one week of any changes to the reported information, and verify their information at least once every 12 months. New impacted payers would be required to report this information **no later than 60 days before they begin covering patients under the applicable CMS program.**

Alternative Proposal: Impacted payers would be required to report to CMS all National Directory of Healthcare Providers & Services (NDH) IG Endpoint Profile resources containing the relevant information for each interoperability API.

Requests for Comment:

- Is the proposal to collect a direct URL for the FHIR capability statements necessary, or would a payer endpoint be sufficient to indicate that the capability statement is located at [API endpoint]/metadata, as is required by the FHIR standard, or is that data element duplicative?
- Whether a single URL to a site that contains the authorization and authentication protocols and implementation details, and API registration information is sufficient, or whether impacted payers should report separate direct URLs for each of these items?
- Whether there are discrete pieces of information, such as the specific authentication protocol a payer uses, that we should collect to facilitate faster API integration with patient health apps, provider EHRs, and payer systems?
- Would aligning the reporting requirements with the NDH Endpoint Profile resource reduce payer burden to report the proposed information and/or developer burden to use a centralized registry?
- If the alternative proposal is finalized, would it negate the need for impacted payers to report URLs to documentation related to authorization and authentication protocols and implementation details and API registration information?
- The burden that reporting API endpoints could place on payers and how CMS can reduce that burden, either with the information we collect or the method of collection.
- How CMS could collect and publish the reported information in a manner that would balance the burden on payers with the benefits to developers, patients, providers, and payers. For example:
    - Would a machine-readable file on CMS's website be sufficient?
    - What would the benefits be of a FHIR-enabled registry, either for reporting or publishing? Would using FHIR standards allow a more streamlined and automated reporting process for payers? Would it allow greater flexibility for third-party app developers and EHR developers, which could improve the patient and provider experience?

Section II.F. Updates to Patient Access, Provider Directory, Provider Access, and Payer-to-Payer APIs; API Usage Metrics

Section II.F.1.b. Information About Prior Authorizations for Drugs in the Patient Access, Provider Access, and Payer-to-Payer APIs - Proposals

Proposals: Impacted payers would be required to add information about prior authorization requests and decisions for all drugs to the categories of data they are required to make available through the Patient Access, Provider Access, and Payer-to-Payer APIs ("Access APIs"), within the timeframes established for non-drug items and services, by **October 1, 2027**.

Section II.F.2.b. Proposed Changes to Patient Access API Usage Metrics for Medicaid Managed Care Plans, CHIP Managed Care Entities, and Individual Market QHP Issuers on the FFEs

Proposals: Medicaid managed care plans and CHIP managed care entities would be required to report Patient Access API usage metrics to the state, by program, as well as by plan, no later than 90 days after the end of each rating period, and QHP issuers on the FFEs would be required to report Patient Access API usage metrics to CMS no later than the QHP certification application deadline for the subsequent year, beginning on **the effective date of the final rule.**[1]

Section II.F.2.c. Proposal to Report Metrics About the Provider Access, Payer-to-Payer, and Prior Authorization API Usage for All Impacted Payers

Proposals:

- Impacted payers would be required to report metrics about the usage of the Provider Access, Payer-to-Payer, and Prior Authorization APIs in the form of aggregated, de-identified data **beginning in 2028 (to report metrics from the 2027 reporting period)**.
    - Deadlines: MA organizations and state Medicaid and CHIP FFS programs would be required to annually report the previous calendar year's metrics no later than March 31, Medicaid managed care plans and CHIP managed care entities would be required to annually report the previous rating period's metrics no later than 90 days after the end of their rating period, and QHP issuers on the FFEs would be required to report the previous plan year's metrics no later than the QHP certification application deadline for the subsequent year.

[1] Information about QHP certification, including deadlines can be found at https://www.qhpcertification.cms.gov/QHP/aboutthemarketplace/Timeline.

- Reporting Level: MA organizations would be required to report at the contract level, state Medicaid and CHIP FFS programs at the state level, Medicaid managed care plans and CHIP managed care entities at the plan and program level, and QHP issuers on the FFEs at the issuer level.

Requests for Comment:

- CMS's position 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.
- With respect to the proposed Provider Access API usage metrics, the feasibility of separately reporting the total number of individual providers and groups of providers who request patient data via the Provider Access API, and whether we should finalize requirements for these payers to report separate metrics for individuals and groups of providers.
- With respect to the proposed Payer-to-Payer API usage metrics, whether we should disaggregate these metrics by data exchanges between an old and new payer and those between concurrent payers.
- Whether there are different metrics that we should consider requiring impacted payers to report.
- With respect to states reporting usage metrics to CMS via the Advance Planning Document (APD) process described in 45 CFR part 95, subpart F, whether there are existing or alternative reporting mechanisms for Medicaid and CHIP data for states to leverage to better facilitate the reporting process. Specifically, whether the use of an online portal or form would be simpler to meet the annual deadlines or whether a FHIR server to automate reporting would be preferred, and what the anticipated level of burden would be.

Section II.F.3.b. Removing Drug Formulary Information from the Provider Access and Payer-to-Payer APIs - Proposals

Proposal: Drug formulary information would be removed 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 beginning on **the effective date of the final rule**.

Request for Comment: Whether there are use cases where it would be helpful for any party to have access to drug formulary data via those APIs.

Section II.F.4.b. Denial or Discontinuation of Access to the Provider Directory API - Proposals

Proposal: MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities would be required to update their Provider Directory APIs denial or discontinuation policies beginning on **the effective date of the final rule**.

Section II.F.5.a. Other Amendments to Access API Requirements - Applicability Date

Proposals: Restructuring regulatory text to incorporate the existing Patient Access API 2021 implementation date into 42 CFR 422.119(a), 42 CFR 431.60(a), 42 CFR 457.730(a), and 45 CFR 156.221(a) and to incorporate the existing requirement for impacted payers to make available data with a date on or after January 1, 2016, into 42 CFR 422.119(b)(1), 42 CFR 431.60(b), 42 CFR 457.730(b), and 45 CFR 156.221(b)(1) beginning on **the effective date of the final rule**.

Section II.F.5.b. Exceptions for QHP Issuers on the FFEs

Proposal: Language in 45 CFR 156.222(c)(1)(ii), 45 CFR 156.222(c)(1)(iii), and 45 CFR 156.223(i)(1)(iii) would be amended to require QHP issuers on the FFEs applying for an exception to describe the impact of non-compliance on all applicable parties beginning on **the effective date of the final rule**.

Section II.G. Open Payments Civil Monetary Penalties

Section II.G.1.b. Proposal to Add a Definition of "Failure to Report" in 42 CFR 403.902

Proposal: A definition for "failure to report" would be added in 42 CFR 403.902, which would allow CMS to impose a civil monetary penalty (CMP) on applicable manufacturers or applicable group purchasing organizations (GPOs) should either of those entities fail to grant timely access (within 30 calendar days of the date of the audit request) to any books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the records for the purposes of an audit authorized by 42 CFR 402.912(e)(2) beginning on **the effective date of the final rule**.

Section II.H. Modifications to HIPAA Standards Related to Prior Authorization

Section II.H.10. Summary of Standards Proposals for Prior Authorization Related Transactions

Proposals:

- Prior authorization would be defined as transmissions described in 45 CFR 162.1301(a) used by health care providers to obtain authorization for health care, and transmissions described in 45 CFR 162.1301(c) used by health plans to respond to such requests.
- The current operating rules that are associated with the "eligibility for a health plan" transaction would be modified to exclude prior authorization-related transmissions beginning on **the effective date of the final rule**.

- The following FHIR specifications would be adopted with a compliance date **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**:
    - As the standard for dental, professional, and institutional "eligibility for a health plan" transactions for health care eligibility inquiry and response, when used to determine whether prior authorization is required:
        - HL7 FHIR, Release 4.0.1.
        - US Core IG, Standard for Trial Use (STU) 6.1.0
        - SMART App Launch IG, Release 2.0.0
        - CRD IG, Version 2.2.1—STU 2.2
    - As the standard for dental, professional, and institutional "referral certification and authorization" transactions, within the proposed definition of prior authorization:
        - HL7 FHIR, Release 4.0.1
        - US Core IG, STU 6.1.0
        - SMART App Launch IG, Release 2.0.0
        - CRD IG, Version 2.2.1—STU 2.2
        - DTR IG, Version 2.2.0—STU 2.2
        - PAS IG, Version 2.2.1—STU 2.2
- The CDex IG, Version 2.1.0—STU 2.1 would be adopted as the attachments standard for prior authorization transactions with a compliance date **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**.

Alternative Proposal: The FHIR standards of this proposed rule would be adopted for all "referral certification and authorization transactions" described in 45 CFR 162.1301.

Request for Comment:

- Whether adopting the FHIR standards for prior authorization transmissions and retaining the currently adopted X12N transaction standards for other referral certification transmission use cases would increase burden on HIPAA covered entities to maintain the ability to conduct electronic transactions using two different standards.
- Whether there are benefits to maintaining the existing X12N 278 Health Care Services Review—Request for Review and Response transaction standard (X12N 278 transaction standard), currently adopted in 45 CFR 162.1302, for referral certification transmissions.
- Should HHS adopt any later versions of the proposed standards, including more recent versions that are currently available and versions that may become available between the publication of the proposed and final rules?
- Should HHS rely on the HL7's Major.Minor.Patch approach to reflect that updates from the adopted version are maintenance changes that do not require additional rulemaking?
- Rather than adopting the CDex IG, would it be appropriate to recommend it at this time to give the industry an opportunity to test the CDex IG in real-world applications?

- Would adopting the CDex IG affect HIPAA covered entities' ability to implement the other proposed FHIR standards (without attachments) for prior authorization transactions before the proposed compliance date, discussed later in this section? Should HHS finalize a later compliance date for CDex to phase in implementation of these proposals?
- Conversely, would it be economical for HIPAA covered entities to implement the CDex IG at the same time as the proposed prior authorization transaction standards?

Section II.H.11. Requests for Comment

Requests for Comment:

- Should we revisit the direct data entry exception in 45 CFR 162.923(b) in order to incentivize or require HIPAA covered entities to move from portal-based transactions to fully electronic transactions using the adopted standards? If so, how should we amend or remove the direct data entry exception to achieve that goal?
- Were we to amend or remove the direct data entry exception, how would that affect standard transactions other than prior authorization?
- Are there benefits to health plan web portals for HIPAA covered entities that we have not considered? Specifically, which types of HIPAA covered entities? Which types of transactions?
- What would be the burden to HIPAA covered entities of amending or removing the direct data entry exception? Specifically, which types of HIPAA covered entities? With respect to which types of transactions?
- Would amending or removing the direct data entry exception lead to greater adoption of electronic transaction standards, or would it perversely incentivize HIPAA covered entities to move to fully manual transactions?
- Are there particular types of HIPAA covered entities that would be especially affected, such as small or rural health care practices?

Section II.J. Adoption of Health Information Technology Standards and Incorporation by Reference

Section II.J.6. Proposal to Adopt Standards for Use by HHS

Proposal: Standards in 45 CFR 170.215(j), (k), (m), and (n) would be adopted on behalf of the Secretary.

Section II.J.7. Proposed Expiration Dates for Certain Versions of Adopted Standards

Proposal: An expiration date of January 1, 2028, would be added to corresponding standards currently in 45 CFR 170.215(j), (k), (m), and (n) if our proposals to adopt newer versions of these standards are finalized.

Alternative Proposal: The standards in 45 CFR 170.215(j), (k), (m), and (n) would be removed and replaced with the newer versions of the standards, without a transition period for use of multiple versions.