Final Interoperability Rules – Major Provisions & Comment Responses

On March 9, 2020, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) released their final regulations on interoperability. Together, these final rules create and implement new mechanisms to enable patients to access their own health care information through third-party software applications.

MHPA submitted a comment letter (https://www.medicaidplans.org/_docs/MHPA_Comment_Response_CMS-9115-PRIN0955-AA01_FINAL.pdf) expressing support for the effort to advance policies to empower patients with easier access to their electronic health information, but also noting concerns with issues of privacy and security and the impact of the numerous requirements, burdens, and costs on the health care system.

A high-level summary of the rules' major provisions related to Medicaid managed care are set forth below. The summary is followed by a Table that compares the key issues raised in the MHPA comment letter and the CMS response (if any). Please note that the Table is not all-inclusive of raised issues.

Summary of Major Provisions

Patient Access Application Programming Interface (API)

- CMS finalized with modifications their proposal to require Medicare Advantage, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to implement and maintain a standards-based Patient Access API.
- This Patient Access API must meet the technical standards finalized by the Department of Health and Human Services in the ONC 21st Century Cures Act final rule (published elsewhere in this issue of the Federal Register) at 45 CFR 170.215 (currently including Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) Release 4.0.1) and the content and vocabulary standards finalized by HHS in the ONC 21st Century Cures Act final rule (published elsewhere in this issue of the Federal Register) at 45 CFR 170.213, as well as content and vocabulary standards at 45 CFR part 162 and the content and vocabulary standards at 42 CFR 423.160.
- CMS finalized that through the Patient Access API, payers must permit third-party applications to retrieve, with the approval and at the direction of a current enrollee, data specified at 42 CFR 422.119, 431.60, 457.730, and 45 CFR 156.221.
- Specifically, CMS finalized that the Patient Access API must, at a minimum, make available:
  - adjudicated claims (including provider remittances and enrollee cost-sharing);
  - encounters with capitated providers; and clinical data, including laboratory results (when maintained by the impacted payer).
- Data must be made available no later than one (1) business day after a claim is adjudicated or encounter data are received.
- Beginning January 1, 2021, impacted payers must make available through the Patient Access API the specified data they maintain with a date of service on or after January 1, 2016.

Provider Directory API

- CMS finalized regulations to require that MA, Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities make standardized information about their provider networks available through a Provider Directory API that is conformant with the technical standards finalized by HHS in the ONC 21st Century Cures Act final rule (published elsewhere in this issue of the Federal Register) at 45 CFR 170.215, excluding the security protocols related to user authentication and authorization and any other protocols that restrict availability of this information to particular persons or organizations.
- Authentication and authorization protocols are not necessary when making publicly available data accessible via an API.
- CMS finalized that the Provider Directory API must be accessible via a public-facing digital endpoint on the payer's website to ensure public discovery and access.
- Payers must make available via the Provider Directory API: provider names, addresses, phone numbers, and specialties.
- All directory information must be made available to current and prospective enrollees and the public through the Provider Directory API within 30 calendar days of a payer receiving provider directory information or an update to the provider directory information.
- The Provider Directory API is being finalized at 42 CFR 438.242(b)(6) for Medicaid managed care plans and at 42 CFR 457.1233(d)(3) for CHIP managed care entities.
- A published Provider Directory API must be fully implemented by January 1, 2021.

Payer-Payer Data Exchange

- CMS finalized with certain modifications to require MA, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to coordinate care between payers by exchanging, at a minimum, the data elements specified in the current content and vocabulary standard finalized by HHS in the ONC 21st Century Cures Act final rule (published elsewhere in this issue of the Federal Register) at 45 CFR 170.213 (currently the "United States Core Data for Interoperability" (USCDI) version 1.
- This payer-to-payer data exchange requires these payers, as finalized at 42 CFR 438.62(b)(1)(vi) for Medicaid managed care plans (and by extension under § 457.1216 CHIP managed care entities, at a current or former enrollee's request, specific information they maintain with a date of service on or after January 1, 2016 to any other payer identified by the current enrollee or former enrollee.
- CMS also finalized that a payer is only obligated to share data received from another payer under this regulation in the electronic form and format it was received. This is intended to reduce burden on payers.

Important Dates

- Patient Access API (Jan. 1, 2021)
- Provider Directory API (Jan. 1, 2021)
- Payer-to-Payer Data Exchange (Jan. 1, 2022)
- Improving the Dually Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges (April 1, 2022)

For additional information, including access to the final rules: https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

ISSUES	MHPA COMMENTS CMS ACTION	INTEROPERABILITY FINALIZED POLICY	IMPLEMENTATION DATE
Interoperability Rule (CMS/ONC) - General Comment	MHPA recommended a phased-in approach or, alternatively, a delayed effective date. ***CMS Action: No substantive changes; no phase-in or delay.***	CMS and the ONC identified Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (FHIR) Release 4.0.1 as the foundational standard to support data exchange via secure application programming interfaces (APIs). This rule finalizes new policies to facilitate patient access to their health information and move the healthcare system toward greater interoperability.	Varied/See below

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Patient Access API	MHPA requested implementation delay due to privacy and security risks. ***CMS Action: Minor change only; no delay.*** ***Finalized implementation date of the Patient Access API as January 1, 2021.*** ***For Medicaid managed care, CMS reminded states should they determine that obligations in this rule warrant a retroactive adjustment to capitation rates then those adjustments must be certified by an actuary in a revised rate certification and submitted to CMS as a contract amendment, pursuant to 42 CFR 438.7(c).*** ***Comment/Response of interest:*** ***"Comment: A few commenters requested that CMS modify the rule to exempt Medicaid managed care plans. Commenters noted that Medicaid managed care plans are already operating with razor thin margins and the proposed rule will substantially increase the costs for Medicaid managed care plans. Further, commenters noted that due to the substantial increase in costs, plans may not be able to meet the MLR requirements in 42 CFR 438.8. Another commenter suggested that CMS explicitly exclude from the requirements of the rule long-term services and supports (LTSS) plans. Some commenters also recommended that CMS exclude dental plans from the requirements in the proposed rule.*** ***Response: We appreciate the commenters' concerns, however we are not exempting Medicaid or CHIP managed care plans, including LTSS or dental plans, from the requirements in this rule, as such an approach would not be consistent with our goal of ensuring that all beneficiaries across the health care market, including Medicaid FFS and managed care, have access to and can exchange specified health care data. We are finalizing the Patient Access API requirements for state Medicaid and CHIP agencies and managed care plans, including LTSS and dental plans. States and managed care plans must make adjudicated claims and encounter data available through the API for all Medicaid-covered services, including LTSS and dental. This requirement extends to all Medicaid-covered services for which a claim, or encounter claim, is generated and adjudicated. Regarding costs for managed care plans – since the Patient Access API requirements must be contractual obligations under the managed care contract – the state must include these costs in the development of a plan's capitation rates."***	Beginning January 1, 2021, CMS is requiring Medicare Advantage (MA) plans, Medicaid, Children's Health Insurance Program (CHIP), and Qualified Health Plan (QHP) issuers on the federal exchanges to share claims and other health information with patients in a safe, secure, understandable, user-friendly electronic format through its Patient Access API. This Patient Access API must meet the technical standards finalized in the ONC Final Regulation, which currently includes HL7® FHIR® Release 4. At a minimum, CMS is requiring that the Patient Access API make available: • adjudicated claims (including provider remittances and enrollee cost-sharing); • encounters with capitated providers; and • clinical data, including laboratory results (when maintained by the impacted payer). Data must be made available no later than one business day after a claim is adjudicated or encounter data are received.	January 1, 2021

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Provider Directory API	To avoid unnecessary duplication of effort and additional avoidable costs, MHPA recommended an explicit exemption for health plans that are already providing this information in the manner that aligns with the requirements under the proposed rule. ***CMS Action: Change from proposal.*** ***To avoid unnecessary duplication of effort and potential confusion, CMS did not finalize the proposal to include provider directory information in the Patient Access API. Instead, CMS finalized the inclusion of this information (consistent in scope as proposed for the Patient Access API) in the public facing Provider Directory API discussed in section IV. of this final rule, which requires MA plans, Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, and CHIP managed care entities to provide public access to complete and accurate provider directory information at 42 CFR 422.120, 431.70, 438.242(b)(6), 457.760, and 457.1233(d)(3).*** ***Appreciating that provider information is already publicly available, and unlike the other information included in the Patient Access API discussed in section III. of this final rule, is of a less sensitive nature, to avoid potential confusion and reduce burden resulting from having the provider directory information included in both the Patient Access API and the Provider Directory API, CMS is only requiring that one API – the Provider Directory API – provide access to provider directory information.*** ***Comment/Response of interest:*** ***"Comment: Some commenters disagreed with the proposal. They stated that payers are already required to make this information available and this proposal could result in unnecessary duplication of effort and additional costs. One commenter suggested CMS provide an exemption for payers that are already providing this information in a manner that aligns with the requirements in the proposed rule.*** ***Response: We appreciate the commenters' concern about potentially duplicative effort. While we understand that different payers are already required to make this information available in a machine readable format or on a public website according to the different rules associated with each program, we believe that making this information available through a standardized API will bring additional benefits to enrollees and prospective enrollees by making it easier for developers to incorporate this information into consumer-facing applications. We note that we did not propose to extend the requirement regarding provider directory information to QHP issuers on the FFEs, as these issuers are already required to make provider directory information available according to a specific standard for the electronic transfer of this information, as discussed in the CMS Interoperability and Patient Access proposed rule (84 FR 7633)."***	CMS is requiring MA plans, Medicaid and CHIP fee-for service (FFS) programs, Medicaid managed care plans, and CHIP managed care entities to make standardized information about their provider networks available through a Provider Directory API. At a minimum, these payers must make available via this Directory provider names, addresses, phone numbers, and specialties.	January 1, 2021.

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Payer-Payer Data Exchange	MHPA expressed concern about the proposed 1-day turnaround time for making claims and encounter data available to patients. In addition to potential system and process changes, health plans will most likely need to modify provider contracts to meet this requirement. We believed that attempts to modify provider contracts by the January 1, 2020 and July 1, 2020 time frames would be a significant challenge and place additional administrative burdens and costs on clinicians who most likely have contracts with multiple plans and payers. ***CMS Action: No substantive changes.*** ***Comment/Response of interest:*** ***"Comment: Several commenters expressed concern that the proposed timeframe for payers to share claims and encounter data with patients could require providers to accelerate their submissions to payers triggering additional requirements in existing contracts for the submission of claims and encounter data. Some commenters cautioned there could be potential downstream consequences such as narrowing a payer's provider network. One commenter recommended removal of proposed rule preamble language suggesting that MA plans, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs could consider adding time requirements for submission of claims and encounter data in their contracts with providers. One commenter recommended CMS provide sample contract language or dedicate resources to educating providers about the intent of these possible contract revisions.*** ***Response: We appreciate the commenters' concerns and recommendations. As discussed in the CMS Interoperability and Patient Access proposed rule, we do appreciate that some payers may consider adding timeframes to contracts with providers to help ensure patients get timely access to their claims and encounter data. Again, we strongly encourage providers to make this information available in as timely a fashion as possible to best assist patients in having access to their health information. Adding language to contracts is one way for payers and providers to work together to ensure patients get this valuable information in as timely a manner as possible. We believe providers can benefit as well if this information is available sooner; it could be shared with them for the purposes of care coordination in a more timely manner, too. It may take some time for providers to improve internal efficiencies to meet potential new timeline requirements, but we believe the long-term benefit outweighs potential short term implementation burden. We do note, however, that the policy being finalized in this rule is specific to payers making adjudicated claims and encounter information available to patients via the Patient Access API within one (1) business day after the payer receives the information. Any***	At a patient's request, CMS is requiring MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to coordinate care between payers by exchanging, at a minimum, the data elements defined in the U.S. Core Data for Interoperability (USCDI) version 1 data set, to other CMS payers, to ensure that the new payer has patients' complete records if the patient change plans. USCDI version 1 includes high-level clinical data including allergies, clinical notes, patient goals and health concerns, immunizations, laboratory tests and results, medications, procedures and vital signs. The USCDI standard aligns with the ONC Rule's definition and exceptions for information blocking and the same API standard for exchanging patients' electronic health information. Patients have up to five years after their coverage ends to submit a request to a payer to share their information.	January 1, 2022.

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Participation in a Trusted Exchange Network	MHPA recommended to not implement the proposed requirement for health plans to use the Trusted Exchange Network framework because Draft 2 of the TEFCA was just released on April 19, 2019 and has not been finalized. ***CMS Action: Policy not finalized.***	CMS is not requiring MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to participate in a trusted exchange network given the concerns commenters raised regarding the need for a mature Trusted Exchange Framework and Common Agreement (TEFCA) to be firmly in place before mandating such a requirement.	N/A
Supporting Payers Educating their Patients	MHPA requested that CMS address issue of responsibility for third party compliance with privacy and security obligations. ***CMS Action: Clarification/Modification*** ***CMS preamble language: "Taking into consideration comments indicating strong public support for additional privacy and security measures, we are further building off of the privacy and security policies we are finalizing in this rule by asserting that MA organizations, Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers on the FFEs are encouraged, but are not required, to request third-party apps attest to having certain privacy and security provisions included in their privacy policy prior to providing the app access to the payer's API.*** ***We are finalizing the requirement with modification that payers must publish on their websites the necessary educational information, but we will help supply the content needed to meet this requirement. The suggested content we are providing for the educational materials will be shared through our normal communication channels including via listservs and is available via our website: https://www.cms.gov/Regulations-and- Guidance/Guidance/Interoperability/index. The modification we are making is to refine the language in the regulation text to expressly state that payers must include a discussion about a third-party app's secondary uses of data when providing factors to consider in selecting an application at 42 CFR 422.119(g)(1), 431.60(f)(1), and 457.730(f)(1), and 45 CFR 156.221(g)(1). In addition, at 42 CFR 422.119(g), 431.60(f), and 457.730(f), and 45 CFR 156.221(g), we are modifying the regulation text to state the payer must make these materials available in an easily accessible location on its public website."***	This document provides an overview of what is required to be included in a payer's patient resource document and some content payers may choose to use to help meet this requirement. Use of this document is not required; this is meant to support payers as they produce patient resources tailored to their patient population. Patient Privacy and Security Resources (PDF)	January 1, 2021
Plan Coverage and Formularies	MHPA recommended an exception to avoid duplication, for health plans already providing information in a manner that aligns with requirements ***CMS Action: No substantive changes.***	Medicaid and CHIP FFS and managed care must make preferred drug lists available. Part D Medicare Advantage plans must also make formulary information available via the Patient Access API.	January 1,2021

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Improving the Dually Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges	MHPA supported CMS's efforts to increase data sharing frequency and respectfully requests clarification if this proposal encompasses a reciprocal daily response from CMS to the states. Further, we seek clarity on whether the proposal provides for Medicaid managed care organizations to have daily access to the MMA data for the purposes of benefit and care coordination between the Medicaid and Medicare programs. ***CMS Action: No substantive changes.*** ***Comment/Response of interest:*** ***"Comment: A few commenters noted the value of the data in the MMA file to Medicaid managed care organizations (MCO), Medicare dual eligible special needs plans (D-SNPs), Health Information Exchanges, and providers for the purposes of coordinating enrollment, benefits, and/or care for dually eligible individuals. These commenters requested access to the daily MMA file. One commenter noted that some states are sharing Medicare plan enrolment data from these files with their Medicaid MCOs while also providing batch inquiry data sharing mechanisms to D-SNPs on Medicaid plan enrollment. This commenter recommended that CMS encourage or require all states to follow this process at a minimum.*** ***Commenters also encouraged CMS to leverage the MMA file to support parties complying with the D-SNP integration standards recently issued in 42 CFR 422.2.*** ***Response: We appreciate these suggestions to promote access to data for plans and providers serving dually eligible individuals, and we will explore these ideas further for potential future consideration. However, we decline to modify the regulation as suggested, as the recommended changes are beyond the scope of the proposal, which is limited to the frequency of the file exchange."***	This final rule will update requirements for states to exchange certain enrollee data for individuals dually eligible for Medicare and Medicaid, including state buy-in files and "MMA files" (called the "MMA file" after the acronym for the Medicare Prescription Drug, Improvement and Modernization Act of 2003) from monthly to daily exchange to improve the dual eligible beneficiary experience, ensuring beneficiaries are getting access to appropriate services and that these services are billed appropriately the first time, eliminating waste and burden. States are required to implement this daily exchange starting April 1, 2022.	April 1, 2022