
SHO # 20-003

**RE: Implementation of the CMS
Interoperability and Patient Access Final
Rule and Compliance with the ONC 21st
Century Cures Act Final Rule**

August 14, 2020

Dear State Health Official:

On May 1, 2020, the Centers for Medicare & Medicaid Services (CMS) published the final rule, “Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers,” (referred to as “CMS Interoperability and Patient Access final rule” in this letter) to further advance interoperability for Medicaid and Children’s Health Insurance Program (CHIP) providers and improve beneficiaries’ access to their data.¹

This letter describes how state Medicaid agencies, Medicaid managed care plans, CHIP agencies, and CHIP managed care entities should implement this final rule in a manner consistent with existing guidance and the recently published “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” final rule (ONC 21st Century Cures Act final rule), by the Office of the National Coordinator for Health Information Technology, published in the Federal Register on May 1, 2020.²

Several new requirements in the CMS Interoperability and Patient Access final rule apply to Medicaid and CHIP, including the following:

- **Implement and maintain a standards-based Patient Access API:** The CMS Interoperability and Patient Access final rule requires state Medicaid agencies, Medicaid managed care plans, CHIP agencies, and CHIP managed care entities to make certain health information about Medicaid and CHIP beneficiaries accessible through a Patient Access application program interface (API) by January 1, 2021. This policy enables beneficiaries to have access to their health data on their internet-enabled devices (such as smartphones). Due to the COVID-19 public health emergency (PHE), CMS is exercising enforcement discretion, however, and does not expect to enforce this requirement prior to July 1, 2021.³
- **Payer-to-Payer Data Exchange - Coordinate care between payers by exchanging, at a minimum, the information contained in the United States Core Data for**

¹ 85 Fed. Reg. 25,510-25,640 (May 1, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf>

² 85 Fed. Reg. 25,642-25,961 (May 1, 2020).

³ Additional information is available at CMS’s website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.

Interoperability (USCDI): The CMS Interoperability and Patient Access final rule requires Medicaid managed care plans and CHIP managed care entities to comply with a beneficiary’s request to have their health data transferred from payer to payer by January 1, 2022. For example, if a patient transfers from one Medicaid managed care plan or CHIP managed care entity to another, the previous plan must honor the patient’s request to have certain data transferred to the new plan and the new plan must incorporate the information into its records. This new policy may reduce the need for unnecessary letters of medical necessity, prior authorization requests and calls or faxes to pharmacies or health plans if the receiving plan decides to use the information shared from the prior plan in administering the beneficiary’s coverage.

- **Make standardized information about provider networks available via a FHIR-based Provider Directory API:** The CMS Interoperability and Patient Access final rule requires Medicaid agencies, CHIP agencies, Medicaid managed care plans and CHIP managed care entities to provide current provider directory information via an API by January 1, 2021. Having this information available through an API will facilitate public access to accurate information about which managed care providers are in-network or accepting new patients, as well as current contact information for providers. As explained above, due to the COVID-19 PHE, CMS is exercising enforcement discretion and does expect to enforce this requirement prior to July 1, 2021.⁴
- **Improving the Dual Eligible Experience:** The CMS Interoperability and Patient Access final rule requires state Medicaid agencies, by April 1, 2022, to exchange certain data with CMS daily on beneficiaries who are dually eligible for Medicaid and Medicare. Currently, many states and CMS exchange these data as infrequently as monthly, which delays coverage status changes and leads to inaccuracies, recoupments, and poor customer experiences. Improving the accuracy and timeliness of data on dual eligibility status is a strong first step in improving how these systems work together for beneficiaries, providers, and payers.
- **The ONC 21st Century Cures Act final rule** also has potential implications for Medicaid agencies, CHIP agencies, Medicaid managed care plans, and CHIP managed care entities. All such entities should review the final rule, particularly the sections on the definition of health information network (HIN) or health information exchange (HIE) and the information blocking exceptions. Those entities should also review existing contractual and financial relationships—especially those related to API usage and access—to evaluate potential compliance implications with regard to the ONC 21st Century Cures Act final rule.

⁴ See *supra* note 3.

The key compliance dates in the CMS final rule are as follows:

Policy	Compliance Date
Patient Access Application Program Interfaces (API)	January 1, 2021 ⁵
Provider Directory API	January 1, 2021 ⁶
Payer-to-Payer Data Exchange	January 1, 2022
Improving the Medicare-Medicaid Dually Eligible Experience	April 1, 2022

Each of these policies is described more fully below.

Patient Access API

The CMS Interoperability and Patient Access final rule adds 42 CFR 431.60 and 42 CFR 457.730, which require state Medicaid and CHIP fee for service programs to implement secure, standards-based APIs and requires them to provide current beneficiaries or their personal representatives with specified claims and encounter data, certain clinical information, and information about covered outpatient drugs. Medicaid managed care plan requirements are codified at 42 CFR 438.242(b)(5); CHIP managed care entity requirements are at 42 CFR 457.1233(d). These managed care regulations require the plans and entities to comply with the same standards that apply to the fee for service programs. The CMS Interoperability and Patient Access final rule requires compliance with the API technical standards adopted by HHS at 45 CFR 170.215 including the Health Level 7 (HL7[®])⁷ Fast Healthcare Interoperability Resources (FHIR[®]) standard⁸ and relevant technical standards.

State Medicaid agencies implementing the API requirements described in 42 CFR 431.60 might be able to claim the enhanced federal financial participation (FFP) described in section 1903(a)(3)(A)(i) of the Social Security Act (the Act) for the design, development, installation, or enhancement of mechanized claims processing and information retrieval systems, and might be able to use the enhanced FFP described in section 1903(a)(3)(B) of the Act for the operation of mechanized claims processing and information retrieval systems, provided that they meet all other requirements applicable to claiming those enhanced federal matching rates.

States are reminded that 42 CFR 433.112(b)(12) and 433.116(c) require them to ensure that any system for which they are receiving enhanced FFP under section 1903(a)(3)(A)(i) or (B) of the Act aligns with and incorporates the ONC Health Information Technology standards adopted in accordance with 45 CFR part 170, Subpart B. The Patient Access API complements this requirement and will further advance interoperability. States may be best able to compile all data elements described for the Patient Access API in 42 CFR 431.60 through connections to health information exchanges or public health agencies, or human services agencies. Specifically, the required data in the United States Core Data for Interoperability (USCDI) described at 45 CFR 170.213 might include information residing in health information exchanges or public health agencies (for immunization data, lab test and result data, etc.), or human service agencies, and states should review if establishing such connections would be appropriate. If so, enhanced FFP might be available under section 1903(a)(3)(A)(i) or (B) of the Act to support such connections

⁵ . See *supra* note 3 and accompanying text.

⁶ . See *supra* note 3 and accompanying text.

⁷ Health Level Seven International (HL7[®]) is a not-for-profit, ANSI-accredited standards development organization (SDO) focused on developing consensus standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

⁸ <https://www.hl7.org/fhir/overview.html>.

between those entities and Medicaid agencies. For CHIP agencies, section 2105(c)(2)(A) of the Act, limiting administrative costs to no more than 10 percent of CHIP payments to the state, would apply in developing these systems.

Provider Directory API

The CMS Interoperability and Patient Access final rule requires state Medicaid agencies, CHIP agencies, Medicaid managed care plans, and CHIP managed care entities to implement an API that makes complete and accurate provider directory information available through a public-facing digital endpoint on the payer’s website. These requirements are in 42 CFR 431.70 for state Medicaid agencies with regard to the provider directory information specified in section 1902(a)(83) of the Act; 42 CFR 438.242(b)(6) for Medicaid managed care plans with regard to provider directory information specified in § 438.10(h)(1) and (2); § 457.760⁹ for CHIP agencies with regard to specified provider information; and § 457.1233 for CHIP managed care entities with regard to provider directory information specified in § 438.10(h)(1) and (2). Under these regulations, the provider directory API must meet the same technical standards as the Patient Access API, excluding the security protocols related to user authentication and authorization. These regulations require the provider directory information to be updated no later than 30 calendar days after the state Medicaid agency, Medicaid managed care plan, CHIP agency or CHIP managed care entity receives the provider directory information or updates to provider directory information.

We strongly encourage leveraging the DaVinci PDex PlanNet IG, which is based on FHIR Version 4.0., and was developed in cooperation with the ONC with guidance from HL7 International.¹⁰ For state Medicaid agencies seeking to access the enhanced FFP at section 1903(a)(3)(A)(i) or (B) of the Act, using the PlanNet IG is required under 42 CFR 433.112(b)(12) and 433.116(c). Additionally, state Medicaid agencies are strongly encouraged to begin collecting digital contact information (such as Direct addresses or FHIR URLs)¹¹ for provider communication and facilitate the populating of this contact information into the CMS National Plan and Provider Enumeration System (NPPES)¹² as an appropriate part of Medicaid provider enrollment.

Payer-to-Payer Data Exchange

The CMS Interoperability and Patient Access final rule finalizes requirements in 42 CFR 438.62(b)(1)(vi) and (vii) for the creation of a process for the electronic exchange of, at a minimum, the data classes and elements included in the United States Core Data for Interoperability (USCDI)¹³ content standard adopted at 45 CFR 170.213. Medicaid managed care plans and CHIP managed care entities¹⁴ must comply with this requirement beginning January 1, 2022. The USCDI data classes and elements received from other plans must be incorporated into the managed care plans’ records about the enrollee. At the request of an enrollee, the managed care plan must incorporate into its records such enrollee data with a date of service on or after January 1, 2016, from any other payer that has provided coverage to the

⁹ Per § 457.760(b)(1) this includes provider names, addresses, phone numbers, and specialties, updated no later than 30 calendar days after the State receives provider directory information or updates to provider directory information.

¹⁰ See <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index> for more information on available IGs to support API implementation.

¹¹ See <https://nppes.cms.hhs.gov/webhelp/nppeshelp/HEALTH%20INFORMATION%20EXCHANGE.html#>.

¹² See <https://npiregistry.cms.hhs.gov/registry/help-details>

¹³ For more information see <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

¹⁴ The regulation at 42 CFR 457.1216 requires compliance with these requirements for CHIP managed care entities.

enrollee within the preceding 5 years, as appropriate. Similarly, at any time the enrollee is currently enrolled in the managed care plan and up to 5 years after disenrollment, the managed care plan must send, upon an enrollee's request, all such data to any other payer that currently covers the enrollee, or a payer that the enrollee specifically requests to receive the data classes and elements included in the content standard specified at 45 CFR 170.213 (USCDI version 1). This requirement will also support dually eligible individuals who are concurrently enrolled in Medicare Advantage plans and Medicaid managed care plans or with CHIP managed care entities. Under this requirement, both of the dually eligible individual's payers would be subject to the requirement to exchange that individual's data, which should improve the ability of payers to coordinate care based on that data. This obligation applies when a request is made with the approval and at the direction of a current or former enrollee or the enrollee's personal representative.

CMS encourages state Medicaid agencies and CHIP fee for service entities to accommodate such requests from beneficiaries, although facilitating such exchange of beneficiary information is not required in the CMS Interoperability and Patient Access final rule for Medicaid agencies and CHIP fee for service entities. Enhanced FFP might be available under section 1903(a)(3)(A)(i) or (B) of the Act for state Medicaid agencies' expenditures to support accommodating such patient requests, provided that all of the applicable conditions for that enhanced FFP are met.

Improving the Dual Eligible Experience

The CMS Interoperability and Patient Access final rule requires daily state-CMS exchange of certain dual eligibility data by April 1, 2022. Ensuring information on dual eligibility status is accurate and up-to-date by increasing the frequency of federal-state data exchange is an important step toward interoperability.

State payment of Medicare premiums ("buy-in") file exchange: CMS and states routinely exchange data on who is enrolled in Medicare, and which parties are liable for paying that beneficiary's Part A and B premiums. These buy-in data exchanges support state, CMS, and Social Security Administration premium accounting, collections, and enrollment functions. Currently, states exchange these data with CMS at least monthly. Through this final rule, we are updating 42 CFR 406.26 and 407.40 to require that all states participate in daily exchange of buy-in data, which includes both sending data to CMS and receiving responses from CMS daily.

Medicare Modernization Act (MMA) file exchange: States submit files at least monthly to CMS to identify all dually eligible individuals. The file is called the MMA file, but is occasionally referred to as the "State Phasedown file." CMS uses the MMA files for a variety of functions, including establishing beneficiary protections related to Medicare cost sharing, auto-enrolling full-benefit dually eligible individuals into Medicare prescription drug plans, and deeming dually eligible individuals automatically eligible for the Medicare Part D Low Income Subsidy. Currently, states exchange these data with CMS at least monthly. Through this final rule, we are updating the frequency requirements in 42 CFR 423.910(d) to require that all states submit the required MMA file data to CMS daily, and to make conforming edits to 42 CFR 423.910(b)(1).

Additional information on the benefits of daily file exchange and technical assistance resources are included in SMD #18-012.

ONC 21st Century Cures Act Final Rule

State Medicaid agencies, Medicaid managed care plans, CHIP agencies, and CHIP managed care entities should review the ONC 21st Century Cures Act final rule, particularly the sections on the

definition of HIN or HIE and the information blocking exceptions. There may be situations when such entities function as a HIN or HIE, as defined in the ONC 21st Century Cures Act final rule, and therefore would be considered an actor regulated under section 4004 of the Cures Act (42 U.S.C. 300jj-52) (referred to as the information blocking provision). As such, those entities should review existing contractual and financial relationships—especially those related to API usage and access—with Medicaid managed care plans, state Medicaid agencies, CHIP agencies, and CHIP managed care entities to evaluate potential compliance implications with regard to the ONC 21st Century Cures Act final rule. The CMS Interoperability and Patient Access final rule does not authorize entities to charge for access to their API for purposes of the Patient Access and Provider Directory APIs.¹⁵

Resources for States

The timeline for compliance with the CMS Interoperability and Patient Access final rule is aggressive, and CMS is committed to providing states with the necessary technical assistance to implement these advancements in improving patient access to their data and interoperability.

States should seriously consider leveraging existing State and Federal investments in health information exchanges (HIEs) to implement these new requirements. For example, HIEs which might have received funding under the HITECH Act as discussed in SMD# 16-003¹⁶ from their state Medicaid agency might be in a position to improve patient access to their data, and would, as such, potentially be demonstrating thoughtful re-use as described in SMD# 18-005.¹⁷ A few key activities a state should undertake immediately are the following:

- The CMS Interoperability and Patient Access final rule requires Medicaid managed care plans and CHIP managed care entities to develop the ability to share the United States Core Data for Interoperability (USCDI) as specified in 45 CFR 170.213 with the approval and at the direction of a current or former enrollee or the enrollee’s personal representative under the Payer-to-Payer Data Exchange policy. An assessment of the ability to create that data set and the completeness of that data set for all parties and the ability to send and receive such data by all parties would be appropriate as a first step in preparation for implementation.
- For purposes of API development, common use of implementation guides ensures better interoperability and thus, state Medicaid agencies, Medicaid managed care plans, CHIP agencies, and CHIP managed care entities may wish to consider beginning an assessment on using the IGs identified by CMS that are available to help facilitate implementation of the API policies. These IGs are listed at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>. Doing so may also be consistent with the requirements at 42 CFR 433.112(b)(10) or (16) for state Medicaid agencies that seek enhanced FFP under 42 CFR 433.112 or 433.116.
- Consider what contract amendments might need to be put in place with managed care plans and entities and what advance planning documents might be necessary.
- Develop a project plan in coordination with the appropriate CMS Medicaid Enterprise System (MES) State Officers. Such project plans might include tasks such as:

¹⁵ The final rule requires public posting of the API documentation without a fee at 42 CFR 431.60(d) and 457.730(d), incorporated by reference for Medicaid (42 CFR 438.242) and CHIP (42 CFR 457.1233) managed care plans and entities. 85 FR 25542 through 25543. For a discussion of the costs of implementation of the API and how CMS expects those costs to be addressed, see 85 FR 25528, 25530–25531, and 25629–25631.

¹⁶ Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16003.pdf>.

¹⁷ Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18005.pdf>.

- Requesting funding through the state’s budgetary process and/or submitting an Advance Planning Document (APD) to CMS to request enhanced FFP.
- Amending a state’s information technology vendor contracts and/or procuring new contracts.
- Revising current state data system designs, business processes, and related efforts, including assessing how to make their data accessible via APIs.
- Evaluating necessary systems changes, which may require contract modifications and/or new procurements with information technology (IT) vendors.
- Developing managed care plan contract amendments reflecting revised rates (as appropriate) and new federal requirements.
- Providing amendments to managed care plans for review and signature.
- Developing the required beneficiary education materials to assist individuals in protecting their health information, making informed choices about which third-party applications they want to use, and informing them about how to submit complaints to relevant federal entities.¹⁸

States are reminded that 42 CFR 433.112(b)(10) explicitly supports exposed APIs as a condition of receiving enhanced FFP under section 1903(a)(3)(A)(i) or (B) of the Act. Similarly, 42 CFR 433.112(b)(13) requires the sharing and re-use of Medicaid technologies and systems, including associated technical documentation, as a condition of receiving enhanced FFP under section 1903(a)(3)(A)(i) or (B) of the Act, and this would include sharing documentation for connecting to APIs.

CMS will continue advancing policies which improve a patient’s right of access to their health information. We encourage states to continue to engage with CMS as stakeholders by providing feedback on these policies. States should reach out to their CMS MES State Officers for technical assistance on enacting these policies where relevant. CMS values the states as partners in expanding patient access to their health information and anticipates more opportunities to support such interoperability.

Sincerely,

Calder Lynch
Deputy Administrator and Director

¹⁸ Additional information to support development of educational resources can be found on CMS’s website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>.