

CMS Interoperability and Patient Access Rule

Response to HCR 52 of the 2020 Regular Legislative Session

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Executive Summary

Background

On March 9, 2020, the U.S. Department of Health and Human Services (HHS) finalized two rules aimed at increasing both patient access to their health data and interoperability between public and private healthcare entities. The two rules, issued by the Office of the National Coordinator (ONC) for Health Information Technology (Health IT) of HHS and the Centers for Medicare & Medicaid Services (CMS), implement key provisions in the 21st Century Cures Act. The two rules are as follows:

- 1. ONC Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule.¹**
- 2. CMS Interoperability and Patient Access Final Rule (CMS-9115-F).²**

The Final Rules were published in the federal register on May 1, 2020, and became effective on June 30, 2020.

The aim of the rules is to shift the way data is shared in the healthcare system, moving away from “may-share data,” per the Health Insurance Portability and Accountability Act to one where providers and payers must share data. Specific goals are as follows:

- Ensuring providers have access to patient health information regardless of where the patient has received care, and regardless of former health plan membership.
- Requiring that payers make patient and provider data available through use of standards-based application programming interfaces (APIs).
- Enabling patient access to health information electronically through third-party applications of their choice.
- Allowing patients and providers to easily identify providers within a plan’s network.
- Preventing providers from inappropriately restricting the flow of information between other providers and payers.

The ONC Final Rule applies to health IT developers and third-party applications and ensures the secure, standards-based technical infrastructure is in place to support implementation of the CMS Final Rule. The CMS Final Rule applies to healthcare providers and CMS-regulated payers, including Medicare Advantage (MA) plans, Medicaid fee-for-service (FFS), Children’s Health Insurance Program (CHIP) FFS programs, Medicaid and CHIP managed care plans and qualified health plan (QHP) issuers in the federally-facilitated exchanges (FfEs).

This report focuses on the CMS Final Rule.

Under the CMS Final Rule, the aforementioned payers must meet certain requirements regarding patient access to their health care information and utilization of APIs.

¹ https://www.healthit.gov/sites/default/files/cures/2020-03/ONC_Cures_Act_Final_Rule_03092020.pdf

² <https://www.cms.gov/files/document/cms-9115-f.pdf>

The Final Rule also requires hospitals that have adopted electronic health record (EHR) systems to implement electronic event reporting of patient admissions, discharges, and transfers (ADT) to patients' primary care practitioners as a condition of participation in the Medicare program. The effective date of the API and ADT provisions is January 1, 2021, however, CMS will not exercise enforcement discretions until July 1, 2021 due to the COVID-19 public health emergency.

The Final Rule also requires that CMS-regulated payers maintain a process for the electronic exchange of the data classes and elements included in the United States Core Data for Interoperability (USCDI) Version 1 data set standard to enable payer-to-payer data exchange by January 1, 2022.

Finally, state Medicaid agencies must increase the frequency of federal-state data exchanges for individuals dually eligible for Medicare and Medicaid from monthly to daily by April 1, 2022.

Document Purpose

On May 22, 2020, the Louisiana Legislature passed House Concurrent Resolution 52 (HCR 52), which "requests a report on actions by the Louisiana Department of Health (LDH) and Medicaid managed care to comply with federal rules on interoperability of health records and patient access to health information."³ As required under the legislation, LDH must submit a report addressing the actions it has taken, or will take, to ensure compliance with the Final Rule by LDH and Medicaid managed care organizations to the House Committee on Health and Welfare, the Senate Committee on Health and Welfare and the David R. Poynter Legislative Research Library by October 1, 2020.⁴ This document represents the initial plan. This plan may be updated as details and activities are finalized throughout the implementation process.

Main Themes and Topics

The document describes the rule provisions in additional detail and provides available resources to assist with compliance, as well as a financial and resource impact statement. The document also includes proposed steps and a timeline that LDH has determined necessary in order to ensure compliance by both the agency and managed care plans. The steps and timeline are subject to change as activities commence.

Summary of the Documents and Conclusions

The final rule applies to the Medicaid agency and managed care plans. While the API requirements are the same, compliance planning will require participation among key resources overseeing the Medicaid Management Information System (MMIS), as well as those in Managed Care Program Operations. Activities will need to commence as soon as possible to facilitate compliance by the required timeline. Industry leaders agree that most payers are not ready to comply, and LDH will continue to monitor other state implementations and upcoming CMS guidance to inform the planning and implementation process.

Section 1: Requirements Set Forth in the Final Rule

Under the CMS Final Rule, CMS-regulated payers, including MA plans, state Medicaid and CHIP agencies' FFS, Medicaid and CHIP managed care plans and QHP issuers in the FFEs will be required to adhere to new policies aimed at improving access to and movement of electronic health information.

³ Louisiana State Legislature. HCR52. <http://www.legis.la.gov/legis/BillInfo.aspx?s=20rs&b=HCR52&sbi=y>

⁴ 2020 Regular Sessions. House Concurrent Resolution No. 52 By Representative Echols.
<http://www.legis.la.gov/legis/ViewDocument.aspx?d=1175291>

Section 1.1 Patient Access Application Programming Interface

CMS believes the combination of claims, encounters, and EHR data can offer patients a more comprehensive understanding of personal interactions with the healthcare system and utilization behaviors. The goal is to empower patients to make informed decisions and facilitate communication with multiple providers through access to this information via a standards-based API. The process and technical infrastructure implemented to comply with this mandate will also support compliance with other requirements.

The basic requirements for implementation of the Patient Access API are as follows:

- Implement and maintain a secure, standards-based (Health Level Seven International [HL7] Fast Healthcare Interoperability Resources [FHIR] Release 4.0.1) API that allows patients to easily access their claims and encounter information including cost and a subset of their clinical information through third-party applications of their choice.
- Third-party applications will be able to retrieve any adjudicated claims (including provider remittances and enrollee cost sharing), encounters with capitated providers, clinical data (including lab results managed by the payer) and information about covered outpatient drugs and preferred drug lists that plans have maintained with a date of service on or after January 1, 2016 (or January 1, 2021 for QHPs on the FFEs).
- Must be made available no later than one business day after a claim is adjudicated or the data is received.
- Medicaid beneficiaries should not be receiving information from the State and managed care plan for the same service. Meaning that if the beneficiary is receiving a service under the State's Medicaid FFS program, the State is required to provide the specified data elements through the MMIS. If the beneficiary is enrolled in managed care, the health plan is responsible.

The requirement is effective January 1, 2021, however, CMS will not exercise enforcement discretions until July 1, 2021.

Section 1.2 Provider Directory Application Programming Interface

In the current landscape, CMS-regulated payers are required to make their provider directory publicly accessible or available on a website. CMS believes that making this information available through an API could support development of applications that would pull in current information about providers that may be available to meet the needs of all beneficiaries.

The basic requirements for implementation of the Provider Directory API are as follows:

- Make provider directory information publicly available via a standards-based API.
- Must include names, addresses, phone numbers and specialties.
- Must be updated no later than 30 calendar days after the payer received the information or an update.

The requirement is effective January 1, 2021, however, CMS will not exercise enforcement discretions until July 1, 2021.

Section 1.3 Payer-to-Payer Data Exchange

CMS envisions that patient health care data will be easily exchanged as patients move between different health plans and at the enrollee's direction or request.

The basic requirements for implementation of payer-to-payer data exchange are as follows:

- MA organizations, Medicaid and CHIP managed care plans and QHPs on the FFEs must maintain a process for the electronic exchange of the data classes and elements included in the USCDI Version 1 data set standard.
- With approval from the current or former enrollee, the payer must receive the information from the previous payer that had covered the enrollee within the preceding five years and incorporate it into its records.
- For current enrollees and for up to five years after disenrollment, a payer must send data to any other payer that currently covers the enrollee based on the enrollee's request.
- CMS anticipates that payers will leverage the API they put in place to comply with patient access requirements to additionally provide other payers access to the same data. CMS does allow payers to use other methods of data exchange to accomplish this requirement.
- CMS elected to not finalize its proposal to require covered plans and agencies to participate in trusted health information exchange networks. Commenters showed support for the proposal, other commenters noted the need for a mature Trusted Exchange Framework and Common Agreement (TEFCA), a set of policies and procedures for interoperable exchange, to be put in place first.

The requirement is effective January 1, 2022.

Section 1.4 Improving the Dually Eligible Experience

CMS believes the interoperability of eligibility systems is critical to modernizing programs and improving the experiences of enrollees and providers. They see increasing the frequency of data exchanges as a strong first step.

The basic requirement for improving the dually eligible experience is as follows:

- Increase frequency of reporting on certain enrollee data for individuals dually eligible for Medicare and Medicaid, including state buy-in files and Medicare Modernization Act (MMA) files (after the Medicare Prescription Drug Improvement and Modernization Act of 2003) from monthly to daily exchange.

This requirement is effective April 1, 2022.

Section 3: Regulatory Impact Analysis

Section 3.1 Implementation of APIs

In the Final Rule, CMS estimates that states and payers can anticipate the initial, one-time set up cost to be between \$788,414 and \$2,365,243 to implement the requirements to comply with the API provisions. Additionally, CMS estimates that the "burden related to the requirements for APIs to have an annual cost of \$157,657 per implementation" (at the state or organization level) "for activities such as testing, upgrades and vetting of third-party applications."

Section 3.2 Increasing Federal-State Data Exchanges for Dual-Eligible Care Coordination

In the Final Rule, CMS estimates that “the one-time cost to be \$85,000 per state, per change, so a state that needs to make systems updates to both send buy-in data daily and receive buy-in data daily would have a **one-time cost of just over \$170,000.**” LDH will need to evaluate its current processes for data sharing with the state to confirm current status and compliance needs.

Section 3.3 Funding for Implementation and Maintenance

As described in the Final Rule, there are different ways in which payers could transfer these new costs. For example, CMS estimates that the 2020 through 2029 total costs for maintenance across all Medicaid and CHIP to be \$79.3 to \$126 million at the state level, with an average cost per enrollee of \$1.10 to \$1.70 for all Medicaid plans (which is \$.10 or under per enrollee for each year). A critical component of the planning process will be negotiations with CMS and managed care organizations. As stated in the rule, “since API requirements must be contractual obligations under the Medicaid managed care contract, the state must include these costs in the development of a plan’s capitation rates.”

For Medicaid FFS, funding can be requested from CMS at a 90% federal match for design, development, and implementation of systems with a 75% federal match for maintenance, as well as 50% for general administrative costs.

Section 4: Nationwide Compliance Planning

Section 4.1 Implementation Challenges

While stakeholders agree in the overall aim of the Final Rule, there are critical challenges to implementation that have been cited by payers and leading Chief Information Officers (CIOs) including:⁵

- Tight implementation timelines.
- Conflicting interpretations of the requirements that complicate initiative planning and execution.
- Vendor offerings to support payer compliance may exist, but the technical content and vocabulary standards that were finalized in the ONC Rule are still emerging (i.e., there is no way to fully evaluate past performance).

As noted in the report from Gartner, while payers have been collecting clinical data from providers to support specific use cases, the Final Rule mandates payers to exchange comprehensive claims and clinical data with members via member-selected, third-party software applications and competing payers. This represents a major shift in procedures and operations and most payers are not ready and will need to develop or acquire new skills and deploy new technologies much faster than usual.

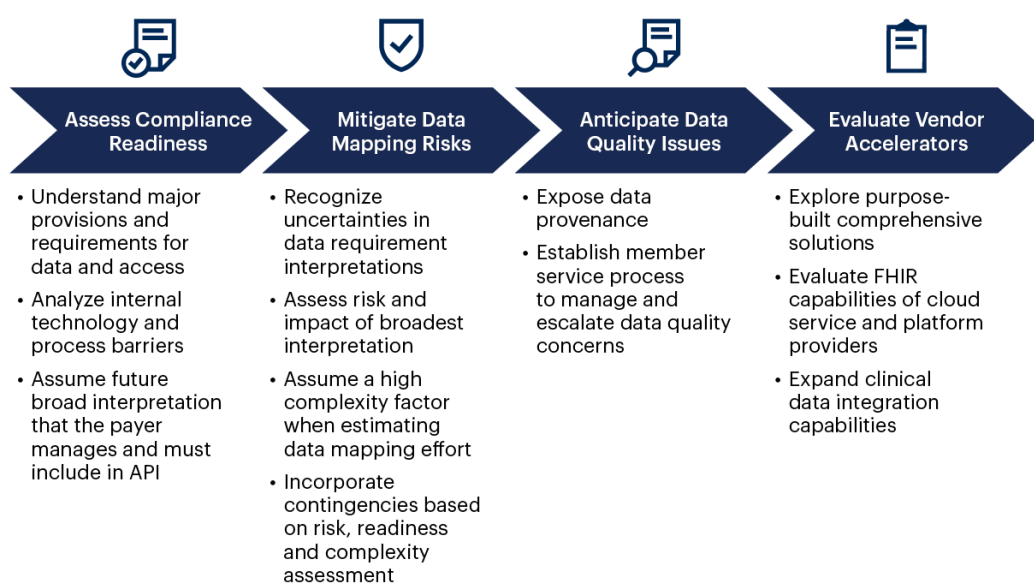
⁵ Prepare for CMS Interoperability and Patient Access API Compliance for U.S. Healthcare Payers. Gartner. June 15, 2020. Available at: <https://www.gartner.com/doc/reprints?id=1-1Z9J7ZAX&ct=200617&st=sb>

In order to lessen the financial and operational burden to states for implementing the APIs and support consistent, interoperable API development and implementation, CMS has worked with HL7 and other industry partners to ensure implementation guides (IGs) and additional resources are freely available to payers and developers to use if they choose. Use of these implementation guides is not mandatory;⁶ however, states must use the implementation guides in order to access enhanced federal funding.⁷

Section 4.2 Industry-Led Recommendations

In consultation with various CIOs, Gartner has created the following recommendations to help payers prepare for compliance with the Final Rule (Figure 1):

Figure 1: Recommended Steps for Payers to Comply with the Final Rule



Source: Gartner (June 2020)

The goal of these steps is to 1) ensure understanding of the requirements; 2) assess organizational readiness to comply; 3) identify key risks that will require mitigation; and 4) evaluate vendor partners that will be needed to assist in meeting the provisions.

This resource from Gartner was published June 2020. LDH did not find any practical applications of this framework in use at the time of report writing.

Section 2.3 CMS Implementation Guidance

On August 14, 2020, CMS released the State Health Official (SHO) letter #20-003 Re: Implementation of the CMS Interoperability and Patient Access Final Rule and Compliance with the ONC 21st Century Cures

⁷ State Health Officer Letter # 20-003 RE: Implementation of the CMS Interoperability and Patient Access Final Rule and Compliance with the ONC 21st Century Cures Act Final Rule

Act Final Rule. The letter includes “Resources for States” and provides the following recommendations to states in planning an approach to comply with the Final Rule, which align with this compliance plan:

- For APIs, begin an assessment on using the implementation guides identified by CMS that are available to help facilitate implementation of the API policies. Implementation guides are publically available.
- 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.
- The rule requires that Medicaid managed care plans and CHIP to develop the ability to share the United States Data for Interoperability (USCDI) under the Payer to Payer 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.

Section 2.4 National Association of Medicaid Directors Meetings

The National Association of Medicaid Directors (NAMD) has recently begun holding conference calls to bring states together to discuss implementation challenges, identify best practices, and create opportunities for collaboration. LDH representatives have attended and will continue to attend these calls as the state develops and implements the compliance plan. Through these collaborative events, LDH has connected with West Virginia, a state that shares the same MMIS vendor, DXC, to jointly develop shared solutions. LDH will continue to participate in collaborative calls.

Section 5: LDH Final Rule Compliance Plan Overview

LDH has been successful in the following MMIS modernization efforts to date:

- The State modernized its eligibility and enrollment system to move to a more standardized enrollment portal, yielding reduced duplications and ineligibilities.
- The new system removes the need for manual entries and reduced the need to stretch eligibility determinations across multiple systems.
- The system uses data from over 20 different sources to verify information, enables real time analysis and can flag issues for internal review.
- The team worked on simulations for a month prior to going live with the new system and is prepared to incorporate similar quality control strategies to this effort.

Louisiana is one of a few states with real time eligibility and has one of the most modern systems in the country. A key modernization objective is that the solution be flexible and adaptable to accommodate evolving needs.

LDH understands the process and procedures necessary to successfully implement systems-wide improvements and is ready to incorporate compliance with the Final Rule into the overall MMIS modernization efforts.

LDH will need to pursue dual tracks in ensuring compliance with the Final Rule:

1. Internal planning, systems evaluations and upgrades, and process modifications under Medicaid FFS.
2. Review and oversight of compliance plans from the current managed care entities.

Oversight of the compliance planning process will be under the Medicaid Chief Technology Officer. LDH Medicaid has acknowledged the need to collaborate with additional internal resources to oversee agency compliance. They will begin outreach and coordination accordingly. LDH may consider forming a committee to collectively oversee compliance planning.

Section 5.1: Internal Analysis of the Final Rule

As stated, the interpretation of the rule and affected parties is varied. LDH must conduct a thorough review of the rule to ensure understanding of the roles and responsibilities of the agencies and care plans and identify other internal resource needs to ensure implementation and ongoing compliance with the rule provisions.

The aim is to 1) understand the requirements for internal planning and to aid in managed care compliance plan review; 2) assess internal processes, data, and technical infrastructure; and 3) identify barriers to compliance by the agency to guide internal planning.

Initial considerations may include, but not be limited to:

- Detailed analysis of the overall financial impact and potential funding needs.
- The State must evaluate the current MMIS and modernization project for readiness to support compliance with API requirements for FFS beneficiaries.
- What role the agency must play to monitor APIs, privacy and security features, potential security risks around third-party applications and patient education.
- Initial review of potential costs for implementing the standards-based API provisions, which ultimately may be built into the capitation rates under managed care.
- While the rule does not specify the system that must be used for the implementation and maintenance of the API (the plan can determine which system is most appropriate), the potential role of the State's MMIS for managed care compliance is unclear.
- The agency will also determine what MMIS upgrades may be necessary to implement the daily frequency of buy-in data to support daily reporting as required by April 2022. Funding for necessary updates and enhancements may be available at a 90% federal match rate, which must be requested through the Advance Planning Document process.

Output: LDH Final Rule Summary Document

Section 6: Compliance by Managed Care Entities

There are currently five managed care organizations (MCOs) in the state: (Aetna Better Health, AmeriHealth Caritas Louisiana, Community Care Health Plan of Louisiana [Healthy Blue], Louisiana Healthcare Connections and UnitedHealthcare of Louisiana), two dental prepaid ambulatory health plans

(MCNA and DentaQuest), and a prepaid inpatient health plan (Magellan of Louisiana). All must follow the CMS requirements in accordance with managed care contracts. As stated in 42 Code of Federal Regulations (CFR) § 438.66, “the state agency must have in effect a monitoring system for all managed care programs and have the authority to request, review and evaluate a plan for compliance with CMS rules”.

Section 6.1 Planned Activities for Managed Care Compliance Oversight

Planned activities to oversee compliance preparation among managed care entities may include, but not be limited to:

- Facilitate a joint meeting with managed care entity representatives to review and discuss the requirements and the technical and operational needs to meet the requirements.
- Create template specifications for a compliance plan.
- Develop evaluation criteria for the compliance plan.
- Request, review and evaluate compliance plans from each managed care entity.
- Monitor compliance plans and activities.
- Design and implement remediation plans for non-compliance.

Output: Compliance plans from each managed care entity that are approved by LDH

Section 6.2 Managed Care Entity Contract Review and Enhancement

LDH may also complete a review of the current contract language and recommend necessary additions to ensure compliance with the Final Rule.

Initial considerations may include, but not be limited to:

- As stated in the rule, “states would have to require each MCO, PIHP, and PAHP to comply with 42 CFR 431.60 (under Medicaid managed care contracts) and 457.730 (under CHIP managed care contracts) as if such requirements applied directly to them.” (42 CFR 431.60 and 457.730 – Beneficiary access to and exchange of data).
- Review of current and necessary data sharing requirements.
- Considerations for required language in provider contracts to ensure uniformity and consistency in timeliness and data quality.

Output: MCO, Dental and Magellan contract requirements

Section 6.3 Monthly Managed Care Coordination Meetings

LDH may consider facilitating monthly collaborative planning sessions with the MCOs, dental plans and Magellan. These sessions would serve as an opportunity to ensure a unified interpretation of the rule and its provisions, mitigate risks, identify best practices on data sharing and management, develop a strategy to hit the milestones outlined in the Final Rule and provide valuable information and guidance for the state planning efforts.

Potential topics may include, but not be limited to:

- Determining the need and creating standard language to be included in managed care provider contracts (e.g., addition of timing requirements for the submission of encounter data and claims).

- Developing an API implementation and maintenance cost structure among the managed care entities relative to capitation rates.

Output: Managed care monthly collaboration meetings

Section 7: Medicaid Agency Compliance with the Final Rule

LDH recognizes the urgency and upcoming challenges regarding agency compliance with the Final Rule API and reporting provisions. The steps below outline an initial compliance plan. The sequence of activities and completion dates are subject to change and activities may be ongoing dependent upon review and confirmation by LDH in collaboration with technical assistance from CMS.

Section 7.1: Develop a Project Plan for State Compliance

The details in this report represent the initial planning stages. However, there will be a need to create a detailed project plan with roles and responsibilities, milestones, and dates assigned and tracked as a component of overall project management activities related to implementation.

Output: Project plan

Section 7.2: Conduct a Gap Analysis

The gap analysis will illustrate the level of knowledge and preparedness, technical infrastructure needs, and necessary activities related to compliance with the Final Rule. The aim is to understand the internal process and technical and data environment to identify any barriers with a target completion date by December 18, 2020.

Initial considerations or activities may include, but are not limited to:

- Evaluation of data latency and data quality (adjudicated claims, capitated encounter data and clinical data).
- Mapping current data flows to identify sources, internal repositories and timeline from data source to target recipient.
- Review current vendor contracts and evaluate needs for necessary contract amendments.
- Evaluate needs for additional third-party contracting.

Output: Gap analysis report

Section 7.3: Facilitate Strategic Planning Sessions

LDH will facilitate monthly strategic planning sessions with representatives from across the agency. These may require sub-committees or workgroups, such as privacy and security and risk management teams, to manage and oversee specific work streams as they are identified.

Initial topics may include, but are not limited to:

- Evaluating or establishing an internal data governance organization to ensure proper management of data and consent management.
- Evaluating developer resources from CMS and applicability to the current state system environment.

- Developing internal systems needs and requirements to ensure compliance for Medicaid FFS, drafting the funding requests, and initiating any necessary development projects.
- Mapping clinical and claims data to FHIR specifications.
- Vendor contract review.
- Evaluation of current vendor solutions and initiation of a competitive bid process for infrastructure needs.
- Development of funding requests.
- Implementation and oversight of enhancement projects.
- Determine how to leverage current in-house infrastructure; If necessary, evaluate sole source options, emergency procurements, etc. in accordance with state procurement requirements.

Output: Monthly planning sessions conducted (at minimum)

Section 7.4 Ongoing Development of the Compliance Plan and General Oversight

LDH will oversee and continue to enhance the agency and the managed care compliance plan as the monthly planning meetings are facilitated. LDH understands there will be a need to continue to enhance and refine the project plan as information is gathered and planning sessions are conducted.

Initial considerations may include, but are not limited to:

- Incorporating outcomes from the strategic planning sessions into the original gap analysis.
- Development of industry best practices. LDH will continue to monitor how other states are developing and overseeing plans to comply with the Final Rule, as well as any additional guidance from CMS.
- Incorporating recommendations and final determinations from the managed care entities.

Output: Ongoing update and enhancement of the planning document

Conclusions

As noted, the rule presents significant implementation challenges, but the end goal is to achieve the longstanding vision of an interoperable health ecosystem in which patients are empowered to manage their health more effectively and payers are enabled to deliver increased value. However, compliance with the rule presents a major shift in operations and the implementation challenges are significant. It will take a multi-disciplinary team and dedicated resources to ensure the agency and care plans are ready and able to comply within the timeframe.

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