State of California—Health and Human Services Agency
Department of Health Care Services

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DIRECTOR

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DATE: December 27, 2022

Behavioral Health Information Notice No: 22-068

TO: California Alliance of Child and Family Services
California Association for Alcohol/Drug Educators
California Association of Alcohol & Drug Program Executives, Inc.
California Association of DUI Treatment Programs
California Association of Social Rehabilitation Agencies
California Consortium of Addiction Programs and Professionals
California Council of Community Behavioral Health Agencies
California Hospital Association
California Opioid Maintenance Providers
California State Association of Counties
Coalition of Alcohol and Drug Associations
County Behavioral Health Directors
County Behavioral Health Directors Association of California
County Drug & Alcohol Administrators

SUBJECT: Interoperability and Patient Access Final Rule

PURPOSE: To notify all Mental Health Plans (MHPs) and Drug Medi-Cal Organized Delivery System (DMC-ODS) counties about the Centers for Medicare and Medicaid Services (CMS) Interoperability and Patient Access final rule requirements.

BACKGROUND:
In May 2020, CMS finalized the Interoperability and Patient Access final rule (CMS Interoperability Rule), which seeks to establish beneficiaries as the owners of their health information with the right to direct its transmission to third-party applications.[1] [2]

[1] 85 Federal Register 25510-25640.
[2] Section 4003 of the Office of the National Coordinator for Health Information Technology 21st Century Cures Act defines "Interoperability" as health information technology that (1) enables the secure exchange and use of electronic health information without special effort on the part of the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (3) does not constitute information blocking as defined in section 3022(a) of the Public Health Service Act.

CMS and the Office of the National Coordinator for Health Information Technology have established a series of data exchange standards that govern such specific transactions.[3]

Assembly Bill (AB) 133 (Committee on Budget, Chapter 143, Statutes of 2021) implements various components of the CalAIM initiative, including those components in Welfare and Institutions Code (W&I) section 14184.100, et seq., and Health and Safety Code section 130290 to implement the California Health and Human Services Data Exchange Framework, including the CMS Interoperability Rule. DHCS is authorized to develop and implement Article 5.51 of the W&I Code and the requirements of the California Health and Human Services Data Exchange Framework through this Behavioral Health Information Notice (BHIN).[4]

POLICY:
The CMS Interoperability Rule requires MHPs and DMC-ODS counties, hereafter referred to as Behavioral Health Plans (BHPs), to implement and maintain a secure, standards-based Patient Access Application Programming Interface (API) and a publicly accessible, standards-based Provider Directory API that can connect to mobile applications, and be available through a public-facing digital endpoint on each BHP's website.[5]

BHPs must also comply with 42 Code of Federal Regulations (CFR) 438.242, 45 CFR 170.215, the provider directory information requirements specified in 42 CFR 438.10, and the public reporting and information blocking components of the CMS Interoperability Rule 45 CFR Part 171.

Patient Access API
BHPs must implement and maintain a Patient Access API that can connect to provider electronic health records and practice management systems, in accordance with requirements specified at 42 CFR section 431.60. The Patient Access API must permit third-party applications to retrieve, with the approval and at the direction of a beneficiary or beneficiary's authorized representative, data specified in this BHIN through the use of common technologies and without special effort from the beneficiary.

[3] The data exchange standards for the Patient Access Application Programming Interface; CARIN Implementation Guide; Payer Data Exchange for US Drug Formulary; Provider Directory Application Programming Interface.
[4] Welfare and Institutions Code section 14184.102(d); Health and Safety Code section 130290(j).
[5] 45 CFR section 170.215; 42 CFR sections 431.60, 431.70, and 438.10.

BHPs must make individual-level United States Core Data for Interoperability (USCDI)[6] data that they maintain for dates of services on, or after, January 1, 2016, available to the beneficiary or their authorized representative as follows:[7]

Type of Information	**Time by Which Information Must be Accessible**
Adjudicated claims data, including claim data for payment decisions that may be appealed, were appealed, or in the process of appeal, provider remittances, and beneficiary cost-sharing pertaining to such claims.	Within one (1) business day after a claim is processed.
Clinical data, including diagnoses and related codes, and laboratory test results	Within one (1) business day after receiving data from providers.
Information about covered outpatient drugs and updates to such information, including formulary of prescription drugs, costs to the beneficiary, and preferred drug list information, if applicable.	Within one (1) business day after the effective date of any such information or updates to such information.
Encounter data from providers compensated on the basis of risk-based capitation payments, as defined in 42 CFR 438.2[8]	Within one (1) business day after receiving data from providers.

Member Educational Resources

In accordance with 42 CFR 431.60(f), BHPs must provide, in an easily accessible location on their public websites and/or through other appropriate mechanisms through which they ordinarily communicate with current and former Beneficiary seeking to access their health information, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:[9]

[6] 45 CFR section 170.213. USCDI is a standardized set of health data classes and component data elements for nationwide, interoperable health information exchange. The February 2020, Version 1 is available at: https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.
[7] 42 CFR section 431.60.
[8] If the BHP does not reimburse providers using risk-based capitation payments, then this requirement to include encounter data in the Patient Access API does not apply.
[9] CMS developed a resource to assist BHPs in meeting this requirement, the *Patient Privacy and Security Resources-Supporting Payers Educating their Patients* document. It includes an overview and sample content to meet these requirements. Use of this document is not required; it is to support BHPs as they produce Beneficiary resources tailored to their Beneficiary population. The document is available at: https://www.cms.gov/files/document/patient-privacy-and-security-resources.pdf.

- General information on steps the Beneficiary may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they entrust their health information; and
- An overview of which types of organizations or individuals are and are not likely to be Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities, the oversight responsibilities of the Health and Human Services Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to the OCR and FTC. Educational resources must be provided to beneficiaries according to the information requirements of CFR 438.10.

Provider Directory API

BHPs must implement and maintain a publicly accessible standards-based Provider Directory API as described in 42 CFR section 431.70, and meet the same technical standards of the Patient Access API, excluding the security protocols related to user authentication and authorization. BHPs are required to update the Provider Directory API no later than 30 calendar days after the BHP receives the provider information, or is notified of a change.[10]

The Provider Directory API must include the following information about the BHPs' network providers for behavioral health providers, hospitals, and any other providers or facilities contracted for Medi-Cal covered services under the MHP's contract or the DMC-ODS Intergovernmental Agreement (IA):

- Name of provider, medical group/foundation, independent physician/provider associations, or site as well as any group affiliation;
- National Provider Identifier number;
- Street address(es);
- All telephone numbers associated with the practice site;
- Website URL for each service location or physician provider, as appropriate
- Specialty, as applicable
- Hours and days when each service location is open, including the availability of evening and/or weekend hours;
- Services and benefits available;
- Whether the provider will accept new beneficiaries;
- Cultural and linguistic capabilities, including whether non-English languages and American Sign Language are offered by the provider or a skilled medical interpreter

[10] 42 CFR section 431.70 and 42 CFR section 438.10(h)(3)(ii).

at the provider's office, and if the provider has completed cultural competence training;
- Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s), and equipment; and
- Telephone number to call the 24/7 access line.[11]

If a BHP is currently maintaining an electronic provider directory on its website as required by 42 CFR 438.10(h) and the MHP contract or the DMC-ODS IA contract, and are meeting the required provider directory data elements above, then the BHP may transfer the information to the Provider Directory API. However, if any of the required data elements are missing from the electronic provider directory, BHPs shall take appropriate steps to ensure the Provider Directory API includes all required data elements.

Oversight and Monitoring

BHPs must ensure that data received from its Network Providers and Subcontractors is accurate and complete by verifying the accuracy and timeliness of reported data; screening the data for completeness, logic, and consistency; and collecting service information in standardized formats to the extent feasible and appropriate. BHPs must make all collected data available to DHCS and CMS, upon request.[12]

BHPs must conduct routine testing and monitoring, and update their systems as appropriate, to ensure the APIs function properly, including conducting assessments to verify that the APIs are fully and successfully implementing privacy and security features such as those required to comply with the HIPAA Security Rule requirements in 45 CFR parts 160 and 164, 42 CFR parts 2 and 3, and other applicable laws protecting the privacy and security of individually identifiable data.[13]

BHPs may deny or discontinue any third-party application's connection to an API if it reasonably determines, consistent with its security risk analysis under the HIPAA Security Rule, that continued access presents an unacceptable level of risk to the security of protected health information on its systems. The determination must be made using objective verifiable criteria that are applied fairly and consistently across all applications and developers, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.[14]

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[11] 42 CFR section 438.10. Welfare & Institutions Code section 14197.1.
[12] 42 CFR section 438.242.(b)(3),(4).
[13] 42 CFR section 431.60(c)(2).
[14] 42 CFR section 431.60(e).

BHPs must comply with the requirements for the Patient Access API and Provider Directory API and must demonstrate their compliance by submitting deliverables as directed by DHCS. BHPs shall update policies and procedures to ensure compliance with this policy. BHPs must communicate the requirements listed above to all of their Subcontractors and Network Providers. DHCS may impose a corrective action plan, as well as administrative and/or monetary sanctions for non-compliance.[15] For additional information regarding administrative and monetary sanctions, see BHIN 22-045, and any subsequent iterations on this topic.

DHCS will begin verifying compliance after July 1, 2023.

If you have any questions regarding this BHIN, please contact your county support liaison or countysupport@dhcs.ca.gov.

Sincerely,

Original signed by

Ivan Bhardwaj, Acting Chief
Medi-Cal Behavioral Health Division

[15] California Welfare & Institutions Code (WIC) 14197.7