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DATE: November 30, 2022

TO: ALL MEDI-CAL DENTAL MANAGED CARE PLANS

SUBJECT: APL 22-013: INTEROPERABILITY AND PATIENT ACCESS FINAL RULE

PURPOSE:

To notify all Dental Managed Care (DMC) Plans 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 members as the owners of their health information with the right to direct its transmission to third-party applications.^{1 2} 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

POLICY:

The CMS Interoperability Rule requires DMC Plans to implement and maintain a secure, standards-based Patient Access Application Program Interface (API) and a publicly-accessible, standards-based Provider Directory API that can connect to mobile

¹ 85 Federal Register 25510-25640 is available here: <https://www.govinfo.gov/app/details/FR-2020-05-01/2020-05050>.

²Section 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 to information blocking as defined in section 3022(a).

³ The data exchange standards for the Patient Access Application Programming Interface are available at: Payer Data Exchange: <http://hl7.org/fhir/us/davinci-pdex/STU1/toc.html>; CARIN Implementation Guide: <http://hl7.org/fhir/us/carin-bb/toc.html>; Payer Data Exchange for US Drug Formulary <http://hl7.org/fhir/us/davinci-drug-formulary/toc.html>. The data exchange standards for the Provider Directory Application Programming Interface is available at: <http://hl7.org/fhir/us/davinci-pdex-plan-net/toc.html>.

applications, provider electronic health records, or practice management systems.⁴ The APIs must, and be available through a public-facing digital endpoint on the DMC Plan's website.⁵

DMC Plans must also comply with the requirements of Title 42 of the Code of Federal Regulations (CFR) section 438.242, 45 CFR 170.215, the provider directory information specified in 42 CFR 438.10, and the public reporting and information blocking components of the CMS Interoperability Rule to the extent these requirements are applicable to DMC Plans.

I. Patient Access API

DMC Plans must implement the Patient Access API that can connect to provider electronic health records and practice management systems, in accordance with requirements specified in 42 CFR 431.60.

The Patient Access API must permit third-party applications to retrieve, with the approval and at the direction of a member or member's authorized representative, data specified in the following United States Core Data for Interoperability (USCDI) through the use of common technologies and without special effort from the member.

DMC Plans must make available to the member or their authorized representative, the following individual-level USCDI⁶ maintained for dates of services on or after January 1, 2016⁷:

Type of Information	Time by Which Information Must be Accessible
Adjudicated claims data and cost data, including claims that may be appealed, were appealed, or are currently under appeal	Within one (1) business day after a claim is processed
Encounter data, including encounter data from any network providers the DMC Plan is compensating and adjudicated claims and encounter data from any subcontractors.	Within one (1) business day after receiving data from providers
Clinical data, including diagnoses and related codes, medical records, laboratory test results,	Within one (1) business day after receiving data from providers

⁴ 45 CFR section 170.215; 42 CFR sections 431.60, 431.70, and 438.1

⁵ 45 CFR section 170.215; 42 CFR sections 431.60, 431.70, and 438.10. The CFR is searchable at <https://www.ecfr.gov/>.

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 431.60

and statements of medical necessity	
Information about covered outpatient drugs and updates to such information, including formulary of prescription drugs, costs to the member, 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

A. Member Educational Resources

In accordance with 42 CFR 431.60(f), DMC Plans must provide an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former members seeking to access their health information, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum⁸:

- General information on steps the member may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application which may provide for secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they entrust their health information;
- An overview of which types of organizations or individuals are and are not likely to be entities subject to the following: Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC);
- The process by which a member can submit a complaint to the Health and Human Services OCR and FTC.

DMC Plans must tailor these member educational resources to best meet the needs of their member populations, including literacy levels, languages spoken, conditions, etc. as required by APLs 21-001, 18-008, and any subsequent iterations on this topic.⁹

⁸ For an overview of what is required to be included in an DMC Plan’s member resource document, DMC Plans may refer to the Patient Privacy and Security Resources document developed by CMS. Use of this document is not required; it is to support DMC Plans as they produce member resources tailored to their member population. The document is available here: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>

⁹ APLs can be found at: <https://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx>

II. Provider Directory API

DMC Plans must implement and maintain a publicly accessible standards-based Provider Directory API as described in 42 CFR 431.70, and meet the same technical standards of the Patient Access API, excluding the security protocols related to user authentication and authorization and any other protocols that restrict the availability of provider directory information to particular persons or organizations. DMC Plans are required to update the provider directory on a weekly basis¹⁰ after the DMC Plan receives the provider information, or is notified of a change.¹¹

The Provider Directory API must include the following information about the DMC Plans' network providers for primary care dentists, specialists, hospitals, pharmacies, and any other providers contracted for Medi-Cal covered services under the DMC contract:

- Name of provider or site, and any group affiliation;
- National Provider Identifier number;
- Street address(es);
- Telephone numbers, including the phone number to call after normal business hours.¹²
- Website URL, as appropriate;
- Provider office's email address, if available;
- Type of practitioner;
- Provider specialty type, including board certification or accreditation, if any¹³;
- California License number and license type, if applicable;
- Name(s) of each allied health care professional to the extent applicable health care services are covered through a contract with the plan;
- Hours and days when each service location is open;
- Cultural and linguistic capabilities, including whether non-English languages and American Sign Language are offered by the provider or a skilled medical interpreter at the provider's office;
- Whether the provider will accept new patients;
- The providers admitting privileges to an identified hospital¹⁴,
- Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s) and equipment; and

¹⁰ Health & Safety Code section 1367.27(d)(2)

¹¹ 42 CFR 431.70; 42 CFR 438.10(h)(3)(ii)

¹² 42 CFR 438.10; HSC 1367.27:

https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB137

¹³ 42 CFR section 438.10

¹⁴ Health & Safety Code 1367.27 (c)(2)

If a DMC Plan is currently maintaining an electronic provider directory on their website as required by 42 CFR 438.10(h), Health and Safety Code (HSC) 1367.27, and the DMC contract, and is meeting the required provider directory data elements above, then the DMC Plan may copy the information to the Provider Directory API.¹⁵ However, if any of the required data elements are missing from the electronic provider directory, the DMC Plan must take the appropriate steps to ensure the Provider Directory API includes all required data elements.

DMC Plans must update their Provider Directory API in accordance with 42 CFR 438.10(h)(3) and attest that the DMC Plan meets all Provider Directory API requirements as outlined in this APL at their next provider directory submission. DMC Plans must continue to submit their bi-annual provider directory reviews to DMCDeliverables@dhcs.ca.gov. Additionally, DMC Plans must continue to submit the monthly file and use provider directories to DMCDeliverables@dhcs.ca.gov each month, with the exception of the month in which their bi-annual review is due to DHCS.

DHCS' provider directory reviews will remain the same per the current DMC contract requirements. All requirements in the DMC contract are subject to audits. Any DHCS findings must be addressed by the DMC within two weeks of being notified of the discrepancies.

III. Reporting Requirements

DMC Plans 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. DMC Plans must make all collected data available to DHCS and CMS, upon request.¹⁶

DMC Plans 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 Health Insurance Portability and Accountability Act of 1996 (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.¹⁷

DMC Plans may deny or discontinue any third-party application's connection to an API if they reasonably determine, consistent with their 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

¹⁵ DMC contract Exhibit A, Attachment 14, Member Services

¹⁶ 42 CFR 438.242(b)(3)-(4)

¹⁷ 42 CFR 431.60(c)(2)

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.¹⁸

The DMC Plan must update its relevant policies and procedures (P&Ps) and submit them to the Medi-Cal Dental Services Division (MDSD) at DMCDeliverables@dhcs.ca.gov within ninety (90) days of the release of this APL. The email confirmation must include the title of this APL, as well as the applicable APL release date in the subject line.

DMC Plans are responsible for ensuring that their subcontractors and network providers comply with all applicable state and federal laws and regulations, contract requirements, and other DHCS guidance, such as APLs.¹⁹ These requirements must be communicated by each DMC Plan to all subcontractors and network providers. DHCS may impose corrective action plans, as well as administrative and/or monetary sanctions, as applicable, for non-compliance.

If you have any questions regarding this APL, please contact MDSD at DMCDeliverables@dhcs.ca.gov.

Sincerely,

Original Signed by:

Adrianna Alcala-Beshara, JD, MBA
Chief
Medi-Cal Dental Services Division
Department of Health Care Services

¹⁸ 42 CFR 431.60(e); 438.242(b)(5)

¹⁹ DMC All Plan Letters are available here:

<https://www.dhcs.ca.gov/services/Pages/DentalAllPlanLetters.aspx>