

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[CMS-0034-N]

Notification Regarding the Use of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification Standards Exceptions Process by the Health Level Seven (HL7) International Da Vinci Project (Da Vinci) and the Availability of the Da Vinci Report

AGENCY: Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice provides the public with information about the availability and location of the Health Level Seven (HL7) International Da Vinci Project (Da Vinci) Report, which includes test results from the use of alternative standards for Referral Certification and Authorization and Eligibility for Health Plan transactions approved under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) exceptions process.

FOR FURTHER INFORMATION CONTACT: Michael Cimmino (410) 786-6408.

SUPPLEMENTARY INFORMATION:

I. Background

Under 45 CFR 162.940, an organization may request an exception from the use of a HIPAA standard to test a proposed modification to that standard. The purpose of the exception is to test how the proposed modification would be a significant improvement to the current standard. In its request, the requestor must explain how the proposed exception would do all the following:

- Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.
- Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses.
- Be uniform and consistent with the other standards adopted under 45 CFR part 162 (HIPAA Administrative Simplification) and, as appropriate, with other private and public sector health data standards.
- Have low additional development and implementation costs relative to the benefits of using the standard.
- Be supported by an ANSI-accredited SSO or other private or

public organization that would maintain the standard over time.

- Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster.
- Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.
- Be precise, unambiguous, and as simple as possible.
- Result in minimum data collection and paperwork burdens on users.
- Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology.

Additional information about the exception request and approval process can be found at: <https://www.cms.gov/files/document/guidance-letter-exception-process.pdf>.

Inquiries regarding the exception request and approval process can be sent to: AdministrativeSimplificationException@cms.hhs.gov.

II. Exception Request

On March 10, 2021, Health Level Seven (HL7) International Da Vinci Project (Da Vinci) submitted a request for an exception from the requirements to use the HIPAA-adopted standards for referral certification and authorization (PA) transactions (X12N 278 Version 5010) and eligibility for a health plan (eligibility) transactions (X12N 270/271 Version 5010), at 45 CFR 162.1302(c) and 162.1202(c), respectively. Specifically, HL7 requested that the exception apply to Da Vinci member organizations designated as payers¹ and their trading partners to allow them to use the HL7 Fast Healthcare Interoperability Resources (FHIR) Prior Authorization Support (PAS) Implementation Guide (IG) in conjunction with the HL7 FHIR Coverage Requirements Discovery (CRD) IG to determine if prior authorization (PA) is required, and for performing Payer Side PA based on the FHIR standards. These alternative standards reference the use of the HL7 Documentation Templates and Rules (DTR) IG.

III. Evaluation of the Exception Request

In evaluating the request for the exception, we considered the following criteria, specified at 45 CFR 162.940(b): (1) whether the proposed modification represented a significant improvement

to the current standard; (2) the extent and length of time of the exception; (3) consultations with designated standards maintenance organizations (DSMOs).

We notified HL7 that its exception request was approved on April 20, 2021, and provided details on the conditions for the approved exception, as required under 45 CFR 162.940(c)(1). The HIPAA exception allowed for Da Vinci member organizations designated as payers and their trading partners to use alternative HL7 FHIR standards to support prior authorization and eligibility transactions (for the CRD IG) without enforcement actions until April 14, 2024. The permitted alternative HL7 FHIR standards were as follows:

- HL7 FHIR PAS IG.
- HL7 FHIR CRD IG to determine if PA is required, and for performing Payer Side PA based on the FHIR standards.

The exception permitted Da Vinci to use the HL7 FHIR Prior Authorization Support (PAS) Implementation Guide (IG) and the HL7 FHIR Coverage Requirements Discovery (CRD) IG to determine if PA is required, and for performing Payer Side PA based on the FHIR standards instead of the HIPAA-adopted standards for referral certification and authorization (prior authorization) transactions (X12N 278 Version 5010) and eligibility for a health plan (eligibility) transactions (X12N 270/271 Version 5010), as required by 45 CFR 162.1302(c) and 162.1202(c), respectively.

IV. Report of Results

An organization that receives an exception under 45 CFR 162.940 must submit to the National Standards Group (NSG) a report of its results, including a cost-benefit analysis, within 90 days after completing the test.² Our approval letter specified that a report of the test results must be submitted to us by July 14, 2024, which was provided on June 25, 2024. Our approval letter for the exception request and the Da Vinci test results report are available at: <https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception>.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office Management and Budget under the authority of the

¹ <https://confluence.hl7.org/display/DVP/Da+Vinci+Project+Members>.

² See <https://www.cms.gov/files/document/guidance-letter-exception-process.pdf>.

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2025-0096]

National Offshore Safety Advisory Committee; Vacancy

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice; request for applications.

SUMMARY: The U.S. Coast Guard is re-soliciting applications from persons interested in membership on the National Offshore Safety Advisory Committee (Committee) to fill one vacant position representing entities engaged in offshore oil exploration and production on the Outer Continental Shelf adjacent to Alaska. The Committee advises the Secretary of the Department of Homeland Security on matters relating to activities directly involved with, or in support of, the exploration of offshore mineral and energy resources, to the extent that such matters are within the jurisdiction of the U.S. Coast Guard.

DATES: Complete applications must reach the Coast Guard on or before June 13, 2025.

ADDRESSES: Applications must include (a) a cover letter expressing interest in an appointment to the Committee and detailing their qualifications to serve as a representative in entities engaged in offshore oil exploration and production on the Outer Continental Shelf adjacent to Alaska, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief 2-3 paragraph biography written in third-person perspective. Applications should be submitted via email with the subject line "Application for NOSAC" to Justin.P.Goff@uscg.mil.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Justin Goff, Alternate Designated Federal Officer of the National Offshore Safety Advisory Committee; Telephone (571) 610-0130; or email at Justin.P.Goff@uscg.mil.

SUPPLEMENTARY INFORMATION: On January 17, 2025, the U.S. Coast Guard published a request in the **Federal Register** (90 FR 5923) soliciting

applications for persons interested in membership on the National Offshore Safety Advisory Committee to represent entities engaged in offshore oil exploration and production on the Outer Continental Shelf adjacent to Alaska. The U.S. Coast Guard is re-soliciting applications for this representative position.

The National Offshore Safety Advisory Committee is a Federal advisory committee. The Committee operates under the provisions of the *Federal Advisory Committee Act*, 5 U.S.C. ch. 10 and 46 U.S.C. 15109.

The Committee was established on December 4, 2018, by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018*, Public Law 115-282, 132 Stat. 4192 and amended by section 8331 of the *Elijah E. Cummings Coast Guard Authorization Act of 2020*, Public Law 116 283, and is codified in 46 U.S.C. 15106.

The Committee will advise the Secretary of Homeland Security on matters relating to activities directly involved with, or in support of, the exploration of offshore mineral and energy resources, to the extent that such matters are within the jurisdiction of the U.S. Coast Guard.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee to meet at least twice a year, but it may meet more frequently. The meetings are generally held in cities that have high concentrations of maritime personnel and related marine industry businesses.

All members serve at their own expense and receive no salary or other compensation from the Federal Government.

Under the provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31 of the third full year after the effective date of your appointment. The Secretary may require an individual to have passed an appropriate security background examination before appointment to the Committee, 46 U.S.C. 15109(f)(4).

In this re-solicitation for a Committee member, we will consider applications for one position representing entities engaged in offshore oil exploration and production on the Outer Continental Shelf adjacent to Alaska. The member who fills the position will be appointed to represent the interest as described above. As a representative, the member is expected to represent and speak on behalf of interests, views, or perspectives of a recognizable group of persons or class of stakeholders.

If you are appointed as a member of the Committee, you will be required to sign a Non-Disclosure Agreement and a Gratuitous Services Agreement.

If you are interested in applying to become a member of the Committee, email your complete application to Justin.P.Goff@uscg.mil as provided in the **ADDRESSES** section of this notice.

The U.S. Coast Guard will not consider incomplete or late applications.

Privacy Act Statement

Purpose: To obtain qualified applicants to fill one vacancy on the National Offshore Safety Advisory Committee. When you apply for appointment to the DHS' National Offshore Safety Advisory Committee, DHS collects your name, contact information, and any other personal information that you submit in conjunction with your application. DHS will use this information to evaluate your candidacy for Committee membership. If you are chosen to serve as a Committee member, your name will appear in publicly available Committee documents, membership lists, and Committee reports.

Authorities: 5 U.S.C. ch. 10; 46 U.S.C. 15106 and 15109; and Department of Homeland Security Delegation No. 00915.

Routine Uses: Authorized U.S. Coast Guard personnel will use this information to consider and obtain qualified candidates to serve on the Committee. Any external disclosures of information within this record will be made in accordance with DHS/ALL-009, Department of Homeland Security Advisory Committee (73 FR 57639, October 3, 2008).

Consequences of Failure to Provide Information: Furnishing this information is voluntary. However, failure to furnish the requested information may result in your application not being considered for the Committee.

Dated: April 15, 2025.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

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