



Application for Registration to Operate as a Health Information Exchange in Maryland

Overview

Health-General Article [§4-301\(i\)\(1\)](#), Annotated Code of Maryland (effective October 1, 2022) defines a health information exchange (HIE) as:

i. An individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that allows, enables, or requires the use of any technology or services for access, exchange, or use of electronic protected health care information:

- 1. Among more than two unaffiliated individuals or entities that are enabled to exchange electronic protected health information with each other; and*
- 2. That is for a treatment, payment, or health care operations purpose, as those terms are defined in 45 C.F.R. §164.501, regardless of whether the individuals or entities are subject to the requirements of 45 C.F.R. parts §160 and §164; or*

ii. A health information technology developer of certified health information technology that develops or offers health information technology, as that term is defined in 42 U.S.C. 300 JJ(5), and has one or more Health Information Technology Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator in accordance with 42 U.S.C 300 JJ-11(C)(5).

[State law](#) requires the Maryland Health Care Commission (MHCC) to adopt regulations for the privacy and security of protected health information (PHI) obtained or released through an HIE. [Code of Maryland Regulations \(COMAR\) 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information](#) (also referred to as “regulations” herein), was adopted in March 2014 and has been amended to keep pace with federal and State policy changes for health data and technology, including the implementation of [protections](#) for legally protected health information (as defined by [COMAR 10.11.08](#)) and use of a centralized [consent management application](#). The MHCC may require HIEs to submit an affirmation of compliance or provide updates on their implementation of certain statutory and regulatory requirements, including, but not limited to, development and implementation of certain technological capabilities and connectivity to and use of the consent management application.

Application Process

Entities operating in Maryland that meet the statutory definition of an HIE are required to register annually with MHCC (COMAR 10.25.18.09, Sections A and B). A listing of registered HIEs is available [here](#). Submission of a complete application that includes all supporting documentation starts the registration process. Applicants must provide a response to all questions and send supporting documentation to hie.registration@maryland.gov. Please include the registering entity's name in the subject line of the email. Within 45 days after receipt of complete information, MHCC will either recognize the HIE as registered in the State or deny the registration for reasons enumerated to the applicant. Registration is valid for one year, unless suspended or revoked by MHCC.

A registering entity that reasonably determines it is unable to independently meet any requirement in the regulations shall develop and implement policies to ensure compliance with the regulations through the execution of written agreements (COMAR 10.25.18.09, Section G). Plans to implement the required policies and associated timelines to ensure compliance must be communicated by the registering entity for MHCC to consider a temporary exemption from certain requirements if requested by the applicant. The MHCC will grant or deny an exemption within 45 days after receipt of complete information (COMAR 10.25.18.09, Section H).

NOTE: All information submitted in this application is subject to the Maryland Public Information Act, General Provisions Article (Gen. Prov.) [§§ 4-101 to 4-601](#). The Maryland Public Information Act requires that MHCC deny a request for disclosure of any of its records that contain confidential commercial or financial information or trade secrets. Therefore, it is important that an applicant clearly identify any information provided in an application that the applicant believes falls within the meaning of [Gen. Prov. § 4-335](#) and should be withheld by MHCC in response to any Public Information Act request.

For questions regarding COMAR 10.25.18, contact Anna Gribble at anna.gribble1@maryland.gov.

For questions regarding this application, please direct inquiries to hie.registration@maryland.gov.

Instructions

An HIE seeking to register with MHCC (initial or renewal) must complete each section of the application and provide supporting documentation. **A complete response must be submitted on this form and any supporting documentation must be provided via email to hie.registration@maryland.gov.** Please include the registering entity's name in the subject line of the email.

NOTE: For entities seeking to register as an HIE operating in Maryland for the first time, please contact MHCC at hie.registration@maryland.gov before completing this application.

Application

Section 1: Registering Entity Information

Legal Business Name:

DBA(s):

Check if corporate entity or subsidiary of a larger organization:

Corporate Entity

Subsidiary (*specify name of organization*):

Web Address:

Business Address:

Street:

City:

State:

Zip Code:

Mailing Address:

Street:

City:

State:

Zip Code:

Federal Tax ID:

State Tax ID:

Name of resident agent:¹

Salutation:

Name of officer of the organization:

Salutation:

Title:

Phone Number:

Email address:

Name of application contact:

Salutation:

Title:

Phone Number:

Email address:

Section 2: Operations

1. Indicate the estimated percentage of Maryland-based clients currently hosted by:

_____ Client-server model

_____ Cloud-based model

2. Specify the total number of states in which the registering entity has clients.

¹ Pursuant to MD. Code Ann., Corporations and Associations. §2-108. Available at:
mgaleg.maryland.gov/mgawebsite/Laws/StatuteText?article=gca§ion=2-108&enactments=false.

3. Specify how the registering entity engages with the Trusted Exchange Framework and Common Agreement (TEFCA) (*check all that apply*).

- Connected to one or more QHINs (specify the QHIN(s))
- In the process of connecting to an QHIN (specify the QHIN(s))
- Registered/Candidate QHIN
- None applicable
- Other

Section 3: Privacy and Security/COMAR 10.25.18

4. Provide evidence of at least one privacy and security audit conducted within the last 12 months that minimally includes a letter or certificate signed by the independent auditor with its opinion on the design and operating effectiveness of the registering entity’s privacy and security controls. The MHCC accepts a SOC 2 Type 2 audit or accreditation or certification by a nationally recognized entity; MHCC recognizes EHNAC, HITRUST, and ISO.

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name] Section 3[Audit Type].

5. Provide a list of any breaches reported by the registering entity as required by the HIPAA Breach Notification Rule (45 CFR §§ 164.400-414) and/or the Maryland Personal Information Protection Act (Md. Code Ann. Comm. Law 14-3504) within the last 12 months or since the registering entity’s last renewal. Include the date of breach discovery, date the breach was reported to OCR and/or the Maryland Office of the Attorney General, and provide a copy of the breach report. If no breaches were reported, enter “None.”

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name] Section 3_Breach.

6. Provide an explanation of how the registering entity has implemented policies to ensure compliance with COMAR 10.25.18; this may include policies through the execution of written agreements with clients, including a participating organization or a business associate that will bring the registering entity into compliance (COMAR 10.25.18.09, Section G).

7. Provide evidence of an independent auditor's assessment of the registering entity's legal compliance with Chapter 18 (COMAR 10.25.18.06 C(1)(d)). A self-attestation indicating the registering entity's compliance with Chapter 18 will be accepted in place of an independent auditor's assessment.

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name] Section 3_Ch 18 Audit.

8. Are there specific provisions under COMAR 10.25.18 for which the registering entity seeks a one-year exemption (COMAR 10.25.18.09, Section H)? A request for exemptions must include the following information to be considered by MHCC: the regulation(s) and applicable section(s)/subsection(s), the reason and supporting justification for each exemption requested, and the registering entity's plan and timeline to comply with the requirement. If no exemptions are requested, enter "None."

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name] Section 3_Exemption Requests.

Section 4: Authorization for HIE Registration Application

An officer of the organization solemnly affirms under penalties of perjury that the contents of this application and supplementary information are true and correct to the best of their knowledge, information, and belief. The officer also understands that any false information provided shall be a cause for denial of this application or revocation of any registration granted.

Signature:

Typing a name is the equivalent of the authorized individual's physical signature.

Title:

Date: