



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 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. **This application must be completed online [here](#).** 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 a written agreement with a participating organization or business associate (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 (initial or renewal) must complete each section of the application and provide supporting documentation. A complete response must be submitted online **here** 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. Registering entities are required to have at least a SOC 2 Type 2 audit or accreditation or certification by a nationally recognized entity; MHCC recognizes EHNAC, HITRUST, and ISO.

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:

E-mail address:

Name of application contact:

Salutation:

Title:

Phone Number:

E-mail address:

Section 2: Operations

1. Provide a detailed diagram mapping the internal and external network data flows for the registering entity to illustrate how data is stored, transmitted, and accessed. The mapping, as recognized in national security frameworks, including the [NIST Cybersecurity Framework 2.0](#) (ID.AM-03), should be a graphical representation of all data inputs and outputs, data storage points, data routes within and outside of the system, and how external entities interact with the system to provide or retrieve data. For more information on data flow diagrams, please consider reviewing the following resources: www.ibm.com/think/topics/data-flow-diagram and sbscyber.com/blog/data-flow-diagrams-101.

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name]_Section 2_Data Flow.

¹ Pursuant to MD. Code Ann., Corporations and Associations. §2-108. Available at: [mgaleg.maryland.gov/mgaweb/Laws/StatuteText?article=gca§ion=2-108&enactments=false#:~:text=%C2%A72%E2%80%9393108.&text=\(2\)%20A%20resident%20agent,authorizes%20the%20designation%20or%20change](http://mgaleg.maryland.gov/mgaweb/Laws/StatuteText?article=gca§ion=2-108&enactments=false#:~:text=%C2%A72%E2%80%9393108.&text=(2)%20A%20resident%20agent,authorizes%20the%20designation%20or%20change).

2. What is the registering entity's business model as it relates to data storage and sharing?

☐ Centralized model

☐ Federated model

☐ Hybrid model

3. Specify all states or regions served by the registering entity.

4. For electronic health record ("EHR") vendors: How many unique EHR instances does the registering entity have for Maryland-based clients?

5. Specify the estimated percentage of Maryland-based clients that are hosted by:

_____ Client-server model

_____ Cloud-based model

6. Specify the status of the registering entity's participation in the Trusted Exchange Framework and Common Agreement ("TEFCA").

☐ Connected to a Qualified Health Information Network ("QHIN") through another network or technology vendor that is connected to a QHIN (specify)

☐ Connected directly to a QHIN (specify)

☐ Planning to become a QHIN (specify which QHIN(s) and when)

☐ Registered QHIN

☐ None Applicable

Section 3: Privacy and Security

7. Provide evidence of auditing policies and procedures for an independent audit of the registering entity's privacy, security, and legal compliance, consistent with COMAR 10.25.18.06C(2). If evidence cannot be submitted, provide a written explanation.

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

8. Which of the following audits are completed at least annually for the registering entity (*check all that apply*)?

- ☐ SOC 2 Type 2
- ☐ EHNAC
- ☐ HITRUST
- ☐ ISO
- ☐ Other (specify)

9. Provide evidence of at least one audit conducted within the last twelve months that minimally includes a letter signed by the independent auditor with its opinion on the design and operating effectiveness of the registering entity's privacy and security controls.

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

10. 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, select "None."

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

Section 4: Artificial Intelligence (AI)

11. What AI policies does the registering entity have in place or plan to establish to ensure responsible use of AI-enabled technologies?

AI Policies	Not in place	Planned	Developing	Established
Accountability mechanisms to monitor the performance and outcomes of AI systems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Equity by design to ensure fairness and mitigate bias in AI systems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transparency to end users about AI processes, algorithms, and data used to foster trust	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acceptable AI use policies outlining what is permitted and prohibited	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. How does the registering entity test and secure its AI systems and upgrades (*select all that apply*)?

- Testing is done using defined and documented acceptance criteria
- Test environments are designed to closely resemble the final production environment
- Scope, methods, and frequency of independent security audits are documented
- Business continuity testing is conducted routinely for AI systems
- A formal process for reporting AI incidents has been established
- Incident response and escalation procedures are tested on a periodic basis
- N/A

13. Specify approximately how many AI use cases the registering entity has in development and how many have been deployed/currently available to clients. If no AI uses cases planned or available, write “None.”

Section 5: Compliance with COMAR 10.25.18

14. What is the status of developing and implementing policies to ensure full compliance with COMAR 10.25.18 through written agreements with business associates or participating organizations, for any provision that the registering entity has determined it is unable to comply with independently (COMAR 10.25.18.09, Section G)?
15. Provide evidence of an independent auditor's assessment of the registering entity's compliance with COMAR 10.25.18, as required by COMAR 10.25.18.09G. If evidence cannot be submitted, provide a written explanation.

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name]_Section 5_Ch 18 Audit.

16. 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, select "None."

Note: Supporting documentation must be submitted to hie.registration@maryland.gov and adhere to the following naming convention: [Applicant Name]_Section 5_Exemption Requests.

Section 6: Authorization for HIE Registration Application

By signing below, 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:

Section 7: Management Service Organization State Designation

In 2009, the Maryland General Assembly passed a [law](#) requiring MHCC to designate one or more entities as a Management Services Organization (“MSO”). An entity may receive MSO State Designation if it offers health information technology and consulting services to providers in the [State](#). This designation was established using the Better Business Bureau accreditation framework, which signifies high standards in business performance, transparency, and accountability.

MSO State Designation is voluntary, and no fees are assessed by MHCC. Registered HIEs that offer health information technology and consulting services to Maryland-based clients are encouraged to obtain MSO State Designation, a recognized symbol of trustworthiness and commitment to supporting secure and efficient diffusion of technology in ways that improve health care operations and the delivery of patient care. Registered HIEs that have MSO State Designation will be featured on MHCC’s website and included in informational materials shared with provider and payer organizations, among other stakeholders.

To Be Considered for MSO State Designation:

By signing below, an officer of the organization affirms that the applicant, a related entity, or a person or entity that is a principal, owner, operator, or part of management of the registering entity has never:

- (a) Plead guilty to, been convicted of, or received probation before judgment or similar diversionary disposition for a crime related to the operation of the registering entity or for a crime involving fraud, dishonesty, or false dealing; or*
- (b) Been found in violation of State or federal laws or regulations governing the operation of the registering entity.*

Signature:

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

Title: