

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

Overview

COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*, subsection .09 requires a Health Information Exchange (HIE) to register with the Maryland Health Care Commission (MHCC) in order to operate in the State of Maryland.¹ HIEs must submit an application for registration to MHCC for approval. There is no HIE registration fee. HIE registration must be renewed annually. For additional information on terminology and definitions, please refer to the Key Terms section on pages 3 and 4 of this application.

This document serves as both the initial and renewal registration application. The MHCC reserves the right to require additional information to support the claims of the applicant as well as the right to deny HIE registration or renewal due to deficiencies in application documents.

Who Is Required to Register?

COMAR 10.25.18.02B(25) defines HIE as an entity that creates or maintains an infrastructure that provides organizational and technical capabilities in an interoperable system for electronic exchange of protected health information (PHI) among participating organizations not under common ownership, in a manner that ensures the secure exchange of PHI to provide care to patients. A payor may act as, operate, or own an HIE subject to these regulations.

The regulations do not apply to an entity that is acting solely as a health care clearinghouse, as defined in 45CFR §160.103 or an HIE that solely exchanges PHI between any of the following: 1) a hospital and a credentialed professional; 2) credentialed professionals of a hospital's medical staff; or 3) a hospital and its affiliated ancillary clinical service provider who is affiliated with the hospital and who, if required by the Health Information Portability and Accountability Act of 1996 (HIPAA), has entered into a business associate agreement with the hospital.

Registration Renewal

COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*, subsection .09 requires a registered HIE to renew its registration with MHCC annually in order to operate in the State of Maryland. HIEs must submit an application for renewal to MHCC for approval.

The following scenarios provide general information regarding the information required upon a registered HIE's first renewal, based on the HIE's fiscal year (FY) end date and initial registration date.

¹ COMAR 10.25.18 available at: http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.25.18.*

1. If the HIE initially registered less than three months prior to its FY end (for first renewal), the HIE is required to submit within 30 days of their FY end:
 - a. An attestation, in the form of a letter, that information on file is the same as its initial registration; or
 - b. Submission of only updated information.
2. If the HIE initially registered, more than three months prior to its FY end, the HIE is required to meet all renewal requirements as outlined in COMAR 10.25.18 subsections .06 and 09.

Application Submission:

1. Parts A through F, H, and I must be completed in entirety for both initial and renewal applications. **Part G** of the application must be completed by **only an HIE applying to renew** its registration. All required documents must be attached to the application. Any attachments submitted must clearly include the applicant's employer identification number (EIN). The individual authorizing the application must be a signatory authority of the HIE.
2. The completed application and required documents must be submitted by e-mail to HIE.Registration@Maryland.gov.

Required Documents for Initial Application:

1. Completed application form
2. Current audited financial statement
3. Provision for reasonable notice to participating organizations and MHCC if the HIE ceases to operate in Maryland
4. Methodology for assigning each authorized user with a unique user name and password in accordance with COMAR 10.25.18.05F(2)
5. Definition of an unusual finding in accordance with COMAR 10.25.18.02B(58)
6. Documentation/samples of core education content

MHCC Application Review and Notification:

1. The applicant will receive an email acknowledgement from MHCC upon receipt of a complete application. The MHCC may require an applicant to take additional steps to obtain its registration, either initial or renewal, in Maryland, such as secure a bond, letter of guarantee, or submit other information from the applicant, its parent company, or other responsible person subject to provisions set forth in COMAR 10.25.18.09.
2. Within 45 days after receipt of a completed application, MHCC shall take one of the following actions:
 - a. Recognize the HIE as registered/renewed in the State; or
 - b. Deny the registration/renewal for reasons specified to the applicant.
3. The MHCC will notify the applicant of its status via email; HIEs that have been registered/renewed will be listed on MHCC's [website](#).

Note: Information submitted to MHCC with an HIE application is subject to the Public Information Act under the State Government Article §10-611 through 10-630, Annotated Code of Maryland.² The MHCC will not divulge or release any proprietary or competitive information to the public. Information pertaining to the protection of your information by MHCC is contained in the Maryland Public Information Act: <https://www.oag.state.md.us/Opengov/Chapter3.pdf>, pages 3-19.

Key Terms

- *Core HIE education content* – In accordance with COMAR 10.25.18.02B(11), this includes educational information developed after consultation with interested parties, includes a general overview of:
 - a. The fundamentals of health information technology, including electronic health records and the exchange of electronic health information;
 - b. Health information privacy and security laws; and
 - c. The benefits and risks to patients of exchanging health information through an HIE as compared to opting-out and exchanging health information through a paper-based system.
- *Covered entity* – As defined in 45 CFR §160.103
- *Health information* – Any information, whether oral or recorded in any form or medium, that:
 - a. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
 - b. Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.
- *HIE* – An entity that creates or maintains an infrastructure that provides organizational and technical capabilities in an interoperable system for the electronic exchange of protected health information among participating organizations not under common ownership, in a manner that ensures the secure exchange of protected health information to provide care to patients. An HIE includes a payor HIE but does not include an entity that is acting solely as a health care clearinghouse, as defined in 45 CFR §160.103. A payor may act as, operate, or own an HIE subject to these regulations.
- *Participating organization* – A covered entity that enters into an agreement with an HIE that governs the terms and conditions under which its authorized users may use, access, or disclose protected health information through the HIE.
- *Protected health information* or *PHI* – A subset of health information, means:
 - a. PHI as defined in 45 CFR §160.103, or
 - b. A medical record as defined in the Health-General Article, §4-301(i); and

² Maryland Public Information Act available at: <http://www.oag.state.md.us/Opengov/pia.htm>

c. Includes sensitive health information.

- *State-Designated HIE* – An HIE designated by the MHCC and Health Services Cost Review Commission pursuant to the statutory authority set forth under Health-General Article, §19-143, Annotated Code of Maryland.
- *Unusual finding* – An irregularity in the manner in which use, access, maintenance, disclosure, or modification of health information or sensitive health information transmitted to or through an HIE should occur that could give rise to a breach, a violation under this chapter or a violation of other applicable privacy or security laws.

Part A: HIE Applicant Information

Legal Name of HIE: _____

DBA(s): _____

Is the HIE a corporate entity or a subsidiary of a larger organization?

Corporate Entity

Subsidiary (*specify name of organization*) _____

Web Address: _____

Mailing Address: _____

City: _____ State: _____ Zip code: _____

Federal Tax ID: _____

State Tax ID: _____

Fiscal Year

From (month/day): _____ To (month/day): _____

Officer of the Organization: _____ Title: _____

Phone number: _____

E-mail: _____

Contact Person: _____ Title: _____

Phone number: _____

E-mail: _____

Mailing Address: _____

Check if same as above.

City: _____ State: _____ Zip code: _____

Indicate if this is an initial or renewal application.

Initial Application

Renewal Application

Part B: HIE Service Areas and Participating Organizations

Note: Information provided in this section will be used only by MHCC in assessing the HIE landscape; information will not be used in determining HIE registration.

Maryland Jurisdictions

- 1) Select all of the Maryland jurisdictions serviced by the HIE.

Jurisdiction	✓ if Applicable	Jurisdiction	✓ if Applicable
All Maryland Jurisdictions		Harford County	
Allegany County		Howard County	
Anne Arundel County		Kent County	
Baltimore City		Montgomery County	
Baltimore County		Prince George's County	
Calvert County		Queen Anne's County	
Caroline County		Somerset County	
Carroll County		St. Mary's County	
Cecil County		Talbot County	
Charles County		Washington County	
Dorchester County		Wicomico County	
Frederick County		Worcester County	
Garrett County			

States

2) Select all states serviced by the HIE (*specify other geographic locations serviced by the HIE not listed*).

State	✓ if Applicable
Delaware	
Pennsylvania	
Virginia	
West Virginia	
Washington, D.C.	
Other (specify)	

Participating Organizations

3) Select which types of organizations participate with the HIE (*specify any other types of participating organizations not listed*).

Participating Organization	✓ if Applicable	Participating Organization	✓ if Applicable
Behavioral or Mental Health Care Organizations		Post-Acute Care (e.g. Long Term Care, Home Health, Skilled Nursing Facilities, etc.)	
Community or Public Health Clinics		Primary Care Physicians	
Emergency Medical Services		Private Payors (health, dental and vision plans)	
Federal/State Plans (Medicare or Medicaid)		Senior Care (e.g. Assisted Living Facilities, Independent Living Facilities)	
Federally Qualified Health Centers		Specialty Care Physicians	
Hospice Facilities or Agencies		State Governmental Agencies (non-treating)	
Hospitals		Other (<i>specify</i>)	
Laboratories, Imaging or Radiology			
Pharmacies (independent or hospital-based)			
Rehabilitation Providers (Physical, Occupational or Speech Therapy)			

Part C: HIE Policies and Procedures

1) Provide the HIE’s definition of what constitutes an “unusual finding” to be used in implementing certain auditing provisions as outlined under COMAR 10.25.18.06A.

Note: COMAR 10.25.18.02B(58) defines an “unusual finding” as an irregularity in the manner in which use, access, maintenance, disclosure, or modification of health information or sensitive health information transmitted to or through an HIE should occur that could give rise to a breach, a violation under this chapter or a violation of other applicable privacy or security laws.

***If this is a renewal application and there are no updates to report for this section, please indicate below.**

Select if supporting documentation is attached. Please provide the file name for the document: _____

Select if no updates to report

- 2) Provide the HIE’s provisions for providing reasonable notice to participating organizations and MHCC if the HIE ceases to operate in Maryland. Include in your response the HIE’s close out business plans involving the anticipated sale, merger, lease, or transfer of all or substantially all of the HIE’s assets or critical components and/or services, including protocols for the destruction of electronic health information contained in the HIE’s core infrastructure, the continuation of an organization’s existing participation agreement during the period of transition, etc.

***If this is a renewal application and there are no updates to report for this section, please indicate below.**

Select if supporting documentation is attached. Please provide the file name for the document: _____

Select if no updates to report

- 3) Provide the HIE’s methodology for assigning each authorized user with a unique user name and password.

Note: COMAR 10.25.18.05F(2) requires such methodology to assure that the HIE uses a commonly accepted protocol to avoid the possibility of duplicate user names and passwords.

***If this is a renewal application and there are no updates to report for this section, please indicate below.**

Select if supporting documentation is attached. Please provide the file name for the document: _____

Select if no updates to report

Part D: HIE Service Profile

- 1) Select all services offered by the HIE (*specify any other HIE services not listed*).

Count	Services		
	NwHIN Specifications	✓ Check if Offered	Brief Description (Include additional information to allow MHCC to understand the HIE’s capabilities related to the service)
1	NwHIN Direct		
2	NwHIN CONNECT		
	Within the NwHIN Exchange Limited Production Network		
	In an independent implementation		

Count	Services		
Transport Protocols		✓ <i>Check if Offered</i>	Brief Description <i>(Include additional information to allow MHCC to understand the HIE's capabilities related to the service)</i>
3	SOAP-based Web Services		
4	HTTPS POST/REST		
5	Other (e.g., PHIN MS), (specify)		
6	Transport Protocol Conversion, (specify)		
HIE Infrastructure		✓ <i>Check if Offered</i>	Brief Description <i>(Include additional information to allow MHCC to understand the HIE's capabilities related to the service)</i>
7	Data Ownership Model		
	Centralized Data Repository		
	Federated Data Repository		
	Hybrid Data Repository		
8	Provider Authentication		
9	Patient Authentication		
10	Provider Directory		
	Entity Level		
	Individual Level		
11	HIE User Directory		
	Include Primary Care Provider Designation		

Count	Services		
	HIE Infrastructure	✓ Check if Offered	Brief Description (Include additional information to allow MHCC to understand the HIE's capabilities related to the service)
12	Secure Messaging/HISP Services		
	Offer Direct Messaging Addresses		
	Provider Authentication		
	Provider to Provider Messaging		
	Provider to Patient Messaging		
	Patient to Provider Messaging		
13	Consent Management/Tracking		
	Management of a patient's choice to opt-out of participation in the HIE		
	Other mechanisms to manage consumer preferences and consent		
14	Patient Matching (Master Patient Index)		
15	Record Access Logging, Auditing, and Reporting		
16	Clinical Data Query via Record Locator Service		
	Support for core IHE Profiles (e.g. XDS, PIX/PDQ)		
	To Retrieve Record Location		
	To Retrieve Clinical Data		
17	Terminology Mapping		
	SNOMED mapping		
	LOINC mapping		
	Other (<i>specify</i>)		

Count	Services		
	Services	✓ Check if Offered	Brief Description (Include additional information to allow MHCC to understand the HIEs capabilities related to the service)
18	Message Conversion		
	Clinical Messages to Clinical Documents		
	Clinical Documents to Clinical Messages		
19	Other (<i>specify</i>)		
20	Administrative Transaction Capabilities		
	Health Plan Eligibility (270/271)		
	Health Claim Status (276/277)		
	Health Care Claim: (837)		
	Other (<i>specify</i>)		
21	Case/Care and Population Management		
	Disease Management Analytics		
	Chronic Disease Registry		
	Risk Stratification		
	Other Population of Care Management Tool (<i>specify</i>)		
22	Personal Health Record or Patient Portal		
23	Data Access Model		
	Web-based Portal		
	From within an EHR System		

Count	Services		
	Services	✓ Check if Offered	Brief Description (Include additional information to allow MHCC to understand the HIEs capabilities related to the service)
24	Immunization Transactions		
	Electronic reporting of immunizations		
	Query for immunization history and delivery		
	Support forecasting decision Support		
25	Laboratory Transactions		
	Electronic Clinical Laboratory Test Ordering		
	Electronic Laboratory Results Delivery		
26	Surveillance Data Transmission		
	Electronic Submission of Syndromic Surveillance Data to Public Health Designee		
	Electronic Submission of Reportable Lab Results to Public Health		
27	Quality Reporting		
	Reporting of Clinical Quality Measures		
28	Clinical Summary Record Exchange		
29	Imaging and Radiology Transactions		
	Radiology Results/Reports		
	Radiology images		
30	Other (<i>specify</i>)		

- 2) Specify the technology solution(s) that support the HIE’s core functions and exchange capabilities and how each solution is used.

Technology Solution	Use
<i>Example: IBM Initiate</i>	<i>Example: Master Patient Index</i>
<i>Example: Mirth Corp</i>	<i>Example: Query Portal</i>

- 3) Specify the EHR vendor(s) the HIE has established interfaces or processes with for sending and receiving of structured data elements.

EHR Vendor

Part E: HIE Financial Assessment

1) Specify all HIE revenue model(s) (*specify any other revenue model(s) not listed*).

Revenue Model	✓ if Applicable
Recurring subscription fee to users of the HIE	
Recurring subscription fee to data providers	
Transaction fees to HIE users	
Funding from health plans	
Funding from Maryland State Medicaid programs	
Other Maryland State government funding (NOT Medicaid)	
Federal government funding	
Services provided to third party organizations (e.g., clinical trials, provider directory, etc.)	
Other (<i>specify</i>):	

2) In accordance with COMAR 10.25.18.09A(1)(b), the HIE must submit a copy of the most current audited financial statement to MHCC no more than 120 days after its FY end.

For example:

- If an HIE's FY ends on December 31st the most current audited financial statement must be submitted to MHCC no later than April 30st.
- If an HIE's FY ends on June 30st the most current audited financial statement must be submitted to MHCC no later than October 31st.

Note: The financial statement should be prepared and certified by a Certified Public Accountant (the auditor) and meet the requirements of the U.S. Generally Accepted Accounting Principles. Include any qualified or unqualified opinion provided by the auditor on the accuracy of the report(s). The MHCC may request additional information based on the HIE's financial performance and/or auditor opinions.

Select if supporting documentation is attached. Please provide the file name for the document:

Renewal Application ONLY

Select if audited financial statement will be submitted to MHCC within 120 days of the HIE's FY end.

Part F: HIE Core Education Content

- 1) Attach documentation/examples of the HIE's core education content targeted to health care consumers.

Note: In accordance with COMAR 10.25.18.02B(11), this includes educational information developed after consultation with interested parties, and includes a general overview of:

(a) The fundamentals of health information technology, including electronic health records and the exchange of electronic health information;

(b) Health information privacy and security laws; and

(c) The benefits and risks to patients of exchanging health information through an HIE as compared to opting-out and exchanging health information through a paper-based system.

***If this is a renewal application and there are no updates to report for this section, please indicate below.**

Select if supporting documentation is attached. Please provide the file name for the document: _____

Select if no updates to report

Part G: Privacy and Security Audit

Renewal Application ONLY

- 1) Attach summary of findings from the HIE's annual privacy and security audit. The privacy and security audit should clearly demonstrate that it was conducted to identify inappropriate access, use, maintenance, or disclosure of PHI and that it was conducted in accordance with all applicable State and federal laws including COMAR 10.25.18.06C(1).

The organization affirms that the privacy and security audit was conducted to detect patterns of inappropriate access, use, maintenance, and disclosure of information that are in violation of current State and federal privacy and security laws, including COMAR 10.25.18. Yes

Select if supporting documentation is attached. Please provide the file name for the document: _____

Part H: Cybersecurity Controls

- 1) Confirm below that the HIE has implemented cybersecurity controls. Please note, if the HIE is unable to attest to implementing cybersecurity controls as outlined below, the MHCC reserves the right to deny the HIE's registration renewal.

The organization affirms that the HIE has implemented cybersecurity controls that are in accordance with industry standards, including but not limited to the National Institute of Standards and Technology (NIST)³, International Society for Automation (ISA)⁴, International Organization for Standardization (ISO)⁵, Control Objectives for Information and Related Technology (COBIT)⁶. These controls are implemented and maintained by the HIE directly and/or by a vendor or vendors supporting the HIE infrastructure. Yes

³ <http://www.nist.gov/>

⁴ <https://www.isa.org/>

⁵ <http://www.iso.org/iso/home.html>

⁶ <http://www.isaca.org/knowledge-center/cobit/pages/overview.aspx>

Part I: Attestation of Accuracy

By submitting this application, your organization agrees to be listed on MHCC's website as a State Registered HIE, including corporate name, address, phone number, website address (if applicable), services provided, software platforms used, and other information as requested by MHCC.

I understand that State registration renewal is in accordance with COMAR 10.25.18, and I agree to make all required information available to MHCC. I recognize that all costs associated with the activities undertaken for State registration and compliance with COMAR 10.25.18 are at the expense of the applicant. I understand that MHCC is not responsible for any costs incurred in an applicant's pursuit of State registration or compliance.

I affirm under perjury and penalty that the information given in this application is true and correct to the best of my knowledge and belief. I also understand that any false information provided shall be a cause for denial of this application or revocation of any registration granted.

Note: *The individual authorizing this application must be an officer of the HIE.*

Electronic Signature: _____

Entering an electronic signature or typing a name in the signature box above is the equivalent of a physical signature.

Title: _____

Date: _____

**Please submit your completed application and all required documents to
HIE.Registration@Maryland.gov**

Within 45 days after receipt of all required information, MHCC will render a decision in writing either recognizing the HIE has renewed its registration in the State or denying the renewal detailing the reason for the denial. For assistance, please contact Jake Rawlings by telephone at 410-764-3330.