

APPLICATION FOR STATE RECOGNITION OF AN ELECTRONIC ADVANCE DIRECTIVES SERVICE

Overview

State law¹ established an Advance Directives Program in Maryland to support creation of and accessibility to electronic advance directives. One aspect of the program is State Recognition of an electronic advance directives service (or vendor). State Recognition is available to vendors that want to establish an interface with the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP).² COMAR 10.25.19: *State Recognition of an Electronic Advance Directives Service* (regulations),³ outlines procedures for State Recognition, which includes submission of an application to the Maryland Health Care Commission (MHCC or Commission).

NOTE: State Recognition is voluntary and contingent upon a vendor's ability to meet all criteria published on MHCC's website.⁴ The State-Designated HIE may charge a fee for technology integration and ongoing maintenance of the connection. The MHCC encourages vendors to contact CRISP about technical specifications and integration fees prior to submitting an application.

Application Process

An electronic advance directives service seeking State Recognition (initial or renewal) must complete this application and submit it to MHCC with all required supporting documentation. For renewals, a completed application must be submitted at least 45 days prior to the expiration of a vendor's State Recognition status. Registration with the Maryland Department of Assessment and Taxation must be completed in advance of an application being submitted.⁵ Submission of an application does not guarantee State Recognition. The MHCC may request additional information to support claims made in this application. If approved, State Recognition is valid for three years, unless suspended or revoked by MHCC.

- 1. All sections of this application must be completed in entirety and demonstrate a vendor meets all criteria for State Recognition.**

¹ 2016 Chapter 510.

² CRISP was designated in 2009 by MHCC and the Health Services Cost Review Commission to build and maintain the technical infrastructure to support a statewide HIE. For more information about CRISP, visit: crisphealth.org.

³ Effective March 12, 2018; amended January 9, 2023.

⁴ mhcc.maryland.gov/mhcc/pages/hit/hit_advancedirectives/hit_advancedirectives.aspx.

⁵ egov.maryland.gov/businessexpress

2. Supporting documentation must be submitted with the application and labeled appropriately as requested in the application. The individual authorizing this application must be a signatory authority of the applicant.
3. Please submit the completed application with all required supporting documentation to ad.staterecognition@maryland.gov. An applicant will receive an email acknowledgement from MHCC upon receipt of an application.
4. During the process of reviewing the application for completeness, MHCC may request additional information from an applicant or its parent company. After MHCC staff determines that an application is complete, MHCC shall take, and notify the applicant in writing, one of the following actions:
 - a. Recognize the applicant as an electronic advance directives service authorized to connect to the State-Designated HIE; or
 - b. Deny the application for reasons specified in writing to the applicant.
5. Recognized vendors will be listed on MHCC's [website](#).

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 (2014).⁶ 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. See Gen. Prov. § 4-335. 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. Refer to Chapter 3 of the [Maryland Public Information Act](#) for more information.

Key Terms

- **Electronic Advance Directives Service or Vendor** – *A corporation, firm, association, or other entity that offers electronic advance directives services by way of a web-based application using cloud-based technology.*
- **State-Designated Health Information Exchange** – *An entity designated by MHCC and the Health Services Cost Review Commission, pursuant to the statutory authority set forth under Health-General Article, §19-143, Annotated Code of Maryland.*
- **State Recognition or State-Recognized** – *The status awarded by the Commission to an electronic advance directive service that has met the required State Recognition Criteria.*

⁶ The full text of the Maryland Public Information Act, Gen. Prov. §§ 4-101 to 4-601, can be accessed on-line at advance.lexis.com/ or at the website of the General Assembly of Maryland, mgaleg.maryland.gov/mgawebsite/, under “Laws - Statutes” tab on the home page.

APPLICATION

Check type of application Initial Renewal

Section A: Applicant Information

Legal Business Name: _____

Doing Business As: _____

Business Model: Business-to-Business (B2B) Business to Consumer (B2C)

Provide a brief explanation of how the business model will be implemented in Maryland:

Check if corporate entity or subsidiary of a larger organization:

Corporate Entity

Subsidiary – specify name of organization: _____

Website URL: _____

Business Address: _____

City: _____ State: _____ Zip code: _____

State Tax ID: _____

Federal Tax ID: _____

Contact Person: _____ Title: _____

Phone number: _____ E-mail: _____

Mailing Address: Check if same as business address:

City: _____ State: _____ Zip code: _____

This information will be used by MHCC for informational purposes.

Check if operations for the electronic advance directive service are:

Domestic International

Specify HIE interfaces. Check if no current connectivity to an HIE

Number	HIE Name	State(s) (Including Maryland)	Date of Connectivity (Month/Year)	Date if Interface was Disabled, if applicable
1				
2				
3				

Specify interfaces with other technology vendors (e.g., electronic health record vendors, personal health record vendors, etc.). Check if no current connectivity to other technology vendors

Number	Technology Vendor Name	State(s) (Including Maryland)	Date of Connectivity (Month/Year)	Date if Interface was Disabled, if applicable
1				
2				
3				

Section C: Policies and Procedures

Attach a brief explanation and supporting documentation for items 1-9. Supporting documentation must be submitted with your application and adhere to the following naming convention: [Applicant Name]_Section C_[Item Number(s)].

Description	Supporting Documentation Attached
1. Method for verifying users' identity and assigning a unique username and password	<input checked="" type="checkbox"/>
	<input type="checkbox"/>

2. Procedural and technical controls (e.g., authorization and authentication) for the exchange of health information with an HIE	<input type="checkbox"/>
3. Method for uploading a paper-based advance directive and creating an electronic advance directive, including: <ul style="list-style-type: none"> • version control protocols for multiple advance directives; • sharing and deletion of advance directives; and • identification of the types of individuals/entities that can obtain access to information in the advance directives database/repository 	<input type="checkbox"/>
4. Process for the transfer of electronic advance directives if the vendor is sold or goes out of business, and provision of notification to consumers within reasonable cure period so they may make alternative arrangements for securing their data	<input type="checkbox"/>
5. Communication with end-users (e.g., consumers, health care agents, health care providers, etc.), including methods, frequency, and anticipated reason for communications	<input type="checkbox"/>
6. Circumstances, if any, allowing user mailing lists/contact information to be shared or sold	<input type="checkbox"/>
7. Cybersecurity testing by type (e.g., penetration test vulnerability scans, etc.) and frequency, including the most recent test date (month and year)	<input type="checkbox"/>
8. Disaster recovery testing by type (e.g., tabletop exercise, simulation, etc.) and frequency, including the most recent test date (month and year)	<input type="checkbox"/>
9. Business continuity plan	<input type="checkbox"/>

Section D: Independent Audits

Attach a brief explanation and supporting documentation for item 10-11. Supporting documentation must be submitted with your application and adhere to the following naming convention: [Applicant Name]_Section D_[Number(s)].

Description	<input checked="" type="checkbox"/> Supporting Documentation Attached
10. Listing of all subcontractors that process, transmit, and store data on behalf of the vendor and an explanation of the services provided (e.g., application software, data storage, identity proofing, etc.)	<input type="checkbox"/>

11. Documentation of the most recent System and Organization Controls (SOC) 2 Type 2 audit report or accreditation or certification by a nationally recognized entity; this information must be provided for the vendor and any subcontractor(s) that maintain and support the technical infrastructure on behalf of an applicant	<input type="checkbox"/>
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Section E: Education Content

Attach a brief explanation and supporting documentation, including examples of education content targeted to consumers, health care agents, and health care providers for items 12-16.

Supporting documentation must be submitted with your application and adhere to the following naming convention: [Applicant Name]_Section E_[Number(s)].

Description	<input checked="" type="checkbox"/> Supporting Documentation Attached
12. Vendor’s scope of services, warranties, and privacy and security practices	<input type="checkbox"/>
13. Disclosures of any cost to a consumer prior to the consumer’s creation of an electronic advance directive or upload of a paper-based advance directive and notice to consumers regarding any changes in fees	<input type="checkbox"/>
14. Actions that can be taken if State Recognition is not renewed, suspended, or revoked	<input type="checkbox"/>
15. Notice of integration with the State-Designated HIE and any other third party(ies), including who can access advance directives through the State-Designated HIE, and a disclosure that only complete advance directives will be accessible to authorized users of the State-Designated HIE	<input type="checkbox"/>
16. Information on how personal information is protected, how the information may be used and with whom it may be shared, when and how notice is provided if personal information is compromised, and steps to take in the event of a breach	<input type="checkbox"/>

Section F: Technical Requirements and Connectivity with State-Designated HIE

Attach a brief explanation and supporting documentation for items 17-27. Supporting documentation must be submitted with your application and adhere to the following naming convention: [Applicant Name]_Section F_[Number(s)].

Description	<input checked="" type="checkbox"/> Supporting Documentation Attached
17. Establishes and maintains application programming interfaces (APIs) consistent with industry-standards	<input type="checkbox"/>
18. Adheres to current protocols including Advanced Encryption Standards (AES) and Transport Layer Security (TLS) for the protection of data at rest and in transit	<input type="checkbox"/>
19. Offers a secure, web-based application to create, update, and store electronic advance directives consistent with the Health Level-7, Consolidated Clinical Document Architecture Personal Advance Care Plan document standard	<input type="checkbox"/>
20. Allows consumers to download their advance directive into a printable document or electronically transfer their advance directive to another system or third party	<input type="checkbox"/>
21. Accepts video recordings for electronic advance directives, allowing a declarant to express their health care wishes and appoint a personal health care agent	<input type="checkbox"/>
22. Stores paper-based advance directives received by fax or other electronic means and makes paper-based advance directives as easily retrievable as electronic advance directives created via the vendor's website	<input type="checkbox"/>
23. Collects consumer demographics consistent with key data elements required by the State-Designated HIE Master Patient Index to assist in appropriately matching patients	<input type="checkbox"/>
24. Allows consumers to delete their electronic advance directive	<input type="checkbox"/>
25. Tracks information on when and by whom an advance directive was created, updated, accessed, or deleted	<input type="checkbox"/>
26. Makes available only completed and signed electronic advance directives to appropriately authorized individuals and the State-Designated HIE	<input type="checkbox"/>
27. Uses at least 12-point font consistent with U.S. Department of Health & Human Services Usability Guidelines	<input type="checkbox"/>

Section G: Reporting and Attestations

By submitting this application, the applicant understands and agrees to items A through G if awarded State Recognition.

- A. Appear on MHCC's website with other materials as a State Recognized electronic advance directives service. Information can include corporate name, address, telephone number, website address, and other information as reasonably deemed appropriated by MHCC.

- B. Annually provide documentation of the most recent SOC 2 Type 2 audit report or accreditation or certification by a nationally recognized entity for the vendor and any subcontractor(s)
- C. Notify MHCC of a breach within 10 business days after discovery. The notice shall detail the extent of the breach, as well as remedial actions taken by the applicant, including notification to consumers. This is in addition to reporting requirements under the Maryland Personal Information Protection Act ([Md. Code Ann. Comm. Law 14-3504](#)).
- D. Escrow data for Maryland residents for a specified time period at the request of MHCC should the organization be sold or go out of business. Applicant agrees to notify MHCC immediately, but no later than 90 days, before its plans to cease operations in Maryland.
- E. Produce, at least quarterly, reports that include the number of unique advance directives on file for Maryland residents. The Applicant further agrees to produce ad hoc reports upon request from MHCC.
- F. Affirm under penalties of perjury that, within the last 10 years, no current or former owner or senior manager of the service or a current or former owner or senior manager of any related or affiliated service has:
 - a. Been convicted of a felony or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony;
 - b. Received a determination of exclusion from participation in Medicare or State health care programs under 42 U.S.C. § 1320a-7 in any case with respect to a criminal or civil charge of Medicare or Medicaid fraud or abuse; or
 - c. Been found in violation of State or federal laws or regulations that govern the operation of, or relate in any way to, an electronic advance directives service.
- G. Affirm under penalties of perjury that the service or any related or affiliated service:
 - a. Has no pending complaints, judgments, liens, or any final judgment or liens;
 - b. Has not been the subject of an investigation by or order of any local, State, or federal governmental agency; or
- H. Notify the Commission in writing of any change in information submitted in the initial application within 10 business days after the change is effective.

The Applicant understands that this application is completed and submitted in accordance with the requirements outlined in COMAR 10.25.19: *State Recognition of an Electronic Advance Directives Service* and that all costs associated with the activities undertaken for State Recognition and compliance with the regulations are at the expense of the applicant and that MHCC is not responsible for any costs that may be incurred in pursuit of State Recognition or compliance.

AFFIRMATION OF ACCURACY BY INDIVIDUAL AUTHORIZED BY APPLICANT

I solemnly affirm under penalties of perjury that the contents of this application (or the supplementary information) are true to the best of my knowledge, information, and belief.

Note: *The individual signing this application must be authorized to sign on behalf of the applicant offering the electronic advance directives service as required by COMAR 10.25.19.04A.(2).*

Electronic Signature: _____

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

Title: _____

Date: _____

Please submit a completed application and all required documentation to
ad.staterecognition@maryland.gov

After receipt of a complete application and all supporting documentation, MHCC will render a decision in writing regarding approval of State Recognition. The letter will serve as proof of State Recognition, and a copy will be sent to the applicant and the State-Designated HIE. If the application is denied, MHCC will render a decision in writing to the applicant detailing the reason for the denial. For assistance, please contact ad.staterecognition@maryland.gov.