

MARYLAND REGISTER

Proposed Action on Regulations

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2. COMAR Codification

Title Subtitle Chapter Regulation

10 25 19 01, .02, .03, .04, .05, .06, .07 and .08

3. Name of Promulgating Authority

Maryland Health Care Commission

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6. Check applicable items:

New Regulations

Amendments to Existing Regulations

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

10.25.19 State Recognition of an Electronic Advance Directives Service

Authority: Health-General Article §§ 4-302.2, 5-602, 5-622, 19-103(c)(2)(i) and (ii), 19-144, Annotated Code of Maryland

Notice of Proposed Action

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The Maryland Health Care Commission proposes to adopt new Regulations .01, .02, .03, .04, .05, .06, .07, and .08 under COMAR 10.25.19 State Recognition of an Electronic Advance Directive Service.

This action was considered by the Commission at an open meeting held on June 15, 2017, notice of which was given through publication in the Maryland Register, pursuant to General Provisions Article, §3-302, Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to clarify the process by which an electronic advance directive service can be awarded State Recognition from the Maryland Health Care Commission (MHCC) to be authorized to connect to the State-Designated Health Information Exchange. The regulations detail the process for developing criteria for State Recognition of an electronic advance directives service; State Recognition application process (initial and renewal); procedure to contest a denial of State Recognition; provisions on the non-transferability of State Recognition including the closure, sale, merger, lease, assignment, or transfer of all or part of a State Recognized electronic advance directives service; and MHCC oversight, including the process to investigate and revoke State Recognition from an electronic advance directives service.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

This new chapter details program requirements for an electronic advance directives service that seeks State Recognition from the Maryland Health Care Commission (MHCC) to connect to the State-Designated Health Information Exchange. The economic impact on an electronic advance directives service is expected to be minimal as MHCC criteria for State Recognition aligns with national benchmarks for privacy and security, which most electronic advance directive services already adhere to given requirements set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

	Revenue (R+/R-)	
II. Types of Economic Impact.	Expenditure (E+/E-)	Magnitude

A. On issuing agency:	(E+)	Within Budget
B. On other State agencies:	NONE	No Impact
C. On local governments:	NONE	No impact

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	Moderate
(2)	(-)	Moderate
E. On other industries or trade groups:	NONE	No impact
F. Direct and indirect effects on public:	(+)	Moderate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The MHCC is the State agency responsible for advancing health information technology throughout Maryland. The chapter requires the MHCC to award State Recognition to qualified electronic advance directive services and monitor compliance with the regulations. The MHCC can support the regulation using current staff within the MHCC's budget.

B. Other State agencies do not have any requirements as it relates to the regulation; as such, there is no impact on State agencies.

C. Local governments do not have any requirements as it relates to the regulation; as such, there is no impact on local governments.

D(1). The regulations are expected to have a moderate financial impact on organizations that seek State Recognition from MHCC. The economic impact on an electronic advance directives service is expected to be moderate as MHCC criteria for State Recognition aligns with national benchmarks for privacy and security, which most electronic advance directive services already adhere to given requirements set forth in the HIPAA.

D(2). The regulations are expected to have a moderate financial impact on organizations that seek State Recognition from MHCC. The economic impact on an electronic advance directives service is expected to be moderate as MHCC criteria for State Recognition aligns with national benchmarks for privacy and security, which most electronic advance directive services already adhere to given requirements set forth in the HIPAA.

E. The regulations are not expected to have an impact on other industries and trade groups.

F. The regulations are expected to have a positive impact on the public. These regulations are necessary to ensure that robust protections are in place for electronic advance directive services and allow health care providers to have more timely and convenient access to their patients' advance directive when needed.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Christine Karayinopulos, Executive Assistant, Center for Health Information Technology and Innovative Care Delivery, MHCC, 4160 Patterson Avenue, Baltimore, MD 21215, or call 410-764-3444, or email to christine.karayinopulos@maryland.gov, or fax to 410-358-1236. Comments will be accepted through 4:30 pm on August 21, 2017. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Maryland Health Care Commission during a public meeting to be held on September 21, 2017 at 1:00 pm, at 4160 Patterson Avenue, Baltimore, MD 21215.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2018

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:
Advance Directive Program Fund

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The regulations are expected to have minimal or no economic impact on small businesses. Small businesses may seek State Recognition from MHCC; however, the economic impact on an electronic advance directives service is expected to be minimal as MHCC criteria for State Recognition aligns with national benchmarks for privacy and security, which most electronic advance directive services already adhere to given requirements set forth in the HIPAA.

G. Small Business Worksheet:

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

Chapter 19 State Recognition of an Electronic Advance Directives Service

Authority: Health-General Article §§ 4-302.2, 5-602, 5-622, 19-103(c)(2)(i) and (ii), 19-144, Annotated Code of Maryland

.01 Scope.

This chapter applies to the State Recognition of an electronic advance directives service. Only an electronic advance directives service that is awarded State Recognition status by the Maryland Health Care Commission pursuant to this chapter may represent itself as a State-Recognized electronic advance directives service that is authorized to connect to the State-Designated Health Information Exchange.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Advance directive" means:

(a) A witnessed written or electronic document, voluntarily executed by the declarant in accordance with the requirements of Title 5 Subtitle 6 of the Health General Article; or

(b) A witnessed oral statement, made by the declarant in accordance with the provisions of Title 5 Subtitle 6 of the Health General Article; or

(c) An unwitnessed electronic document in which the declarant's identity is authenticated in accordance with the National Institute of Standards and Technology Special Publication 800-63-2: Electronic Authentication Guideline or subsequent replacement publications to 800-63.

(2) "Commission" means the Maryland Health Care Commission.

(3) "Declarant" means a competent individual who makes an advance directive while capable of making and communicating an informed decision.

(4) "Electronic advance directives service" or "service" means a corporation, firm, association, or other entity that offers electronic advance directives services by way of a web-based application using cloud-based technology.

(4) "Executive Director" means the Executive Director of the Commission.

(5) "Health care agent" means an individual appointed by a declarant under an advance directive to make health care decisions on behalf of a declarant.

(6) "State-Designated HIE" means an entity designated by the Maryland Health Care Commission and the Health Services Cost Review Commission pursuant to the statutory authority set forth under Health-General Article, §19-143, Annotated Code of Maryland.

(7) "State Recognition" or "State-Recognized" means the status awarded by the Commission to an approved electronic advance directives service that has met State Recognition criteria.

(8) "State Recognition criteria" or "criteria" means technology, security, privacy, and other standards established by the Commission in accordance with Regulation .03 of this chapter and for non-witnessed advance directives, must meet National Institute of Standards and Technology Special Publication 800-63-2: Electronic Authentication Guideline or subsequent replacement publications to 800-63 to authenticate a declarant's identity.

.03 Establishment of Criteria for State Recognition of an Electronic Advance Directives Service.

A. The Commission will assess the application of an electronic advance directives service for State Recognition in accordance with criteria approved by the Commission in accordance with the process set forth in this Regulation.

B. Commission staff shall publish in the Maryland Register and on the Commission's website a notice and draft criteria by which the Commission may consider an application by an electronic advance directives service for State Recognition.

(1) The notice shall specify the date by which public comments are due.

(2) Commission staff shall analyze public comments received and recommend criteria for use by the Commission in determining whether the Commission will award State Recognition to an electronic advance directives service.

C. The Commission will consider the public comments and Commission staff's recommendation in establishing the applicable criteria.

D. The criteria approved by the Commission shall be published in the Maryland Register and in a dated posting on the Commission's website.

.04 Procedure for Initial State Recognition.

A. Application.

(1) An electronic advance directives service seeking State Recognition shall submit an application in the form and manner specified by the Commission.

(2) The application, and all information supplementing the application, shall be signed by at least one person authorized by the applicant, who shall sign a statement as follows: "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."

B. An electronic advance directives service seeking State Recognition shall:

(1) Demonstrate that it meets all State Recognition criteria in effect at the date of the Commission's receipt of the initial application;

(2) Affirm under penalties of perjury that, within the last ten 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 US Code 1320a-7 in any case with respect to a criminal or civil charge of Medicare or Medicaid fraud or abuse;

(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;

(3) Affirm under penalties of perjury that the service or any related or affiliated service has:

(a) No pending complaints, judgments, liens, or any final judgment or liens; or

(b) Is not the subject of an investigation by or order of any local, State, or federal governmental agency;

(4) Provide all required documentation;

(5) Timely provide additional information requested by Commission staff as needed to complete analysis of the application and make a recommendation to the Commission;

(6) Send written notice to the Commission of any change in information submitted in the initial application within ten business days after the change is effective; and

(7) Agree to comply with the requirements of this chapter.

C. Review of Applications.

(1) Commission staff shall:

(a) Review an application to determine its compliance with State Recognition criteria; and

(b) Prepare a recommendation to the Commission on the application, detailing the reasons for the recommendation.

(2) If Commission staff recommends denial of an application for State Recognition:

(a) An applicant has ten days after electronic delivery of the Commission staff's recommended denial in which to make a written filing taking exceptions to the staff's recommendation; and

(b) Each applicant that timely submits a written filing may present oral argument on its written exceptions to the Commission, not to exceed ten minutes per applicant unless time is extended by the Chair of the Commission.

(3) The Commission may award State Recognition to each electronic advance directives service that meets all State Recognition criteria unless the Commission:

(a) Determines that it is in the public interest to award State Recognition to fewer than all the electronic advance directives services that meet the qualifications for State Recognition; and

(b) Details the bases for its decision.

D. Duration of State Recognition.

(1) State Recognition is valid for three years from its issuance, unless suspended or revoked by the Commission.

(2) An electronic advance directives service to which the Commission grants State Recognition shall acknowledge the status in writing and agree to comply with the terms and conditions of the award of State Recognition status.

.05 Procedure for Renewal of State Recognition.

A. An electronic advance directives service seeking renewal of its State Recognition status shall:

(1) At least 45 days prior to the expiration of State Recognition status, file a complete application for renewal in a form and manner specified by the Commission; and

(2) Demonstrate compliance with the State Recognition criteria in effect at the date of the Commission's receipt of the application for renewal.

B. Commission staff shall review a renewal application and make a recommendation to the Commission regarding:

(1) The applicant's compliance with the State Recognition criteria;

(2) The applicant's compliance with terms and conditions of the prior recognition; and

(3) Its assessment of the quality of the service provided by the electronic advance directives service.

C. The Commission shall approve an application for renewal of State Recognition status by an electronic advance directives service that:

- (1) Continues to meet all State Recognition criteria;
- (2) Has complied with the terms and condition of its previous award of State Recognition status; and
- (3) Has provided high quality service to persons who utilize its electronic advance directives service.

D. If Commission staff recommends denial of a renewal application, the procedure in Regulation .04C(2) of this chapter applies.

.06 Non-transferability of State Recognition.

State Recognition issued pursuant to this chapter may not be sold, assigned, leased, or transferred in any way, except as provided in Regulation .07 of this chapter.

.07 Closure, Sale, Merger, Lease, Assignment, or Transfer of All or Part of a State Recognized Electronic Advance Directives Service.

A. At least 90 days before a State Recognized electronic advance directives service closes on a sale, merger, lease, assignment, or transfer of all or part of a State Recognized electronic advance directives service, the State Recognized electronic advance directives service shall:

(1) Submit in writing to the Commission information requested by Commission staff about the desired change and a plan that assures the proposed transaction:

- (a) Results in the secure transfer either to another State Recognized electronic advance directives service;
- (b) Provides notice of the proposed transaction to the Commission, to the Department of Health, to the State-Designated Health Information Exchange, and to the Consumer Protection Division of the Office of the Maryland Attorney General; and
- (c) Provides notice of the proposed transaction electronically and on the website to each declarant who prepared an electronic advance directive through the service and health care agent named in an electronic advance directive, which at a minimum, includes:

(i) Information about the transfer of the declarant's advanced directives to another State Recognized entity;

(ii) The name, contact information and web address of the State Recognized receiving entity;

(iii) The date the transfer will occur; and

(iv) Specific instructions about how the transfer of an advance directive impacts the declarant and the health care agent.

(2) Not proceed with the proposed transaction until it receives written determination from the Executive Director of the Commission that State Recognition status may be transferred as a result of the proposed sale, merger, lease, assignment, or transfer of all or part of a State Recognized electronic advance directives service.

(3) The provisions of §A(1) of this regulation do not apply to a State Recognized electronic advance directives service that seeks to sell, merge, lease, assign, or transfer all or part of a State Recognized electronic advance directives service to:

(a) A person who was identified as a majority owner of the electronic advance directives service at the time of the most recent State Recognition by the Commission; or

(b) To an entity identified as the majority owner of the electronic advance directives service at the time of the most recent State Recognition by the Commission and whose membership or ownership, and percentage of ownership remain substantially the same as identified at the time of the most recent State Recognition by the Commission.

B. As soon as a State Recognized electronic advance directives service has information that sets forth a reasonable basis to believe that its ability to continue to operate as a State Recognized electronic advance directives service will be materially affected, and no fewer than three months prior to an anticipated closure, it shall submit complete written information to the Commission, along with a plan including provisions that assure the following:

(1) The secure transfer of electronic advance directives to another State Recognized electronic advance directives service to the extent that such transfer is consistent with State and federal law;

(2) Submission of any reporting required under an existing State or federal grant;

(3) Plans for the continuation of electronic advance directives services during a period of transition and for a mutually agreed timeframe prior to the transfer of electronic advance directives to another State Recognized electronic advance directives service or until the Commission awards State Recognition to a new electronic advance directives service to whom the existing service shall transfer existing advance directives;

(4) Plans for such transition services to a successor State Recognized electronic advance directives service as are reasonably feasible given the circumstances of the closure; and

(5) A minimum of 45 days advance notice of the full or partial closure to each declarant who prepared an electronic advance directive through the service and health care agent named in an electronic advance directive in accordance with §A(1)(c) of this regulation, to the Commission, to the Department of Health, to the State-Designated Health Information Exchange, and the Consumer Protection Division of the Office of the Maryland Attorney General.

.08 Commission Oversight of State Recognized Electronic Advance Directives Services.

A. Commission staff may, on its own initiative or in response to information provided to the Commission, investigate any State Recognized electronic advance directives service.

B. Failure by a State Recognized electronic advance directives service to provide full information requested by Commission staff in a timely and complete manner is grounds for suspension or revocation of State Recognition status.

C. Following Commission staff's investigation, the Executive Director may issue a notice of proposed action, which may include the following:

(1) A time-limited opportunity to correct deficiencies identified by the investigation;

(2) Suspension of the State Recognition of an electronic advance directives service for a definite period of time after which, depending upon the circumstances of the case and completion of appropriate corrective actions, the vendor may seek reinstatement of its State Recognition; or

(3) Revocation of State Recognition.

D. An electronic advance directives service that receives a notice of proposed action from the Executive Director may request an opportunity to show cause why the proposed action should not be implemented. A written request to show cause shall be filed with the Commission within 20 days of the issuance of the notice of proposed action and shall:

(1) State with particularity the grounds and factual basis for the electronic advance directives service's disagreement with the proposed action;

(2) Include each fact upon which the electronic advance directives service relies to show cause why the proposed action should not be taken; and

(3) Be supported by relevant documentation and affidavits.

E. The Commission shall determine whether to impose the proposed action or a different action under the exceptions procedure provided in Regulation .04C(2) of this chapter.

F. In the event the Commission suspends or revokes State Recognition status, the electronic advance directives service must notify each declarant who prepared an electronic advance directive through the service and health care agent named in an electronic advance directive about the impact of the action on accessibility of the advance directive.