



COMAR 10.25.19

State Recognition of an Electronic Advance Directives Service

Draft Regulations

For Informal Public Comment

The draft regulations, COMAR 10.25.19: *State Recognition of an Electronic Advance Directives Service*, were developed based on House Bill 1385, *Procedures, Information Sheet, and Use of Electronic Advance Directives* and House Bill 188, *Public Health - Advance Directives - Witness Requirements, Advance Directives Services, and Fund*, passed by the General Assembly.¹ Among other things, the law requires the Maryland Health Care Commission (MHCC) to develop a State Recognition program for electronic advance directives services in order to connect to the State-Designated Health Information Exchange.

In general, the draft regulations detail the process for developing criteria for State Recognition of an electronic advance directives service and application processes to be awarded State Recognition from MHCC. The MHCC is seeking informal public comment to this draft. Comments will be accepted until **4:30pm on Friday, June 2, 2017** and should be submitted via email or mail to:

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¹ In general, HB 1385 (2016 legislative session) alters witness requirements for electronic advance directives, expands the scope of education and outreach efforts, and requires MHCC to develop a State Recognition program for electronic advance directive services in order to connect to the State-Designated Health Information Exchange. HB 188 (2017 legislative session) clarifies the definition of an advance directive and that DHMH may contract with one or more electronic advance directives services as well as establishes an advance directives program fund.

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, 5-622, 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 witnessed written or electronic document, witnessed oral statement, or 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, that is voluntarily executed by a declarant that specifies the types of treatment the declarant does or does not want and appoints a health care agent to make health care decisions on behalf of a declarant who is unable to make such decisions.

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

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

(4) "Electronic advance directives 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 who is unable to make such decisions.

(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 the required technology, security, and privacy standards and is authorized to connect to the State-Designated HIE.

(8) “State Recognition criteria” or “criteria” means standards established by the Commission in accordance with Regulation .03 of this chapter for State Recognition of an electronic advance directives service.

.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 entity or a current or former owner or senior manager of any related or affiliated entity 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 such case with respect to any criminal or civil charges of Medicare or Medicaid fraud or abuse; or

(b) 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) Provide all required documentation;

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

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

C. Review of Applications.

(1) Commission staff shall review an application to determine its compliance with State Recognition criteria and 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 for which staff recommends denial has ten days after electronic delivery of the recommendation in which to make a written filing taking exceptions to the staff's recommendation;

(b) An applicant not taking exceptions to the staff's recommendation may file a written response to the exceptions within five days of electronic delivery of the written exceptions; and

(c) Each applicant that timely submits written exceptions or a written response to exceptions may present oral argument regarding its position 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 two 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 .04C(2) applies.

.06 Nontransferability 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 needed by the Commission about the desired change and present a plan that assures that the proposed transaction:

(a) Will result in the secure transfer either to another State Recognized advance directives service or to an entity that qualifies for State Recognition status; and

(b) Takes steps deemed necessary by the Commission to assure that notice of the proposed transaction is provided to each person who prepared an electronic advance directive through the service, to each health care agent named in an electronic advance directive, to the Commission, to the Department of Health and Mental Hygiene, to the State-Designated Health Information Exchange, and to the Consumer Protection Division of the Office of the Maryland Attorney General.

(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 .07A(1) 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 six 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 Commission's recognition of a new State Recognized electronic advance directives service, if necessary.

(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 person who prepared an electronic advance directive through the service, to each health care agent named in an electronic advance directive, to the Commission, to the Department of Health and Mental Hygiene, 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 may determine whether or not to impose the proposed action or a different action under the exceptions procedure provided in subsection .04C(2).