
**SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT’S RESPONSE
& LIST OF CHANGES MADE TO THE FINAL RULE**

10-146 CMR, Ch. 15

On November 27, 2019, public notice of the proposed 10-146 CMR chapter 15, Death with Dignity Act Reporting Rule, a new major substantive rule, was published in five newsprints and posted on the Secretary of State website. On this day, the Department of Health and Human Services, Maine Center for Disease Control and Prevention (Maine CDC) posted the proposed Death with Dignity Act Reporting Rule on the agency’s website. The Maine CDC held a public hearing on December 16, 2019 for comments on this rulemaking. Written comments were accepted through December 26, 2019.

Commenter ID #	First and Last Name Last Name	Date Received	Organization/ Affiliation	Format
1	Christine Woodman	12/02/2019	Town of Arrowsic LHO	Written
2	Dennis Smith, Esq.	12/13/2019	State of Maine Board of Licensure in Medicine	Written
3	Leann Sebrey	12/16/2019	Androscoggin Home Health and Hospice	Oral
4	Sandra Parker	12/16/2019; 12/19/2019	Maine Hospital Association	Oral and written
5	Andrew MacLean	12/16/2019; 12/26/2019	Maine Medical Association	Oral and written
6	R. Scott Hanson, M.D.	12/16/2019	Maine Medical Association	Oral
7	Lisa Harvey-McPherson	12/20/2019	Northern Light Health	Written
8	Ashley Cardenas	12/26/2019	Compassion & Choices	Written

Commenters 1 - 8 provided comments on the proposed major substantive rulemaking for 10-146 CMR, chapter 15. Oral and written comments have been summarized in this document, with similar comments synthesized for the Department to address in a single response efficiently. The Department’s response follows each comment and explains whether a change was made to the final rule in response to the comment. The Department also provides a summary listing of rule changes resulting from public comment and recommendations issued by the Assistant Attorney General through legal review.

GENERAL COMMENTS

Comment 1: Commenter 1 stated an interest in sharing about the rulemaking with town residents.

Response: No change suggested by commenter. The Department made no change to the rule based on this comment.

Comment 2: Commenter 4 expressed “general support for the state’s proposed death certificate language,” and purported “an obligation to clearly reference the law on the death certificate.” Commenter 4 and 7 suggested the following revision to the options listed in #38 Part I (a.) of the reporting form to eliminate redundant language and include a reference to the law:

Self-administration of life-ending drugs in accordance with the provisions of P.L. 2019, Chapter 271.

Commenter 5 and 7 requested to have the option to report the patient’s underlying disease as a contributing factor entered into the electronic death certificate record. Commenter 7 suggested that the underlying disease(s) would be listed as “*Due to or as a consequence of.*”

Response: In response to this comment, the Department reviewed the related section of statute (22 MRS § 2140 (20)) which states “state reports must refer to acts committed under this Act as obtaining and self-administering life-ending medication.” The Department refers to the specifications for U.S. standard certificates of live birth and death and the Report of Fetal Death, and follows these standards as closely as possible to promote uniformity in data collection across registration areas (<https://www.cdc.gov/nchs/nvss/revisions-of-the-us-standard-certificates-and-reports.htm>). The Department made no change to the rule based on this comment. Comments on the electronic death certificate report, unless otherwise specified in the Act, are outside the scope of this rulemaking.

Comment 3: Commenter 5 expressed “concern about the electronic prescribing requirement of P.L. 2015, Chapter 488 because some electronic medical record systems cannot electronically prescribe the compounded medications necessary for patients to pursue services under Chapter 271.” Commenter 5 urged the Department “to consider a standing waiver or exception to this requirement for these prescriptions.”

Response: The Department made no change to the rule based on this comment. The Department asserts that comments specific to P.L. 2015, Chapter 488 are outside the scope of this rulemaking and that changes related to the electronic medical record system require amendment to rule administered by the Office of Substance Abuse and Mental Health Services (SAMHS). In response to this comment, the Department reviewed 14-118 CMR Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications, and concluded that Chapter 11 provides for waivers appropriate for physicians acting under the Act. The Department directs the commenter to the electronic medical record system requirements and waivers permitted under SAMHS rules.

SECTION 1

Comment 4: Commenter 2 referenced Sections 4 and 11 of the Death with Dignity Act and asked, “*Should the proposed rule provide a definition of the term “oral request” or “verbal request” to include the use of interpreters for patients who are unable to communicate verbally or orally (e.g. deaf patient who communicates using sign language or patients suffering from medical conditions that preclude their ability to verbally communicate and use devices that speak for them)?*” Commenter 2 asked whether the law or the rule intends to restrict access to the law. Commenter 3 submitted comments similar to Commenter 2 and commented further that, as a registered nurse, she is in support of the law and of clear clinical rules and clarification of the law for safe and effective implementation. Commenter 3 asked the Department to clarify how a patient, who can not speak or write, can comply with rule requirements to verbalize a request or to write, and how patient access and participation is affected if that patient is dependent on enteral feeding, cannot swallow or otherwise unable to ingest the medication that, by law, is to be self-administered.

Response: In response to this comment, the Department reviewed terms and definitions in rule and statute, and the Department finds that the definition of “*competent,*” included in rule and statute, addresses commenters’ expressed concern for a patient who may be communicating through an interpreter, and the Department concluded that, by virtue of being deemed a qualified *competent* adult, this patient has full access to the law. The Department finds the rule is consistent with the authority specified in the Act which, for compliance, describes the medication prescribed under the law as self-administered. To further clarify that qualified patients may be communicating through another person, the Department revised Section 3(B) by adding “*competent*” as a qualifier for the patient completing the Request for Medication to End My Life in a Humane and Dignified Manner. The Department revised terminology used throughout the rule to be consistent with the statute’s use of the terms by replacing “verbal” with “oral.”

Comment 5: Commenter 3 suggested that the rule include definitions or language to otherwise clarify “competency vs. capacity as it relates to the law”, and “psychological or psychiatric disorders that would disqualify an individual from accessing life-ending medications under the law.” Commenter 3 suggested that the Department consider Oregon and California’s approaches to implementation of similar laws.

Response: The Department refers to the Act and the Governor’s Executive Order 9 FY 19/20, An Order Implementing the Death with Dignity Act (June 12, 2019) for its authority to promulgate rules to collect documentation related to patient-directed care at the end of life for compliance purposes and for use in compiling an annual report to the Legislature. The Department finds that the comment relates to areas of the law that are beyond the Department’s scope of authority. The Department made no change based on this comment.

SECTION 3

Comment 6: Commenter 2 expressed concern that “witnesses,” as written in rule, may be interpreted in a way that may conflict with the statute. Commenter 2 suggested Section 3 (B)(1) of the proposed rule be revised to reduce potential of conflicting interpretations. Commenter 2 submitted the following language and format for the Department’s consideration:

1. *Witness. The qualified patient’s signature on this form must be witnessed by at least two individuals who, in the presence of the qualified patient, attest that to the best of their knowledge and belief, the patient is competent, is acting voluntarily, and is not being coerced to sign the request.*
 - a. *One witness must be a person who is not:*
 1. *A relative of the patient by blood, marriage, or adoption;*
 2. *A person who at the time the form is signed would be entitled to any portion of the estate of the patient upon death, under any will or by operation of any law;*
 3. *An owner, operator or employee of a health care facility where the patient is receiving medical treatment or is resident; or*
 - b. *Attending Physician. The patient’s attending physician at the time the written request is signed may not be a witness.*
 - c. *Patient in a Long-Term Care Facility. If the patient resides in a long-term care facility at the time of the patient’s written request, one witness must be a licensed healthcare provider designated by the facility. The facility’s designee may be an owner, operator or employee of the healthcare facility where the patient resides.*

Response: In response to this comment, the Department amended Section 3 (B)(1) of the rule to reflect the commenter’s suggested format and improve readability. The Department revised the rule format to read as follows, noting that there is no change made to the language initially proposed:

1. *Witnesses. The qualified patient’s signature on this form must be witnessed by at least two individuals who, in the presence of the qualified patient, attest that to the best of their knowledge and belief, the patient is competent, is acting voluntarily, and is not being coerced to sign the request.*
 - a. *One witness must be a person who is not:*
 - i. *A relative of the patient by blood, marriage, or adoption;*
 - ii. *A person who at the time the form is signed would be entitled to any portion of the estate of the patient upon death, under any will or by operation of any law; or*
 - iii. *An owner, operator or employee of a health care facility where the patient is receiving medical treatment or is a resident.*
 - b. *Attending Physician. The patient’s attending physician at the time the written request is signed may not be a witness.*
 - c. *Patient in a Long-Term Care Facility. If the patient resides in a long-term care facility at the time of the patient’s written request, one witness must be a licensed healthcare provider designated by the facility. The facility’s designee may be an owner, operator or employee of the healthcare facility where the patient resides.*

Comment 7: Commenter 4 referred to the Department’s interpreter attachment form and the “Note” that is qualifying language for an interpreter not also specified in 22 MRS § 2140 (25). Commenter 4 referenced regulations under Title VI of the Civil Rights Act of 1964 that require healthcare providers to provide interpreters and translated material to patients at no cost. Commenter 4 stated interpretive services are often provided by and paid for by the healthcare provider and that, consequently, many interpreters might be considered the health care providers’ employees. Commenter 5 echoed these interpreter-related issues raised by Commenter 4. Commenter 4 suggested the Department make revisions so that physicians are able to comply with both State and federal law regarding interpreter services. Commenter 4 requested that the note on the Department’s form be removed. Commenter 4 offered the following recommendation as an alternative:

Any interpreter required under this subsection must be a person who is not:

- (1) A relative of the patient by blood, marriage or adoption; or*
- (2) A person who at the time the request is signed would be entitled to any portion of the estate of the qualified patient upon death, under any will or by operation of any law.*

Response: The Department reviewed related sections of the Act and concluded that the Interpreter Attachment Form generated by the Department includes the qualifiers for “any interpreter,” as specified in 22 MRS § 2140 (5)(C), which provides as follows:

§ 2140 (5)(C). At least one of the 2 or more witnesses required under this subsection and **any interpreter** required under this subsection must be a person who is not:

- (1) A relative of the patient by blood, marriage or adoption;
- (2) A person who at the time the request is signed would be entitled to any portion of the estate of the qualified patient upon death, under any will or by operation of any law; or
- (3) An owner, operator or employee of a health care facility where the qualified patient is receiving medical treatment or is a resident. [PL 2019, c. 271, §4 (NEW).]

The Department determined that the commenters’ concern requires resolution through legislative action to amend the statutory language. In response to this comment, the qualifiers specified in statute and found under “Interpreter Limitations” in Section 3 (C)(1) of the Department’s proposed rule are removed from the final rule. Additionally, the Department will amend the Interpreter Attachment Form by removing the statutory language that is included as a note on the form; however, these changes to the rule and Department-issued form do not remove the statutory requirements with respect to interpreters. The revised Interpreter Attachment Form is consistent with 22 MRS § 2140 (25) which outlines substantially the form that is to serve as the interpreter attachment.

SECTION 4

Comment 8: Commenter 2 referenced Section 4 (A)(2) of the proposed rule and asked, “Should the term “submitted” be used in lieu of “mailed” in the event the Department develops a form which could be completed and submitted electronically online?”

Response: The Department accepts this comment and revised Section 4 (A)(2) to read as follows:

Copies of completed forms must be sent via postal mail to the following address or submitted to the State Registrar electronically by encrypted email. Fax filing of reports is not accepted under this rule.

DHHS - Office of Data, Research, and Vital Statistics
Attn: State Registrar
11 State House Station
220 Capitol Street
Augusta, Maine 04333-0011

Comment 9: Commenter 4 expressed support of testimony spoken by Commenter 3 and offered additional comments “limited to reporting form issues.” Commenter 4 referenced section D of the Attending Physician Reporting Form which requires the physician to report the date of dispensing. Commenter 4 submitted that the

attending physician does not know the date of dispensing, the pharmacy is not required to report this information and the Department needs this data. Commenter 4 suggested that the Prescription Monitoring Program (PMP) be used to collect this information, as done in other states, to benefit physicians, who would be flagged in the electronic system for entering the prescription information, and also the Department obligated to comply with reporting requirements. Commenter 4 requested that section D of the Attending Physician End-of-Life Reporting form be deleted.

Response: The Department finds that the rule refers to an attending physician who is prescribing *or* dispensing the life-ending medication, and the Department's form is directed at this physician. The Department agrees that the rule does not include reporting requirements for pharmacists who may be filling prescriptions for qualified patients and dispensing the end-of-life medication. The Department made no change to the rule based on this comment; however, as revised, Section D of the Department's Attending Physician Reporting Form, will document the date that the prescription is written.

Comment 10: Commenter 5 spoke in support of rules and the guidance that has been received regarding completion of the death registration following the adoption of the emergency rule. Commenter 5 stated that there are clinical issues that remain for physicians, while acknowledging that, by statute, the Department's authority is limited to data collection and reporting. Commenter 5 expressed agreement with testimony submitted by Commenter 4, and Commenter 5 added that there are issues with the guidance received from the Department regarding reporting for medical certification of cause of death and electronic death registration processes.

Response: The Department made no change to the rule based on this comment. The Department finds comments specific to the death certification form to be outside the scope of this rulemaking. The Department refers to provisions of law that prohibit references to acts committed under this Act as "suicide" or "assisted suicide" and that require state reports to refer to acts committed under this Act as "obtaining and self-administering life-ending medication." (See 22 MRS § 2140 (20) below.)

20. Authority of Act; references to acts committed under Act; applicable standard of care. This Act does not authorize a physician or any other person to end a patient's life by lethal injection, mercy killing or active euthanasia. Actions taken in accordance with this Act do not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide under the law. State reports may not refer to acts committed under this Act as "suicide" or "assisted suicide." Consistent with the provisions of this Act, state reports must refer to acts committed under this Act as obtaining and self-administering life-ending medication. Nothing contained in this Act may be interpreted to lower the applicable standard of care for the attending physician, the consulting physician, a psychiatrist or a psychologist or other health care provider providing services under this Act.

Comment 11: Commenter 6 spoke in support of the rule and commented on the importance of clear rules to implement the statute. Commenter 6 referred to Maine's database application for vital records (DAVE) and the Prescription Monitoring Program (PMP) in terms of systems currently supported by the Department for data collection. Commenter 6 agreed with commenter's suggestion to use an existing electronic data collection system to report data required for the Act. Commenter 6 submitted that, if Department revised reporting requirements to allow data collection via DAVE or PMP, duplicative fields could be removed from paper forms which would ease reporting burden and improve data integrity.

Response: The Department has assessed electronic systems for needed upgrades and, as authorized by the Act, has instituted paper forms for data collection to implement the major substantive rule timely. The Department made no change to the rule based on this comment.

Comment 12: Commenter 7 submitted that reporting requirements under the Controlled Substance Prescription Monitoring Program (PMP) are not addressed in the proposed rule, and urged the Department "to create a specific exemption reporting code" within the PMP to distinguish prescriptions written and dispensed in compliance with the Act. Commenter 5 suggested that it "would be helpful to Maine prescribers under Chapter 271 to have a

specific exemption code in the Controlled Substances Prescription Monitoring Program Rule (OSAMHS Rule Chapter 11) for prescriptions of opioid medication above the limits for prescription pursuant to Chapter 271.”

Response: The Department made no change to the rule based on this comment but does plan to share this concern with the Department of Health and Human Services Office of Substance Abuse and Mental Health Services.

Comment 13: Commenter 8 expressed concern about burdensome reporting requirements in the proposed rule, and stated that “the proposed rules surpass the requirements of the law.” Commenter 8 submitted that the law requires reporting within 30 days of writing or dispensing the life-ending medication and within 30 days of the patient’s death. Commenter 8 stated, if six months has passed without confirmation of the patient’s death, “this rule would effectively require the attending physician to recertify the qualified patient’s eligibility under the law every 6 months which poses not only an overwhelming administrative burden to participating providers and the Department itself, but also invades the privacy of the patient.” Commenter 8 suggested that Maine has created an additional reporting period for physician and that the required data should “be collected in the two reporting period as required under the law.” Commenter 8 requested that the Department remove the language requiring the physician to “recertify” and report “following the six-month prognosis period.”

Response: The Department confirmed that, to comply with the Act, physicians must report information specified in subsection 14 within 30 days of writing a prescription for life-ending medication (22 MRS §2140 (17)(B)(1)), and must also submit documents required by the Department 30 days after the patient’s death. The Department revised Section 3 (F) by removing the required reporting at six months when the death of qualified patient is not confirmed and clarifying that, if the Department does not receive an adequate report or an incomplete report has been filed, the Department may contact the physician.

SUMMARY LIST OF CHANGES TO THE RULE

- The term “oral” is used in place of “verbal” to be consistent with statute.
- Section 3(B) is revised by adding “*competent*” as a qualifier for the patient completing the Request for Medication to End My Life in a Humane and Dignified Manner to further clarify that the patient may be communicating requests through another person.
- Section 3 (B)(1) format is revised to improve readability.
- “*Interpreter Limitations*” is removed from Section 3 (C).
- Section 3 (F) is revised by removing the requirement for physicians to complete the End-of-Life Closure Form when the death is not confirmed and six months have passed since prescribing the life-ending medication.
- Section 4 (A)(2) is revised to allow for physicians to submit reports via email or postal mail, while prohibiting fax filing of reports.
- The following language was added to Section 4 (C) “*Except as otherwise provided by law,...*”.