COLORADO
Department of Public Health & Environment

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To: Members of the State Board of Health

From: Kirk Bol, MSPH, Manager, Registries and Vital Statistics Branch, Office of e-Health and Data, Center for Health and Environmental Data **-KAB**

Through: Chris Wells, PhD, MS, Director, Office of e-Health and Data, Center for Health and Environmental Data ***-CSW***

Date: April 19, 2017

Subject: **Rulemaking Hearing**
Proposed promulgation of 6 CCR 1009-4, Reporting and Collecting Medical Aid-in-Dying Medication Information, for consideration at a rulemaking hearing to occur in April, 2017

The Center for Health and Environmental Data is proposing new rules concerning the Department's collection and reporting of information as required under Section 25-48-111(2), C.R.S., of the "Colorado End-of-Life Options Act." The proposed rules require the attending physician to provide the Department key components of the patient's medical record and health care providers that dispense medication to provide the Department the dispensing record. The Department is required to review a sample the submitted information and generate an annual statistical report. The rule also reaffirms that the information submitted is confidential.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for promulgation of
6 CCR 1009-4, Reporting and Collecting Medical Aid-in-Dying Medication Information

Basis and Purpose:

Overview of the statutory requirements governing this rulemaking:
In 2016, Colorado voters approved Proposition 106, "Access to Medical Aid In Dying", which amends Colorado statutes to include the Colorado End-of-life Options Act (hereinafter "Act") at Article 48 of Title 25, C.R.S. The Act:

- Allows a terminally ill individual with a prognosis of six months or less to live to request and self-administer medical aid-in-dying medication in order to voluntarily end his or her life;
- Authorizes a physician to prescribe medical aid-in-dying medication to a terminally ill individual under certain conditions; and
- Creates criminal penalties for tampering with a person's request for medical aid-in-dying medication or knowingly coercing a person with a terminal illness to request the medication.

The Act delineates a series of responsibilities applicable to attending/prescribing physicians and the medical record documentation requirements. These requirements span the time frame from when a patient makes an initial request of his/her attending physician for a prescription for medical aid-in-dying medication, the period of subsequent medical consultation and mental health evaluation (when applicable), and the prescription and dispensing of medical aid-in-dying medication, either directly by the attending physician or licensed pharmacist.

Section 25-48-111(2)(a), C.R.S., requires the Department to adopt rules to facilitate the collection of medical record information documented by the attending physician. The Department will sample the collected information annually to monitor compliance with the Act. The Act has not conferred any enforcement authority to the Department; rather, this information will be used to develop an annual statistical report. The report will not contain identifying information. The Act expressly states that the information submitted to the department is not a public record and is not available for public inspection. Along with confidentiality being established in Section 25-48-111(2)(a), C.R.S., reported mortality information is confidential pursuant to Section 25-1-122, C.R.S. The proposed rules delineate the information from the medical record that must be submitted to the department, the manner of submitting the information, and the relevant time frames.

Section 25-48-111(2)(b), C.R.S., states that the Department shall require health care providers to file a copy of a dispensing record with the department. To ensure the department effectively communicates the requirement and receives the data needed to monitor compliance with the Act, the proposed rule includes the dispensing record reporting requirements. This portion of the rule is authorized pursuant to Section 25-1-108(1)(C)(I), C.R.S. which authorizes the Board to promulgate such rules the board deems necessary to carry out the public health laws of the state and Section 25-1.5-101, C.R.S., which authorizes the Department to collect, compile and tabulate reports of deaths and to require any person having information with regard to the same to make such reports and submit such information as the Board of Health requires by rule. Similarly, Section 25-1-122, C.R.S., authorizes the board to set the manner, time period, and form in which morbidity reporting occurs.

Section 25-48-111, C.R.S. reads:

25-48-111. Medical record documentation requirements - reporting requirements - department compliance reviews - rules.

(1) The attending physician shall document in the individual's medical record, the following information:

(a) dates of all oral requests;

(b) a valid written request;

(c) the attending physician's diagnosis and prognosis, determination of mental capacity and that the individual is making a voluntary request and an informed decision;

(d) the consulting physician's confirmation of diagnosis and prognosis, mental capacity and that the individual is making an informed decision;

(e) if applicable, written confirmation of mental capacity from a licensed mental health professional;

(f) a notation of notification of the right to rescind a request made pursuant to this article; and

(g) a notation by the attending physician that all requirements under this article have been satisfied; indicating steps taken to carry out the request, including a notation of the medical aid-in-dying medications prescribed and when.

(2)(a) The department of public health and environment shall annually review a sample of records maintained pursuant to this article to ensure compliance. The department shall adopt rules to facilitate the collection of information defined in subsection (1) of this section [concerning medical records]. Except as otherwise required by law, the information collected by the department is not a public record and is not available for public inspection. However, the department shall generate and make available to the public an annual statistical report of information collected under this subsection (2).

(b) The department shall require any health care provider, upon dispensing a medical aid-in-dying medication pursuant to this article, to file a copy of a dispensing record with the department. The dispensing record is not a public record and is not available for public inspection.

Rationale for proposed definitions:

The proposed rule includes two definitions. The first is the definition of "attending physician." Section 25-48-102(2), C.R.S., reads, ""Attending physician" means a physician who has primary responsibility for the care of a terminally ill individual and the treatment of the individual's terminal illness." Stakeholders consistently supported clarifying that the attending physician responsible for reporting was the attending physician that prescribed the medication. This clarification distinguishes the responsibilities of the prescribing attending physician from other physicians that may be providing care to the patient. This clarification also ensures that the reporting is undertaken by the individual with first-hand knowledge that she and the patient has complied with the Act, and that reporting is limited to instances where medical-aid-in-dying medication is in-fact prescribed. The rule acknowledges that the attending physician may have a designee complete the act of emailing or mailing the attending physician's record to the Department.

The second definition defines "health care provider." Section 25-48-102(4), C.R.S., reads, ""health care provider" or "provider" means a person who is licensed, certified, registered, or otherwise authorized or permitted by law to administer health care or dispense medication in the ordinary course of business or practice of the profession. The term includes a health care facility, including a long-term care facility as defined in Section 25-3-103.7(1)(f.3) and a continuing care retirement community as described in Section 25.5-6-203(1)(C)(I), C.R.S." The Act uses the term "health care provider" in the context of administering medical services; the Act affords the health care provider discretion as to whether he will participate in providing medical aid-in-dying medication.

The term "health care provider" is also used in the context of dispensing medical aid-in-dying medication. It is this use of the term that is relevant to the proposed rule. It is anticipated that in the vast majority, if not all cases, the health care provider that is required to submit the dispensing record information will be the attending physician that dispenses the medication pursuant to Section 25-48-106(I)(I), C.R.S., or the licensed pharmacist that dispenses the medication as recognized in Section 25-48-106(I)(II), C.R.S.

The emergency rule adopted by the Board of Health on January 18, 2017 contained a two-part definition of "Health care provider", specifically defined as "the person defined in Section 25-48-102(4), C.R.S., who:, (1) Dispenses the medical aid-in-dying medication directly to the patient, or (2) to fulfill the attending physician's written prescription for medical aid-in-dying medication, dispenses the medical aid-in-dying medication directly to the patient, the attending physician or an individual expressly designated by the patient.

Stakeholder feedback received since the emergency rule was put into effect revealed that this definition could result in duplicate reporting of the dispensing record. Specifically, in instances where a pharmacist prepares and packages aid-in-dying medication, and subsequently provides it to an attending physician, who in turn gives it to the eligible patient, the definition could reasonably be interpreted as requiring both the pharmacist and attending physician to report the dispensing form.

We do not feel that duplicate reporting is the intent of the Act, but rather, through further consideration of the Act, we believe the onus of reporting is intended to fall on to the person with first-hand knowledge of preparation and packaging of the aid-in-dying in response to an attending physician's prescription, whether given directly to a patient, or to an attending physician. Thus, in condensing the definition of "Health care provider" by striking the first portion or the original definition and keeping only the second portion, confusion leading to duplicate reporting of the dispensing record can be avoided.

~~As with the definition of "attending physician," this definition ensures the dispensing record is filed by the individual with first-hand knowledge of filling the prescription.~~

Rationale for proposed medical record reporting requirements:
The medical record reporting requirements mirror those in statute. The proposed rule also requires the attending physician to provide minimal patient information and contact information so the Department is able to reconcile the medical record reporting with the dispensing record information. During the stakeholder process, the community discussed whether additional reporting, beyond what is listed in the statute, is needed. The consensus was to begin with the statutorily mandated elements and the minimum information needed for the department to execute its statistical analysis and reporting responsibilities. Along with minimizing the burden to attending physicians, this approach ensures that the reporting is not a barrier to patients or physicians participating in activities permitted under the Act. If through implementation the Department and stakeholders determine that additional data is needed, a stakeholder process will be initiated.

The proposed rule also contains one substantive requirement that is not identified in statute. This is the requirement that when the attending physician does not dispense the medication but instead delivers a written prescription to a licensed pharmacist, the physician document and report that she or he informed the licensed pharmacist that the medication was prescribed pursuant to the Act. The stakeholders opined and the Department agrees that that this is a necessary step to ensure that the licensed pharmacist has notice that she is required to file the dispensing record information.

Rationale for proposed dispensing record requirements:
The Act does not expressly authorize rulemaking specific to filing the dispensing record; rather, the Act states that, "the Department will require any health care provider that dispenses medical aid-in-dying medication to file a copy of the dispensing record," Section 25-48-111(2)(b). The Department has relied upon its broad rulemaking authority to specify a timeframe for filing the record and what the record is to contain. This ensures both the attending physician and the health care provider who fills the attending physician's prescription, is aware of each other's reporting responsibilities and ensures that all impacted stakeholders have notice of the reporting requirements through a public rulemaking process.

Rationale for the confidentiality provision:
The rule repeats the statute to assure attending physicians, health care providers dispensing medication and patients that this information is confidential.

Additional considerations:
The proposed rule was constructed to maintain the distinction between those individuals that are required to report under the Act, and health facilities and health facility licensing requirements. The Act requires health facilities to have a policy and provide patient notification. It is anticipated that health care facilities will rely upon these regulations as they develop those policies and practices. As the Act is implemented the community may find that further clarification of the definition of health care provider is needed in statute or within these regulations. The Office of eHealth and Data will continue to work closely with the Health Facilities and Emergency Medical Services Division and stakeholders to monitor whether the rule can be improved.

The rule does not contain any directives to the State Department as it atypical for rules promulgated by a board to impose mandates on the executive agency. Stakeholders asked about what steps the Department would take if the Department became aware that an attending physician failed to report. The Department did not incorporate the stakeholder recommendation that the rule direct the Department to follow-up with physicians rather than report non-compliance with the Colorado Medical Board. The Department intends to provide technical assistance and education to assist physicians with the reporting requirements. While the Department anticipates that it would work with physicians, there may be circumstances where the Colorado Medical Board would need to be aware of a physician's failure to report.

The Act contemplates self-administration of the medical aid-in-dying medication. While some patients may be in the care of the attending physician that prescribed the medication or in the care of a hospice facility, the Department anticipates that patient deaths will occur in a variety of settings. There are benefits of knowing that the medication was used; however, the statute does not require this reporting and there will be circumstances where neither the attending physician nor the health care provider that dispensed the medication prescribed by the physician will know if the medication has been taken. Conversely, the Department anticipates that there will be circumstances where the death certificate is completed by an individual that is unaware that the patient's death occurred pursuant to this Act. While the Department contemplated asking attending physicians to report use of the medication when it was known to the attending physician, after further discussion with stakeholders and given the statutory structure, the Department concluded that it is unlikely that this reporting will generate useable data and thus, the Department's confidence and ability to analyze it is greatly reduced. As the Act is implemented, if it found reporting use of the medication is necessary, the Department and stakeholders will determine if a statutory or regulatory change is needed.

Emergency Rulemaking Finding and Justification:

An emergency rule-making was held on January 18, 2017, which waive~~s~~d the initial Administrative Procedure Act noticing requirements, ~~is~~ was necessary to comply with state law. Emergency rulemaking is authorized pursuant to Section 24-4-103(6), C.R.S.

Thise emergency rule shall become effective on adoption. It will be was approved and was to be effective for no more than 120 days after its adoption unless made permanent through a. It will be superseded by this rulemaking that satisfies the Administrative Procedure Act noticing requirements.

Rationale: Proposition 106, Access to Medical Aid-in-Dying Medication, passed November 8, 2016. The Secretary of State, pursuant to Section 1-40-123, C.R.S., transmitted the certificate of election to the Governor on December 9, 2016. The Governor signed Proposition 106 into law on December 16, 2016. Article 48, Title 25, End-of-life Options, became effective upon the Governor's signature.

This rulemaking is necessary to comply with Section *25*-48-111(2), C.R.S.

Specific Statutory Authority:
These rules are promulgated pursuant to the following statutes: Sections 25-48-111(2), 25-1-108(1)(C)(I), 25-1.5-101, and 25-1-122, C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

___X___ Yes, Proposition 106. Rules are ___ authorized _X__ required.
_____ No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
___X___ No

Does this rule incorporate materials by reference?

_____ Yes
___X___ No

If "Yes," the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rule create or modify fines or fees?

_____ Yes
___X___ No

REGULATORY ANALYSIS

for promulgation of

6 CCR 1009-4, Reporting and Collecting Medical Aid-in-Dying Medication Information

1. **A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.**

Attending physicians and health care providers that maintain medical records pertaining to medical aid-in-dying requests will be required to submit the information delineated in the proposed rules. Though patients are not required to report, patients need to be informed that a portion of their medical record will be submitted to the Department. Monitoring attending physicians' and health care providers' practices as it relates to the End-of-Life Options Act (hereinafter "Act") benefits the patients they serve. It also benefits the medical community because uniform reporting enables consistency in practice and medical professionals may be interested in the annual report.

2. **To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**

No significant time or economic impacts for attending physicians or health care providers dispensing medical aid-in-dying medication are foreseen. Attending physicians are required to report the minimum information needed to monitor compliance with the Act. The proposed rule aligns the submission of medical record information with statutory requirement that health care providers submit a copy of the dispensing record. A single submission ensures coordination across the individuals that are serving a patient, eliminates duplication and can reduce data incongruities that arise when multiple persons are required to report on the same information.

3. **The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**

The Department ~~was allocated a .3 FTE for State FY 2016-17 and~~is pursuing allocation of .5 FTE for State FY 2017-18, and thereafter, to implement the requirements delineated in Section 25-48-111, C.R.S. The rule does not generate revenue or give rise to additional costs. The staff will develop the reporting forms and modify as appropriate, provide ongoing education and technical support, sample the submissions to monitor compliance, and perform the annual statistical analysis and reporting required under the Act.

4. **A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.**

The benefits of the rule (and its associated costs) include a review of compliance with the Act to better serve patients, and provide on-going and reliable information concerning the impact of this Act to Coloradoans. Inaction is not a possibility as rules are required by the statute. Inaction would result in non-compliance with Colorado statute and an uninformed implementation of Colorado's medical aid-in-dying statute.

5. **A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

A uniform approach to reporting key data elements is necessary for the annual report to be of value. There is no less intrusive method for meeting the directive delineated in statute. The requirements delineated in the rule are the most efficient way for the Department to obtain all information needed to ensure compliance and generate an annual statistical report. While on-site inspection of a sample of medical records could occur, this would be more intrusive of attending physicians and other parties involved and would require more financial resources and FTE to allow for arranging on-site visits, traveling, reviewing records for the needed information and copying

the relevant portions. Similarly, while uniform reporting is not required, it is necessary for the annual report to be of value. The Department will remain open to feedback and adjust the forms as needed to make the process as efficient as possible for the reporting entities.

6. **Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.**

No other alternatives to rulemaking were considered. Rulemaking is explicitly required per Section 25-48-111(2)(a), C.R.S. Other mechanisms for ensuring compliance were considered, though felt to be less efficient or less effective (see response to question 5).

7. **To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.**

The Department is uncertain of either the short- or long-term impact of the "Colorado End-of-Life Options Act", for it has not previously been in place in Colorado, and no Colorado-specific data exists to provide a good estimate. However, similar laws have been enacted in other states. In Oregon, a state with a slightly smaller population, 24 patients were prescribed medication under the "Oregon Death With Dignity Act" (Chapter 127.800, Oregon Revised Statute) in its first year (1998), with 16 deaths following utilization of the medication. The number increased to 218 patients prescribed medication in 2015 and 132 subsequent deaths following utilization of the medication. It is anticipated that Colorado will experience a similar trend in patients exercising this new right. The proposed rules draw upon the Act as well as the administrative rules promulgated by the Oregon Health Authority (Division Rule 9: Reporting Requirements of the Oregon Death With Dignity Act). Over time, as the medical and dispensing record information required by this rule is analyzed and reported the Department will be able to better understand patient characteristics, physician practices and the ultimate use of medical aid-in-dying medication. Through the stakeholder process, the Department became aware of and studied how other states, such as Oregon and Vermont, implemented comparable statutes.

STAKEHOLDER COMMENTS
for promulgation of
6 CCR 1009-4, Reporting and Collecting Medical Aid-in-Dying Medication Information

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

1. Department of Regulatory Agencies, State Medical Board and State Pharmacy Board
2. Colorado Hospital Association
3. Colorado Medical Society and the Council of Ethical and Judicial Affairs
4. Denver Medical Society
5. CDPHE Health Facilities Emergency Medical Services Division, Home and Community Facilities Branch, health facilities where notified through the Health Facilities portal
6. Compassion and Choices
7. Colorado Center for Hospice and Palliative Care
8. Home Care Association of Colorado
9. Colorado Health Care Association
10. Home Care Association of Colorado
11. Colorado Center for Hospice & Palliative Care
12. Colorado Medical Directors Association
13. Colorado Gerontological Society
14. Colorado Department of Human Services, Office of Behavioral Health
15. CDPHE, Office of e-Health and Data
16. CDPHE, Office of the State Registrar of Vital Records
17. Horan & McConaty Funeral Services
18. Care Synergy Network
19. Colorado Home Care Advisory Committee
20. Colorado Academy of Family Physicians
21. Colorado Society of Osteopathic Medicine
22. COPIC
23. The Iris Project
24. UC Health
~~16.~~ Kaiser Pemanente of Colorado
~~17.~~25. Private Individuals and health care professionals ~~or agencies that have~~who expressed interest in the rulemaking~~, including:~~ and wished to be included in stakeholder communications.
    ~~a. Dr. Nathan Pollack, MD, Hospice Medical Director~~
    ~~b. Dr. David Pollack, MD, Psychiatrist, Oregon Health Sciences University~~
    a. ~~Horan & McConaty~~

The Department discussed the proposed rule or received feedback from: the Colorado Medical Society, Council on Ethical and Judicial Affairs; Colorado Hospital Association; Colorado Society of Osteopathic Medicine; Hospice and Palliative Care Association of Rockies; Colorado Academy of Family Physicians; Care Synergy (Pike's Peak Hospice, Halcyon Hospice, Denver Hospice, and Pathways Hospice); Compassion and Choices~~, and~~; Homecare Advisory Committee members~~.~~; UC Health; Kaiser Permanente of Colorado; COPIC; DRCOG, and; private individuals and health care providers via comments received directly or through the Board of Health administrator.

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

See Previous.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department agrees with the stakeholder feedback that communicating the processes for reporting medical record information and dispensing record information is essential and the Department agrees that developing a form and related resources will assist stakeholders in meeting the new statutory and regulatory mandate.

As discussed in the Statement of Basis and Purpose, the rule does not contain language that limits the Department's capacity to coordinate with other agencies, such as the Colorado Medical Board, when such action may be necessary to comply with statute or protect the public health and safety of Coloradans.

Stakeholders expressed concern that Section 25-48-109(1), C.R.S., requires that the attending physician or the hospice medical director to sign the death certificate and Section 25-48-109(2), C.R.S., requires the underlying terminal condition to be listed as the cause of death on the death certificate. Stakeholders fear this requirement places physicians in the situation of falsifying the death certificate. Given that the statute expressly authorizes this entry on the death certificate, it is unlikely to be a statutory violation but the Department appreciates that this is a significant deviation in practice. The Department is also concerned that there will be instances where the attending physician no longer has a relationship with the patient and those completing the death certificate will be unaware that the deceased executed his or her rights under the End-of Life Options Act (hereinafter "Act"). This may create disparate outcomes for participating patients. These concerns are outside the scope of this rulemaking but they relate directly to the State Registrar and Office of Vital Statistics. The Department is studying these issues further.

Stakeholders also expressed concern that Section 25-48-120, C.R.S., requires individuals to return unused medication to the attending physician that prescribed it or through a state or federally approved medication take-back program. Stakeholders indicated that returning medication to the attending physician does not align with health care providers' practices and gives rise to health and safety concerns. While medication take-back programs can be incentivized and health facilities' policies can direct the attending physician's conduct, the policy cannot undo the statutory requirement. This concern also falls outside the scope of this rulemaking; however, the Department appreciates the concern. Safe disposal is essential to protect the patient's families, health facility staff and public from harm. Licensed health care facilities' appropriately want to ensure the safety of their patients and their staff. The Department will continue to work with the community, the Division of Health Facilities and Emergency Medical Services, and the state's medication take-back experts at the Department and at the Department of Regulatory Agencies on this issue.

Several stakeholders made the recommendation that the Department collect additional information that is beyond the scope of those data points identified in these proposed rules. Specifically identified was information about demographics of patients participating in the Act, and whether or not the patient used and died from aid-in-dying medication. Other stakeholders, however, suggested that collection of this additional information would be burdensome on health care providers, may not be sufficiently complete or accurate to be useful, and is beyond the scope of the reporting requirements described in Section 25-48-111, C.R.S.

The Department acknowledges that there may be benefits to knowing that the medication was used, both in assessing participation in the Act, and in addressing potential risks created by unused aid-in-dying medication. However, citing the statutory structure and limits to authority for data collection, instances where neither the attending (prescribing) physician nor the health care provider dispensing aid-in-dying medication may know about eventual use, and concern about the reliability and usability data concerning utilization, the Department chose not to incorporate requirements for reporting patient use of aid-in-dying medication or other outcomes.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

These proposed rules are designed to facilitate the uniform documentation and reporting of the facts surrounding prescribing and dispensing of medical aid-in-dying medication in Colorado. It is unknown if requests by patients for medical aid-in-dying medication will vary geographically and demographically in Colorado. It is not anticipated these rules will result in differential treatment of Coloradans, geographically or demographically. Adherence to the requirements outlined in the proposed rules will ensure sufficient information for the Department to generate an annual statistical report, intended to assess the utilization by Coloradans of the rights afforded by this Act.

As discussed above and in the Statement of Basis and Purpose, the Department appreciates the feedback from stakeholders concerning the death certificates and unused medication disposal. These provisions may create barriers that limit physician and health care provider participation and as such, limit a patient's ability to execute the rights delineated in the Act. There is the potential for some populations to have greater risks created by confusion surrounding the completion of death certificates or exposure to unused medical aid-in-dying medication. The Department will monitor these issues and continue to work with the stakeholders as the Act is implemented.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Office of e-Health and Data

Reporting and Collecting Medical Aid-in-Dying Medication Information

6 CCR 1009-4

Adopted by the Board of Health on _____, 2017. Effective _____, 2017.

I. **Definitions**

A. "Attending physician," as used herein, shall be the attending physician defined in Section 25-48-102 (2), C.R.S., who prescribes medical aid-in-dying medication pursuant to Article 48, Title 25, C.R.S.

~~B.~~ "Health Care Provider," as used herein, shall be the person defined in Section 25-48-102(4), C.R.S., who~~:~~,

~~1. Dispenses the medical aid-in-dying medication directly to the patient, or~~

~~2.~~B. ~~T~~to fulfill the attending physician's written prescription for medical aid-in-dying medication, dispenses the medical aid-in-dying medication directly to the patient, the attending physician or an individual expressly designated by the patient.

II. **Requirements for Reporting Medical Record Information to the Department**

A. Within 30 calendar days of writing a prescription for medical aid-in-dying medication to end the life of a qualified patient, the attending physician or the attending physician's designee, shall submit, in the form prescribed by the Department, the following:

1. Patient's name and date of birth;

2. Dates of all oral requests made by the patient;

3. The prescribing attending physician's name, mailing address and phone number;

4. The patient's completed written request for medical aid-in-dying medication to end life that complies with Section 25-48-112, C.R.S.;

5. The attending physician's:

a. Diagnosis of a terminal disease;

b. Prognosis of six months or less;

c. Mental capacity determination that documents that the individual is making a voluntary and informed request;

d. Notation(s) of notification provided to the patient of the right to rescind a request made for medical aid-in-dying medication;

e. Notation of the medical aid-in-dying medications prescribed, dose and date prescribed;

f. i) Notation and date when the medical aid-in-dying medication was dispensed directly by the attending physician, or

ii) If the attending physician delivered a written prescription to a licensed pharmacist, the name and phone number of the pharmacist and the pharmacy, and a notation that the pharmacy was informed that medical aid-in-dying medication was prescribed pursuant to Article 48, Title 25, C.R.S., and the date of the notification, and;

g. Notation that all requirements under Article 48, Title 25, C.R.S. have been satisfied and indicating the steps taken to carry out the patient's request.

6. The consulting physician's name, mailing address and phone number and a copy of the consulting physician's written confirmation of the attending physician's diagnosis, prognosis, and mental capacity determination.

7. If obtained by the physician, a written confirmation of mental capacity from a licensed mental health provider.

B. All information submitted pursuant to this Section II will be submitted by mail or secure e-mail as directed by the Department.

III. Requirements for Reporting Dispensing Record Information to the Department

A. Pursuant to Section 25-48-111(2)(b), C.R.S., within 10 calendar days of dispensing medication pursuant to the Act, the health care provider dispensing a medical aid-in-dying medication shall submit to the Department a completed, signed and dated copy of the dispensing record. The health care provider shall submit, in the form prescribed by the Department, the following:

1. Patient's name and date of birth;

2. Prescribing physician's name and phone number;

3. Dispensing health care provider's name, address and phone number;

4. Medication dispensed and quantity;

5. Date the prescription was written, and;

6. Date the medication was dispensed.

B. All information submitted pursuant to this Section III will be submitted by mail or secure e-mail as directed by the Department.

IV. Confidentiality

Except as otherwise required by law, all information collected pursuant to Section 25-48-111(2), C.R.S. and this rule, is confidential.