COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Gabrielle Elzinga, Public Health Interoperability Specialist, Center for Health and Environmental Data

Through: Chris Wells, Director, Center for Health and Environmental Data CW

Date: May 19, 2021

Subject: Rulemaking Hearing concerning 5 CCR 1006-3, Advance Directives Registry

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Advance Directives are a critical component in the process of advance care planning - these documents allow patients to express their preferences should a medical crisis arise or at end of life. Healthcare provider access to these documents at times of need are critical to ensuring patients' preferences are fulfilled, and to clarify desired courses of action for both providers and family members in crisis situations. In Colorado, there is currently no statewide registry to promote provider access to these documents.

The purpose of these proposed regulations is to facilitate the creation of a statewide Advance Directives Registry, established by Section 25-54-101 of the Colorado Revised Statutes. The goals of this Registry are to provide secure, electronic storage for Advance Directive documents, improve ease of access to these documents in emergent cases, and to reduce the burden on patients, families, and caregivers to store and produce these documents in crisis situations. As required by the legislation, CDPHE is partnering with our state Health Information Exchanges to create, implement, and maintain this Registry.

Specifically, these proposed regulations seek to clarify the following portions of the legislation: criteria for which qualified individuals may access the Registry; criteria in which an electronic affidavit is required; procedures for uploading and removing documents from the Registry; procedures and safeguards for confidentiality and security; and special considerations for telehealth visits.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for New Rule
5 CCR 1006-3, Advance Directives Registry

Basis and Purpose.

The general purpose of these proposed rules is to facilitate the creation of a statewide electronic registry of Advance Directives, pursuant to Section 25-54-101 of the Colorado Revised Statutes. Section 25-54-101 CRS requires the Department to promulgate rules to administer the Registry system. These rules establish the criteria by which an individual is considered qualified, and procedures to access, upload, download, and replace Advance Directives from the Registry. They also clarify situations in which an electronic affidavit is required, and provide special considerations for telehealth visits.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:
Section 25-54-101, C.R.S.
Other relevant statutes: Section 25-1-1203, C.R.S.; Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)

Is this rulemaking due to a change in state statute?
___XX___ Yes, the bill number is ___SB 19-073___. Rules are ___ authorized _XX__ required.
_____ No

Does this rulemaking include proposed rule language that incorporate materials by reference?
_____ Yes ___ URL
___XX___ No

Does this rulemaking include proposed rule language to create or modify fines or fees?
_____ Yes
__XX____ No

Does the proposed rule language create (or increase) a state mandate on local government?
_XX_ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

___ Yes.

This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service. The state mandate is categorized as:
___ Necessitated by federal law, state law, or a court order
___ Caused by the State's participation in an optional federal program
___ Imposed by the sole discretion of a Department
___ Other: _____

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes _XX__No. If "yes," please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.
N/A

REGULATORY ANALYSIS
for New Rule
5 CCR 1006-3, Advance Directives Registry

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

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/S/B
Health Information Exchanges	2	C
Healthcare Systems (Hospitals, Clinics, etc.)	15,000	C/S
Healthcare Providers	7,000	C/S/B
Prospective participants in registry (i.e., patients) and family members	4,000,000	B
State Public Health and Environment agency	1	C/S
State Information Technology agency	1	S
State Health Care Policy and Financing agency	1	S
State Office of eHealth and Innovation	1	S

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.

S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.

B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

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.

Non-Economic Outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

C: The proposed rule will provide the Health Information Exchange (HIE) administering the Registry with clear parameters around appropriate user access and data security that call upon already-adopted standards through HIPAA and state legislation that protects Electronic Medical Records. This safeguard also benefits providers and, ultimately, patients by ensuring the Registry follows the same security standards as their other medical records.

This proposed rule will allow nurses, medical assistants, and support staff at healthcare delivery organizations to upload documents into the system, and clarifies how providers may use telehealth services. This could alleviate burden on physicians and mid-level providers. This rule also clarifies that it is the responsibility of individual patients to ensure their documents in the Registry are up-to-date, which provides protection to providers and health systems.

This proposed rule will also impact healthcare providers and healthcare delivery organizations by setting some procedures by which providers may upload, download, or update Advance Directives in the Registry. Health systems will need to develop processes and workflows to ensure uptake of the Registry system, and this may require training and personnel time.

S: Stakeholders have been engaged since the origin of the project, and include members from the Health Information Exchanges, healthcare providers, individuals from related advocacy organizations, and members of the state agencies primarily engaged in the development of this system (CDPHE, HCPF, and OIT). Before the rules were drafted, multiple conversations were had with key stakeholders from the HIEs and provider partners to inform the rulemaking process. Additionally, 12 stakeholders provided detailed feedback on the draft rule.

B: This rule will impact the general public. Patients and family members will benefit from their healthcare providers having improved access to their Advance Directives documents. Improved provider access will make it easier to correctly respond to a patient's treatment wishes and to appoint the correct Power of Attorney or other proxy in the event of a medical crisis. Safeguards on data security and storage will ensure patients' Advance Directives are stored following the same standards as their other medical records.

<u>Economic outcomes</u>

Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

C: The proposed rule will have no specific impact on the financial costs incurred as a part of the legislation and development of the Registry system. The Health Information Exchanges currently are not allowed to increase subscriber fees to give subscribers access to the Registry; as such, the HIEs may incur a financial cost to keep the Registry active after funding expires. If the HIEs are allowed to increase subscriber fees, health systems may incur an increased cost associated with using the Registry. The Department will work closely with the HIEs to develop a sustainability plan to address these questions before the funding period ends.

Health systems and healthcare providers may receive increased reimbursement if there is increased use of billing codes associated with Advance Care Planning services when uploading documents to the Registry. Health systems may incur some cost in time or resources associated with developing new policies and workflows that integrate the Registry into their practice, and associated training.

Please describe any anticipated financial costs or benefits to these individuals/entities.

S: Stakeholders who are not associated with the above entities should not see a significant economic impact from the proposed rule.

B: Since only providers may access the Registry, patients and family members will not incur a direct cost associated with using the system. However, patients may need to schedule a visit with their healthcare provider to have their documents uploaded into the Registry. This is dependent on how health systems set up their workflows and is the result of a requirement in the legislation that only qualified providers may upload documents into the Registry. The proposed rule includes special considerations for telehealth, which could allow patients to update their Advance Directive documents without scheduling an in-person physician visit. The use of telehealth may make Advance Care Planning more affordable for patients.

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.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

Type of Expenditure	**FY 2019-20**	**FY 2020-21**	**FY 2021-22**
Personal Services	$32,100	$14,007	$14,007

Operating Expenses and Capital Outlay	$5,178	$190	$190
IT System for Advance Medical Directives	$0	$750,000	$0
OIT Project Manager	$126,546	$126,456	$0
OIT Operating and Maintenance Cost	$79,413	$41,913	$41,913
Annual Maintenance	$0	$0	$150,000
Centrally Appropriated Costs	$96,921	$19,552	$21,671
FTE - Personal Services	0.5 FTE	0.2 FTE	0.2 FTE
Total	$340,068	$952,118	$227,781

Anticipated CDPHE Revenues: N/A

A. Anticipated personal services, operating costs or other expenditures by another state agency:

Anticipated Revenues for another state agency: $995,869 of the aforementioned budget is reallocated to OIT as required by the appropriation.

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

Along with the costs and benefits discussed above, the proposed revisions:

_XX__ Comply with a statutory mandate to promulgate rules.
___ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_XX__ Maintain alignment with other states or national standards.
___ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
___ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023.

___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Performs targeted programming to increase immunization rates. ___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.

___ Creates a roadmap to address suicide in Colorado.
___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.
___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.
___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.

7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.

___ Conducts a gap assessment.
___ Updates existing plans to address identified gaps.
___ Develops and conducts various exercises to close gaps.

8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.

___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.
___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.
___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.

9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.

___ Implements the CDPHE Digital Transformation Plan.
___ Optimizes processes prior to digitizing them.
_XX__ Improves data dissemination and interoperability methods and timeliness.

10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.

___ Reduces emissions from employee commuting
___ Reduces emissions from CDPHE operations

11. Fully implement the roadmap to create and pilot using a budget equity

assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.

___ Used a budget equity assessment

___ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

N/A, it is a requirement of the legislation to promulgate rules.

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

   Rulemaking is proposed when it is the least costly or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholders. The benefits, risks and costs of these proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with the statute.

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

   Stakeholders have proposed a number of opportunities for rulemaking that were not feasible within the constraints of the legislation. Providers brought up concerns during the stakeholder engagement process regarding the requirement for providers, rather than individuals, to be able to upload documents to the system. Stakeholders expressed concerns that this is not consistent with Colorado's approach to empowering patients to have increased ownership over their healthcare data. It also introduces potential burdens to both patients (who may need to pay for provider visits to make edits to their documents) and providers (who face increased burden in accessing the system).

   Additionally, concerns were raised about the requirement for an electronic affidavit that stakeholders wished to address through rulemaking. An affidavit is not a legal requirement for most Advance Directives documents in Colorado, and stakeholders had concerns that raising the legal requirement for these documents would limit uptake and therefore reduce utility of the system.

   Both of these concerns have been incorporated into the proposed rule to the extent possible, however, a legislative change would be needed to fully address these issues.

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.

An early assessment was performed of states with Advance Directive Registries to understand their implementation and approach. Additionally, the Department has worked closely with the Health Information Exchanges throughout the planning and development processes. The HIEs are leveraging both their own expertise, the expertise of their providers, and lessons learned from the subcontractor developing the Registry, which has been engaged in parallel efforts nationally.

The stakeholder feedback process was documented through a survey delivered to the Advance Directives Registry Advisory Group. Feedback was thoroughly reviewed, documented, and weighted based on the expertise and role of the individual providing it.

STAKEHOLDER ENGAGEMENT
for New Rule
5 CCR 1006-3, Advance Directives Registry

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:

Organization	**Representative Name and Title (if known)**
CDHS	Sarah Nelson, Administrative Solutions
CDPHE	Chris Wells, Director
CDPHE	Eric Lucas, Data Manager
CDPHE	Jenn Klus, Oncology Systems Specialist
CIVHC	Kari Degerness, Director of Health Care Services
CORHIO	Anne Harrington, Legal Counsel
CORHIO	Brad Hoffner, Business Analyst
CORHIO	Janeece Lawrence, VP Project Management
CORHIO	Kelly Procopio, VP Grants and Contracts
Denver Probate Law	Carl Glatstein, Attorney
Donor Alliance	Andrea Smith, Director of PR
Donor Alliance	Jennifer Prinz, CEO
Dufford-Waldeck	Annie Murphy, Attorney
HCPF	Chris Underwood, Deputy Chief of Staff, Health Information
HCPF	Micah Jones, Medicaid Health IT Coordinator
HCPF	Michelle Miller, CNO
OeHI	Carrie Paykoc, Director
OIT	Brad Barfield, Program Manager
OIT	Greg Tenenbaum, Senior Business Analyst
OIT	Kristi LaBarge, Deputy Director
QHN	Laura Head, EMR Interface Analyst
QHN	Marc Lassaux, CTO
QHN	Rick Curtsinger, Director External Affairs
SCL Health	Dr. Carol Fowler, MD
University of Colorado	Dr. Hilary Lum, MD
University of Colorado	Dr. Jean Abbott, MD

Stakeholder meetings were held with either the larger stakeholder group or the Executive Steering Committee on a monthly basis beginning in September 2019. Due to staff turnover and Covid-19, meetings with the broader group were suspended and members were provided updates as the project kicked off in September 2020, but meetings with the Executive Steering Committee and the implementation team continued at least monthly. Additionally, meetings with individual stakeholders were held as the proposed rule was being drafted.

The stakeholder group was notified that they would be asked to provide feedback to the draft rule on January 27, 2021 and the draft rule was shared with the group on February 3, 2021, along with a brief recorded webinar orienting the group to the rulemaking process and a survey in which to provide written feedback. Reminder emails were sent to the group on February 12 and 16, 2021 in anticipation of the February 19 deadline. Twelve individuals from the group provided written feedback.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

____ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

__XX__Yes.

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.

Several major policy concerns were identified through the Stakeholder Feedback process. The Department attempted to resolve these concerns via rulemaking, where possible. First, the requirement for electronic affidavit in the legislation raises the legal requirements for properly executed Advance Directives, and introduces challenges to provider workflow. Several stakeholders noted that it is rare, and in some cases impossible, for individuals to provide electronic signature through an Electronic Health Record. Additionally, the requirement for electronic affidavit complicates the ability for individuals to reasonably upload documents to the Registry via telehealth. As such, the Department attempted to align the requirements for electronic affidavit with signature requirements for properly executed Advance Directives according to their statutory and regulatory requirements.

Additionally, stakeholders have consistently expressed concern with the legislative requirement for a Qualified Provider to upload documents to the Registry, rather than

individuals themselves. While stakeholders acknowledged that it is critical for individuals to be protected from coercion in the development and execution of advance care planning, stakeholders expressed that this requirement is in violation of Colorado's approach to providing its residents with autonomy in executing their own healthcare decisions. Requiring the input of a provider does raise the standard for appropriate document execution. Stakeholders also expressed concern that this restriction may limit access and uptake of the Registry, especially for individuals in medically underserved communities, or those communities with limited bandwidth for telehealth. In order to address concern about the cost and burden of requiring physicians or mid-level providers to upload documents, the proposed rule defines Qualified Provider in alignment with federal and state statute for individuals at HIPAA-covered entities who have legal authority to view Protected Health Information (PHI). This will allow support staff and nurses to upload documents to the Registry, which may reduce the cost and burden on individuals and healthcare systems. The Department also clarified that individuals themselves may have access to the Registry to empower individuals to ensure their documents are accurate and properly executed. However, due to the legislation, the Department is not able to allow individuals to upload their own documents to the Registry.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

The Registry attempts to increase access for both providers and individuals to individuals' Advance Directive documents. One of the goals of the Registry is to ensure patients and their families may have their preferences properly executed at times of medical crisis. The creation of a statewide Registry will facilitate improved coordination amongst providers, including providers at smaller health systems or located in medically underserved areas who may not have existing access to electronic Advance Directives storage or access. Improved access to Advance Directives also has the potential to improve quality of care, especially end-of-life care, for individuals with complex healthcare needs and elderly individuals.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	X	Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.

	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.

SENATE BILL 19-073

BY SENATOR(S) Ginal, Court, Bridges, Fields, Lee, Moreno, Pettersen, Priola, Story, Tate, Todd, Garcia;
also REPRESENTATIVE(S) Landgraf and Roberts, Arndt, Bird, Duran, Esgar, Galindo, Gray, Herod, Hooton, Jackson, Kennedy, Kipp, Kraft-Tharp, Lontine, McCluskie, Michaelson Jenet, Singer, Snyder, Titone, Valdez A., Becker.

CONCERNING A STATEWIDE SYSTEM OF ADVANCE MEDICAL DIRECTIVES, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, **add** article 54 to title 25 as follows:

ARTICLE 54
Statewide System for Advance Health Care Directives

25-54-101. Definitions. AS USED IN THIS ARTICLE 54, UNLESS THE CONTEXT OTHERWISE REQUIRES:

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(1) (a) "ADVANCE HEALTH CARE DIRECTIVE" MEANS:

(I) A DIRECTIVE CONCERNING MEDICAL ORDERS FOR SCOPE OF TREATMENT EXECUTED PURSUANT TO ARTICLE 18.7 OF TITLE 15;

(II) A DECLARATION AS TO MEDICAL TREATMENT EXECUTED PURSUANT TO SECTION 15-18-104;

(III) A DIRECTIVE RELATING TO CARDIOPULMONARY RESUSCITATION EXECUTED PURSUANT TO ARTICLE 18.6 OF TITLE 15;

(IV) A MEDICAL DURABLE POWER OF ATTORNEY EXECUTED PURSUANT TO SECTION 15-14-506; OR

(V) ANY OF THE ADVANCE HEALTH CARE DIRECTIVES LISTED IN SUBSECTIONS (1)(a)(I) TO (1)(a)(IV) OF THIS SECTION OR THIS SUBSECTION (1)(a)(V) THAT HAS BEEN PROPERLY EXECUTED IN ANOTHER STATE.

(b) A POWER OF ATTORNEY FORM EXECUTED PURSUANT TO SECTION 15-14-741 IS NOT AN ADVANCE HEALTH CARE DIRECTIVE FOR THE PURPOSES OF THIS ARTICLE 54.

(2) "AUTHORIZED SURROGATE DECISION-MAKER" MEANS A GUARDIAN APPOINTED PURSUANT TO ARTICLE 14 OF TITLE 15, AN AGENT APPOINTED PURSUANT TO A MEDICAL DURABLE POWER OF ATTORNEY, A PROXY DECISION-MAKER FOR MEDICAL TREATMENT DECISIONS APPOINTED PURSUANT TO ARTICLE 18.5 OF TITLE 15, OR A SIMILARLY AUTHORIZED SURROGATE, AS DEFINED BY THE LAWS OF ANOTHER STATE, WHO IS AUTHORIZED TO MAKE MEDICAL DECISIONS FOR AN INDIVIDUAL WHO LACKS DECISIONAL CAPACITY.

(3) "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT CREATED AND EXISTING PURSUANT TO SECTION 24-1-119.

(4) "HEALTH INFORMATION ORGANIZATION NETWORK" MEANS A COLORADO ORGANIZATION THAT HAS EXPERIENCE IN OVERSEEING AND GOVERNING THE EXCHANGE OF HEALTH-RELATED INFORMATION AMONG ORGANIZATIONS ACCORDING TO COLORADO LAW AND NATIONALLY RECOGNIZED STANDARDS INCLUDING BUT NOT LIMITED TO THE FEDERAL

"HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996", PUB.L. 104-191, AS AMENDED.

(5) "INDIVIDUAL" MEANS THE INDIVIDUAL WHOSE MEDICAL TREATMENT IS THE SUBJECT OF THE ADVANCE HEALTH CARE DIRECTIVE.

(6) "QUALIFIED PROVIDER" MEANS A PERSON OR ENTITY THAT MAY USE OR DISCLOSE PROTECTED HEALTH INFORMATION FOR TREATMENT PURPOSES IN ACCORDANCE WITH GUIDELINES UNDER THE FEDERAL "HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996", PUB.L. 104-191, AS AMENDED.

25-54-102. Statewide system for advance directives created - rules. (1) THE DEPARTMENT HAS THE FOLLOWING POWERS AND DUTIES WITH RESPECT TO THE PROVISION OF A STATEWIDE ELECTRONIC SYSTEM, REFERRED TO IN THIS SECTION AS THE "SYSTEM", THAT ALLOWS QUALIFIED INDIVIDUALS TO UPLOAD AND ACCESS ADVANCE MEDICAL DIRECTIVES:

(a) TO ENSURE THAT QUALIFIED INDIVIDUALS MAY ACCESS THE SYSTEM FOR TREATMENT PURPOSES THAT ARE ALLOWED UNDER THE FEDERAL "HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996", PUB.L. 104-191, AS AMENDED;

(b) TO CONTRACT WITH ONE OR MORE HEALTH INFORMATION ORGANIZATION NETWORKS FOR THE CREATION, ADMINISTRATION, AND MAINTENANCE OF THE SYSTEM; AND

(c) TO PROMULGATE RULES IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24 TO OVERSEE THE PROVISIONS OF THIS ARTICLE 54, INCLUDING BUT NOT LIMITED TO RULES ESTABLISHING:

(I) CRITERIA FOR QUALIFIED INDIVIDUALS TO HAVE ACCESS TO THE SYSTEM AND ADVANCE MEDICAL DIRECTIVES;

(II) PROCEDURES BY WHICH A QUALIFIED INDIVIDUAL MAY ADD OR REMOVE AN ADVANCE MEDICAL DIRECTIVE TO OR FROM THE SYSTEM;

(III) PROCEDURES BY WHICH A QUALIFIED INDIVIDUAL MAY ACCESS AND DOWNLOAD AN ADVANCE MEDICAL DIRECTIVE FROM THE SYSTEM; AND

(IV) PROCEDURES AND SAFEGUARDS FOR ENSURING THE CONFIDENTIALITY AND SECURE STORAGE OF THE INFORMATION CONTAINED IN AN ADVANCE MEDICAL DIRECTIVE THAT IS ADDED TO AND MAINTAINED IN THE SYSTEM.

(2) (a) UPON THE REQUEST OF AN INDIVIDUAL, OR AUTHORIZED SURROGATE DECISION-MAKER, A QUALIFIED PROVIDER THAT HAS AN AGREEMENT WITH THE HEALTH INFORMATION ORGANIZATION NETWORK AS REQUIRED UNDER THE FEDERAL "HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996", PUB.L. 104-191, AS AMENDED, MAY UPLOAD THE INDIVIDUAL'S ADVANCE HEALTH CARE DIRECTIVE TO THE SYSTEM. THE ADVANCE HEALTH CARE DIRECTIVE SHALL ONLY BE UPLOADED TO THE SYSTEM BY A QUALIFIED PROVIDER AFTER THE INDIVIDUAL OR AUTHORIZED SURROGATE DECISION-MAKER HAS CONSULTED WITH THE QUALIFIED PROVIDER IN PERSON OR THROUGH TELEHEALTH, AS DEFINED IN SECTION 10-16-123 (4)(e)(I). A QUALIFIED PROVIDER WHO UPLOADS AN ADVANCE HEALTH CARE DIRECTIVE TO THE SYSTEM IS NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR REGULATORY SANCTION FOR ACTION TAKEN IN ACCORDANCE WITH THIS SUBSECTION (2).

(b) PRIOR TO THE UPLOAD OF AN ADVANCE HEALTH CARE DIRECTIVE TO THE SYSTEM, THE INDIVIDUAL, OR AUTHORIZED SURROGATE DECISION-MAKER, SHALL SIGN AN ELECTRONIC AFFIDAVIT IN THE PRESENCE OF A QUALIFIED PROVIDER AFFIRMING THE ADVANCE HEALTH CARE DIRECTIVE IS APPROPRIATELY EXECUTED, CURRENT, AND ACCURATE. SIGNING THE ELECTRONIC AFFIDAVIT REVOKES ANY PRIOR ADVANCE HEALTH CARE DIRECTIVES OF THE SAME TYPE PREVIOUSLY UPLOADED TO THE SYSTEM.

(c) THE INDIVIDUAL, OR AUTHORIZED SURROGATE DECISION-MAKER, IS RESPONSIBLE FOR ENSURING THAT THE ADVANCE HEALTH CARE DIRECTIVE UPLOADED TO THE SYSTEM IS APPROPRIATELY EXECUTED, CURRENT, AND ACCURATE.

(3) EMERGENCY MEDICAL SERVICE PERSONNEL, AN INDIVIDUAL HEALTH CARE PROVIDER, A HEALTH CARE FACILITY, OR ANY OTHER PERSON OR ENTITY THAT COMPLIES WITH AN ADVANCE HEALTH CARE DIRECTIVE ACCESSED FROM THE SYSTEM IS NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR REGULATORY SANCTION FOR ACTION TAKEN IN ACCORDANCE WITH THE ADVANCE HEALTH CARE DIRECTIVE, UNLESS THE PERSON OR

ENTITY HAS ACTUAL KNOWLEDGE OF AN ADVANCE HEALTH CARE DIRECTIVE PROPERLY EXECUTED AFTER THE DATE OF THE ADVANCE HEALTH CARE DIRECTIVE THAT IS UPLOADED TO THE SYSTEM.

SECTION 2. Appropriation. (1) For the 2019-20 state fiscal year, $993,147 is appropriated to the department of public health and environment. This appropriation is from the general fund. To implement this act, the department may use this appropriation as follows:

(a) $32,100 for use by the center for health and environmental information for personal services related to health statistics and vital records, which amount is based on an assumption that the center will require an additional 0.5 FTE;

(b) $211,047 for use by the center for health and environmental information for operating expenses related to health statistics and vital records; and

(c) $750,000 for the purchase of information technology services.

(2) For the 2019-20 state fiscal year, $750,000 is appropriated to the office of the governor for use by the office of information technology. This appropriation is from reappropriated funds received from the department of public health and environment under subsection (1)(c) of this section. To implement this act, the office may use this appropriation to provide information technology services for the department of public health and environment.

SECTION 3. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 2, 2019, if adjournment sine die is on May 3, 2019); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless

approved by the people at the general election to be held in November 2020 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Leroy M. Garcia
PRESIDENT OF
THE SENATE

KC Becker
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED May 16, 2019 at 10:12 A.M.
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
Center for Health and Environmental Data
ADVANCED DIRECTIVES REGISTRY
5 CCR 1006-3

Adopted by the Board of Health on _____; effective _____.

I. General Purpose for Establishing Rules and Regulations

The general purpose of this regulation is for the Colorado Department of Public Health and Environment (herein referred to as CDPHE) to facilitate the creation of a statewide electronic registry of Advance Directives, pursuant to Section, 25-54-101 of the Colorado Revised Statutes.

II. Definitions

The following terms, whenever used in or referred to in these regulations, shall have the following respective meanings, unless a different meaning clearly appears from the context:

1. "Advance Care Planning (ACP)" means the process of an individual learning about, making, and documenting decisions to be implemented in the event of a medical crisis or a need for end-of-life care.
2. "Advance Health Care Directive" or "Advance Directive" means a legal document in which an individual specifies their wishes relating to medical treatment, cardiopulmonary resuscitation, or medical durable power of attorney, per the requirements established in § 25-54-101.1(a), CRS. These documents include, but are not necessarily limited to:
    i. Medical Orders for Scope of Treatment (MOST) or Physicians' Orders for Life-Sustaining Treatment (POLST): A type of Advance Directive that summarizes and consolidates information about an adult patient's preferences for life-sustaining treatment including CPR, medical intervention, and artificially administered nutrition;
    ii. Behavioral Health Orders for Scope of Treatment: A document that outlines an individual's instructions concerning behavioral health treatment, medication, and preferences;
    iii. Living Will (including a properly executed Five Wishes form): A document that instructs providers regarding artificial life support;
    iv. Medical Durable Power of Attorney: A document that allows individuals to appoint a health care agent to make decisions on their behalf and grants access to medical records;
    v. CPR Directive: A medical order that instructs providers not to resuscitate if an individual's heart should stop;

vi. Any Advance Directive document properly executed in another state, including a Physician's Order for Life Sustaining Treatment (POLST) or Medical Order for Life Sustaining Treatment (MOLST).

3. "Advance Directive Registry" (ADR or "Registry") means the system of Advance Directive documents being established in § 25-54-101.1(a), CRS. This system specifically references the statewide registry being established through the relevant legislation, and does not reference other organizational or regional registries that may include health directives.
4. An "Authorized Surrogate Decision Maker" (or "authorized surrogate") means a person appointed pursuant to the means stated in § 25-54-101.2, CRS.
5. A "Qualified Provider" (or "Provider") is a person or entity that may use or disclose protected health information in accordance with guidelines under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended, including all accompanying regulations. For the purposes of these rules, a Qualified Provider includes any staff member at a HIPAA-covered entity who has approval from their HIPAA-covered employer to access patient Protected Health Information (PHI), where the covered entity has a treatment relationship with the patient whose Advance Directives are being uploaded or accessed in the Registry.
6. A "Qualified Individual" is a person or entity authorized to access the Registry. Qualified Individuals include both Qualified Providers (as defined above) and individual patients and their authorized surrogate decision maker who have Advance Directive documents existing in the Registry.
7. A "Health Information Organization Network" means a Colorado organization that has experience overseeing and governing Health Information Exchange among organizations according to state and federal law.

III. Criteria for Qualified Individuals to Have Access to the System and Advance Medical Directives

1. HIPAA-covered entities (i.e., hospitals, health systems, clinics, etc.) may designate criteria for qualified individuals to access the Registry following the organizational policies for staff accessing patients' medical records and Protected Health Information (PHI). Entities must ensure that only appropriate staff members access the system. These staff members are considered Qualified Providers in the context of these rules, as defined above.
2. A Qualified Provider is not required to enter into an HIE Services Agreement with a state-recognized HIE in order to access the Registry. Instead, a Qualified Provider need only comply with the access requirements outlined in this rule and the associated statute, and any contractual obligations required to facilitate access to the Registry.
3. Individuals (i.e., patients or their authorized surrogate decision makers) may access the Registry to view and verify their Advance Directive documents. Only a Qualified Provider may upload or remove documents from the Registry.

IV. Criteria in Which an Electronic Affidavit is Required

1. An Electronic Affidavit, signed by the individual or their authorized surrogate, is required for newly executed documents that require both individual and authorized provider signature. These documents include a Colorado Medical Order for Scope of Treatment (MOST) form/Physician Orders for Life-Sustaining Treatment (POLST) form, and a Colorado CPR Directive.
    i. Existing, executed documents do not require a new Electronic Affidavit. These documents may be uploaded to the Registry following the procedures outlined below.
    ii. It is not required for signatures from the individual and the authorized provider be collected simultaneously.
    iii. In situations in which an Electronic Affidavit is required, individuals may submit the affidavit either through the Registry or by electronic or physical signature. If an affidavit is signed outside of the Registry, it must be submitted to the Qualified Provider via physical mail, email, or fax. It is the responsibility of the individual to ensure that their affidavit has been received by the Qualified Provider and appropriately uploaded to the Registry.
2. Other documents that pertain to advance care planning, but do not require physician signature, require only a patient signature (electronic or written) and do not require an Electronic Affidavit for upload. These documents include, but are not limited to, a Medical Durable Power of Attorney or a Living Will.

V. Procedures by Which a Qualified Individual May Add or Remove an Advance Medical Directive To or From the System

1. The Registry shall provide a free flow of information between patients, health care providers, and their associated HIPAA-covered entities.
2. The Registry shall collect individuals' name and email address, where available. It is the responsibility of the individual to ensure their contact information is up-to-date.
3. Existing Advance Directive documents electronically hosted in Health Information Exchange or Electronic Health Record systems remain binding and in effect. It is not a requirement for an Advance Directive document to be uploaded to the Registry in order to be considered binding.
    i. Other sources of Advance Directives documents should be considered in addition to the Registry. The Registry is not comprehensive and valid documents may exist elsewhere.
    ii. Existing documents may be uploaded to the Registry from the Health Information Exchange, Electronic Health Records systems, or paper documents on file with a HIPAA-covered entity may be scanned and uploaded into the Registry following its launch.

iii. Valid, properly executed, self-uploaded documents, such as those uploaded to Electronic Health Records systems, may be uploaded to the Registry by a Qualified Provider.

4. Qualified Providers must collect a signed affidavit in some cases. Please see Section IV, Criteria in Which an Electronic Affidavit is Required, above.
5. A Qualified Provider may remove documents from the Registry upon request from the individual or their authorized surrogate. If an individual requests document removal, the Qualified Provider must act to remove the document in a timely manner. However, it is the responsibility of the individual or their authorized surrogate to confirm removal.
6. The Registry shall provide an annual reminder to individuals with documents in the Registry via email, where available, to verify their documents. It is the responsibility of the individual to ensure their contact information in the Registry is up-to-date.
7. It is the responsibility of the individual or their authorized surrogate to ensure the documents included in the Registry are appropriately executed, accurate, and current.
    i. If an Advance Directive document is executed in another state, it is the responsibility of the individual to ensure their document is properly executed according to that state's laws.
8. A Qualified Provider and their associated HIPAA-covered entity may not bill individuals an additional fee to upload documents to the Registry in excess of allowable Advance Care Planning services.

VI. Procedures by Which a Qualified Individual May Access and Download an Advance Medical Directive from the System

1. A Qualified Provider may access and download Advance Directives from the Registry at any time, including, but not limited to, the following purposes:
    i. During a medical crisis;
    ii. In a situation in which decisions about an individual's end-of-life care are needed;
    iii. At request of an individual or their authorized surrogate;
    iv. During a medical visit with an individual in which advance care planning is being discussed.

VII. Procedures and Safeguards for Ensuring the Confidentiality and Secure Storage of the Information Contained in an Advance Medical Directive that is Added To and Maintained in the System

1. All documents uploaded to the Registry shall be and remain strictly privileged and confidential as electronic medical records, pursuant both to § 25-1-1203, CRS, Electronic storage of medical records, and federal law, specifically the Health Information Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules.

VIII. Special Considerations for Telehealth

1. For situations in which an Electronic Affidavit is required:
    i. An individual or their authorized surrogate may sign the affidavit in the presence of a Qualified Provider either in person or via telehealth (over video or telephone).
    ii. In situations in which an individual is not able to access the Electronic Affidavit in the Registry, the individual may either electronically or physically sign the affidavit in the presence of a Qualified Provider either in person or via telehealth (over video or telephone).
    iii. A signed affidavit must be submitted to the Qualified Provider by the individual either via mail, email, or fax to the Qualified Provider in a timely manner.
    iv. It is the responsibility of the individual to ensure their documents have been received and appropriately uploaded to the Registry.
    v. If the visit occurs via telehealth, a Qualified Provider must follow their existing organizational telehealth policies to ensure identity verification and adequate privacy and confidentiality.
2. For situations in which an Electronic Affidavit is not required:
    i. An individual or their authorized surrogate may elect to meet with a Qualified Provider to discuss Advance Care Planning in person or via telehealth, but it is not required.
    ii. If an individual or their authorized surrogate elects not to discuss their documents at a visit with a Qualified Provider, the Provider is responsible for uploading their documents to the registry in a timely manner. However, the individual or their authorized surrogate are responsible for ensuring that the provider has received their documents (electronically or in hard copy) and that their Provider has uploaded their documents to the Registry.