REGULATORY ANALYSIS
for Amendments to 6 CCR 1015-3, Chapter Two
Rules Pertaining to EMS Practice and Medical Director Oversight
Adopted by the Chief Medical Officer on October 29, 2021; effective December 30, 2021

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 (as of September 2, 2021)	Relationship to the Proposed Rule Select category: C/CLG/S/B
Licensed/Certified Critical Care Paramedics	436	C
Licensed/Certified Paramedics	5015	C
Agencies with waivers allowing the use of ketamine for pain management	104	C/CLG*
Agencies with waivers allowing the use of ketamine for RSI adult/RSI pediatric	30/6	C/CLG*
Medical directors overseeing agencies with any waiver for ketamine	60	C
Prehospital patients on whom ketamine might have been used for "excited delirium or any subsequent term for excited delirium" or "to subdue, sedate, or chemically incapacitate and individual for alleged or suspected criminal, delinquent, or suspicious conduct." (Language from HB 21-1251)	Unknown	B

*This denotes entities that may include local governments. However, while some agencies are overseen or run by a local government, the impact of this rule change is the same on all agencies.

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.
CLG = local governments that must implement the rule in order to remain in compliance with the law.

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. 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.

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.

Economic outcomes

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/CLG: This rulemaking does not have a direct fiscal impact on those parties required to implement and apply the rule at the patient care level or an economic impact on the agencies themselves. There has been no discussion about the cost of ketamine or cost of alternative medications. In the application of this rule, it is assumed to be cost neutral as there are other medications described in the formulary for behavioral management. (*see* 6 CCR 1015-3, Chapter Two, Table B.3.)

C/CLG Medical Directors: All medical directors that previously had ketamine waivers allowing for use for "excited delirium" or any similar term have already been required to change those protocols and provide re-training for EMS providers based on the new protocols. These changes were occasioned by the change in statute, and thus there are truly no additional economic outcomes based on this regulatory change, which brings rule into clear alignment with statute.

B: This rulemaking does not have quantifiable positive or negative economic outcomes for the beneficiaries of the rule change (those prehospital patients who will not be treated with ketamine as a behavioral management tool).

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/CLG: Non-economic outcomes for those required to implement the rule are likely limited to the time necessary for any re-training related to modified formulary protocols. Changes in the formulary are not uncommon and thus modification to the use of any specific medication is likely to be absorbed into the normal course of education and skills training.

B: It is hoped that the discontinuation of the use of ketamine for "excited delirium or any subsequent term for excited delirium" or "to subdue, sedate, or chemically

incapacitate and individual for alleged or suspected criminal, delinquent, or suspicious conduct." (Language from HB 21-1251) will result in public health and safety benefits. Please note that these benefits would be expected to result from the statutory change but are reinforced by the regulatory change.

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:

   N/A

   B. Anticipated CDPHE Revenues:

   N/A

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

   N/A

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

   The rule changes have little, if any, economic impact. Inaction is not an option since statute has changed and the rule changes reflect the change to statute.

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

   __ Comply with a statutory mandate to promulgate rules.
   _X Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
   __ Maintain alignment with other states or national standards.
   ___ Implement a Regulatory Efficiency Review (rule review) result
   __X 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.
___ 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

_X__ Advance CDPHE Division-level strategic priorities.

Promulgation of these rules implements new legislation (HB 21-1251) in accordance with the Division's regulatory review policies and 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

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 method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunctions with stakeholders. The proposed revisions provide the most benefit for the least amount of cost and are the most feasible manner to achieve compliance with statute.

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

   The specific revisions were developed in conjunction with and with the approval of the Emergency Medical Practice Advisory Council. This expert panel helped craft the exact language and went on to provide a recommendation for the adoption of this language. These are considered the minimum rule changes necessary to comply with statute.

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.

   There were no quantitative data used for this analysis since this change is directly responsive to a statutory change. The consequences of inaction are that state rule would be inconsistent with state statute.

COLORADO
Department of Public Health & Environment

Adoption of changes to 6 CCR 1015-3, Chapter Two,
Rules Pertaining to EMS Practice and Medical Director Oversight

On October 20, 2021, a Chief Medical Officer hearing was held via Zoom to consider revisions of 6 CCR 1015-3 Emergency Medical Services Chapter Two, Rules Pertaining to EMS Practice and Medical Director Oversight. The changes increase the number of voting members on the Emergency Medical Practice Advisory Council from eight to ten and limit the use of the drug ketamine for certain purposes. At the time of the hearing, oral testimony was received from the public.

I hereby adopt the proposed changes to 6 CCR 1015-3, Chapter Two, Rules Pertaining to EMS Practice and Medical Director Oversight, as presented at the October 20, 2021 hearing, along with the statement of basis and purpose, specific statutory authority and regulatory analysis.

Eric K. France, MD MSPH
Chief Medical Officer

October 29, 2021
Date