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EXECUTIVE SUMMARY

KETAMINE INVESTIGATORY REVIEW PANEL

COLORADO
Department of Public Health & Environment

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As has been widely reported in the media, during the summer of 2019, Elijah McClain was detained by police, and then emergency medical services (EMS) administered ketamine to Mr. McClain for excited delirium. Mr. McClain went into cardiac arrest during ambulance transport and died in the hospital a few days later. The coroner concluded that Mr. McClain died of undetermined causes. His death occurred the summer before the murder of George Floyd, but the circumstances of his death gained national attention during the Black Lives Matter demonstrations in the summer of 2020. These demonstrations protested the social injustices perpetrated against people of color and gained traction as the deaths of other young African American men that occurred during police interactions came under intense public scrutiny.

The review that culminated in this report was not undertaken to investigate Elijah McClain's death or any particular case in which a Coloradan was administered ketamine by state-certified or state-licensed paramedics. Rather, the circumstances surrounding Elijah McClain's death, and the resulting questions around the administration of ketamine for "excited delirium syndrome," (ExDS) prompted the Colorado Department of Public Health and Environment (CDPHE) to undertake an investigatory review of its program that allows paramedics to administer ketamine.

One of CDPHE's responsibilities is to certify or license individuals who provide medical care to patients in the emergent, prehospital environment and transport those patients to hospitals by ambulance. Upon certification or licensure (see p. 22 for discussion of distinction between certification and licensure), these individuals are referred to as EMS providers and they include four levels: three levels of Emergency Medical Technicians (EMTs), and Paramedics. Through rulemaking, the acts and medications that can be performed and administered by each level of EMS provider are authorized and are referred to as the EMS provider's scope of practice. EMS providers are not independent practitioners; instead, in order to practice, they must be under the direction of a Colorado-licensed physician medical director. All EMS ambulance agencies are required to have a medical director who is responsible for ensuring the competency of the EMS providers for whom medical direction is provided. The Colorado Medical Board (CMB) in the state Department of Regulatory Agencies (DORA) regulates physicians, and CDPHE sets standards for physicians to be EMS medical directors. CDPHE does not regulate ground ambulance agencies.

Currently, the administration of ketamine, a dissociative anesthetic,[1] is out of scope for all EMS providers except for paramedics who have obtained a Critical Care Endorsement (P-CC) from CDPHE. However, to accommodate recognized community needs, CDPHE is authorized to issue individual waivers to EMS agency medical directors who can successfully meet several criteria. These waivers expand the scope of practice of identified paramedics to include ketamine administration. It is through these waivers that paramedics are authorized to administer ketamine for various conditions, including excited delirium and/or extreme or profound agitation.[2]

The overarching goals of the review were to evaluate the safety and efficacy of ketamine's use in the prehospital setting by paramedics, and to determine whether CDPHE can improve its regulatory

[1] *A medication that causes altered sensory perceptions and a feeling of disconnect between the environment and self.*

[2] *In July 2021, after the panel had commenced its review, CDPHE suspended the ketamine waiver program for excited delirium and/or extreme or profound agitation due to HB 21-1251's enactment into law. (See Section II.B.)*

oversight of the ketamine waiver program. In order to have the necessary medical expertise for the review, CDPHE established a panel of external medical professionals, hereinafter referred to as the Ketamine Investigatory Review Panel (KIRP or panel). The panel's review was facilitated by CDPHE's Chief Medical Officer, Dr. Eric France.

The KIRP was charged with determining whether CDPHE's existing waiver process for ketamine administration for excited delirium and/or extreme or profound agitation provides adequate oversight and training to ensure public health and safety. The panel focused on systems and processes rather than on individual cases of ketamine use, in keeping with CDPHE's public health focus of protecting the health of people and their communities. The work of the panel was entirely separate from any regulatory investigations being conducted by CDPHE into complaints received about particular incidents. The panel did not review the use of ketamine for pain management or rapid sequence induction (RSI) in the prehospital setting.

Ketamine Investigatory Review Panel Scope of Work:

- the pharmacology of ketamine
- the diagnosis of Excited Delirium Syndrome (ExDS)
- the use of and indications for ketamine for ExDS and other medical conditions
- implicit and explicit bias and structural racism as it relates to indications for and administration of ketamine
- Colorado and national data on ketamine administration
- complications associated with ketamine use for ExDS
- the dosing of ketamine
- the monitoring of patients following ketamine administration
- the education and training for paramedics
- EMS medical director oversight, protocols, and quality assurance
- the state and local oversight processes

The COVID-19 pandemic necessitated online rather than in-person meetings. Beginning in early 2021, the panel convened numerous times via Zoom. The meetings were not open to the public to allow the panel members to speak freely and without fear of recrimination during the pendency of their work. The meetings were also closed to protect against an inadvertent identification of patients during data presentations.

The panel spent several months gathering and reviewing information, including articles, research studies, professional organizational documents and statements, videos and data. CDPHE enlisted a series of subject matter experts in other relevant areas to assist the panel in its work. A listing of the subject matter experts and the issues on which they presented is shown below:

- Dr. Whitney Barrett, board-certified EMS physician in Albuquerque, New Mexico; Assistant Medical Director for Denver Health Paramedics Division until January 2021. Dr. Barrett presented data on ketamine administration by the Denver Health Paramedic Division.

- Dr. William Hall, Emergency Medicine Telluride Regional Medical Center; Medical Director Nucla-Naturita Fire Protection District and the National Park Service; previous EMS medical

director for Mesa County (9 agencies) for 17 years. Dr. Hall presented on the practice of EMS medical direction, including in rural settings.

- Dr. Brent Myers, triple-board certified in emergency medicine, EMS, and clinical informatics; past-President of the National Association of EMS Physicians; currently serves as the Chief Medical Officer for ESO; and Associate Medical Director for Wake EMS in Raleigh, North Carolina. Dr. Myers previewed data from the Annals of Emergency Medicine article: "Out-of-Hospital Ketamine: Indications for Use, Patient Outcomes, and Associated Mortality."

- Dr. Scott Simpson, MPH, Medical Director for Psychiatric Services at Denver Health and Associate Director of Behavioral Health Services. Dr. Simpson presented on agitation management in psychiatric emergency services.

- Dr. Michele Sweeney, emergency medicine physician for 23 years; EMS Department Medical Director and faculty member, Pueblo Community College. Dr. Sweeney presented on paramedic education and challenges facing rural emergency medical services.

- Dr. Steven Zeichner, Anesthesiologist, President-Elect, Colorado Society of Anesthesiologists (CSA). Dr. Zeichner presented CSA's concerns and recommendations related to CDPHE's ketamine waiver program for excited delirium.

PANEL RECOMMENDATIONS

The findings of the panel encompass four broad areas: the indications for the use of ketamine, including the diagnosis of Excited Delirium Syndrome; the patient-side care when using ketamine in the prehospital setting; the education and training of the paramedics using ketamine; and the local and state oversight of EMS care in Colorado. All four areas play a role in ensuring consumer protections and appropriate care delivery by paramedics in the field.

The panel agreed that ketamine is a safe drug if used properly and monitored closely by properly trained and qualified paramedics. However, certain adverse events appear to have arisen primarily from the administration of ketamine and other sedatives to individuals who may not have a medical need for these medications and who could have been managed with a less assertive alternative. Further, other societal and systemic factors at play may have allowed chemical restraints to be disproportionately applied to marginalized populations and communities of color in Colorado and across the nation. Although the panel's scope of review concerned the administration of ketamine in the prehospital setting, the panel agreed that the issues surrounding ketamine administration in the prehospital setting are not exclusively about the drug ketamine.

A. Indications for Ketamine Use and Excited Delirium Syndrome

This section contains recommendations concerning the Excited Delirium Syndrome diagnosis that is often used to support ketamine administration, mitigation of the role that explicit and implicit bias can play in prehospital ketamine administration, and the limited circumstances in which ketamine can be appropriately administered in the prehospital setting.

A.1 Panel Recommendation: Rejection of Excited Delirium Syndrome Diagnosis

The diagnosis of Excited Delirium Syndrome has come under scrutiny for a number of years (predating the deaths of Elijah McClain and George Floyd) for the potential of bias. This is in part because descriptors such as “hyper aggression,” “increased strength,” and “police noncompliance” are listed as criteria for this assessment and have been associated with racial bias against African American men.

Besides the fact that the Excited Delirium Syndrome diagnosis lends itself to discriminatory practices that result in systemic bias against communities of color, its lack of a uniform definition and specific, validated medical criteria allows for the possibility of inaccurate assessments and the inappropriate administration of ketamine to patients for non-medical reasons.

Consequently, the panel recommends that Excited Delirium Syndrome no longer be used as a condition that warrants waivers for the administration of ketamine. While making this recommendation, the panel acknowledges that in the prehospital setting a patient’s agitation and disorientation can present a direct threat to the patient’s safety as well as to the safety of the public and first responders. (See Recommendation A.3)

A.2 Panel Recommendation: Findings of Implicit and Explicit Racism

The panel affirms that patient care and the administration of ketamine in the prehospital setting are strictly within the purview of the paramedic. Paramedics must not administer ketamine for law enforcement restraint and/or custodial purposes.

CDPHE should analyze whether there is disproportionate use of ketamine for marginalized persons and communities of color in Colorado. CDPHE's data collection processes should facilitate this analysis by capturing accurate race/ethnicity and zip code information in order to perform this analysis. The panel further recommends that paramedics be trained on assigning a race/ethnicity element.

CDPHE and the Emergency Medical Practice Advisory Council (EMPAC) should develop and implement ketamine waiver policies, procedures, and guidance that incorporate objective criteria and promote racial equity.

CDPHE and EMPAC should incorporate a Racial Equity Impact Assessment in the ketamine waiver process that requires community stakeholder participation from different racial and ethnic groups that have been or may be affected by the disparate use of ketamine in the prehospital setting, in line with national best practices. In doing so, CDPHE should utilize its existing resources, including the Equity, Diversity and Inclusion Officer as well as the Office of Health Equity.

CDPHE should engage with the national organizations that develop paramedic education standards and advocate that the standards include education in the areas of racial equity, explicit/implicit bias, verbal de-escalation and law enforcement-to-EMS hand-off protocols. In the meantime, the panel recommends that CDPHE develop training programs in these areas and make them available to all EMS medical directors for the purpose of providing training to EMS medical directors and their providers. Completion of these training programs should be required of EMS medical directors and their paramedics as a condition of obtaining a ketamine waiver.

CDPHE should revise its regulations on continuing education requirements for the certification/licensure of EMS providers to include minimum hours in the areas of racial equity and explicit/implicit bias in the field of health care.

A.3 Panel Recommendation: Appropriate Administration of Ketamine

The panel concludes that paramedics should only administer ketamine in the prehospital setting when there are no other means available to safely assess, treat, and transport a patient. These circumstances are limited to patients presenting a serious, probable, imminent threat of bodily harm to self or others. CDPHE should therefore only issue waivers that allow paramedics to use ketamine when patients whose serious, probable, and imminent threat of harm to self or others prevents EMS providers from safely assessing, treating, and transporting the patient to a hospital.*

The panel acknowledges that if ketamine is administered for this purpose, the safeguards set forth in the "Protection of Persons from Restraint" law (Sections 26-20-101 *et seq.*, C.R.S.) must be followed. However, EMS providers often respond to a chaotic scene in the prehospital setting that requires their undivided attention and immediate intervention. In those situations, EMS providers may lack the time necessary to make a telephone call to a physician to receive a verbal order to administer ketamine. The panel therefore recommends that the General Assembly amend the chemical restraint statute to allow EMS providers to administer ketamine as a chemical restraint in these situations under the authority of an EMS medical director's standing order, rather than a verbal order as the law currently requires.**

**Note: This recommendation is only associated with waivers for excited delirium and/or extreme or profound agitation and does not impact waivers for ketamine use for pain management or RSI.*

***Note: The panel understands that HB 21-1251 requires the paramedic to attempt to obtain a verbal order while the existing restraint law requires that paramedics engage in telephone consultation with a physician and receive a verbal order to administer ketamine after determination that chemical restraint by ketamine is the least restrictive and most appropriate alternative available.*

B. Patient-Side Care

This section provides recommendations regarding the care that paramedics provide to the patient when administering ketamine in the prehospital setting. The panel emphasized that paramedics should begin monitoring immediately after the ketamine is given, instead of waiting until the patient is in the ambulance.

B.1 Panel Recommendation: Indications for Chemical Restraint

The panel determined that the benefits of administering ketamine in the prehospital setting outweigh the potential risks if the following indications are satisfied:

1. The patient's ability to cause/effect serious, probable, and imminent bodily harm to him/herself or others prevents safe assessment, treatment and transport; and
2. Efforts at verbal de-escalation have failed; and
3. The paramedic independently determines the patient requires treatment and transport to the hospital; and
4. The paramedic independently determines the patient needs to be chemically restrained for safe transport because less restrictive alternatives, including physical restraint, would be inappropriate, ineffective, or unsafe; and
5. The paramedic is acting under the parameters of a standing order,* or a verbal order given by a physician; and
6. The paramedic complies with all monitoring requirements as recommended by this panel in Recommendation B.4.

**Note: The panel understands that Colorado House Bill 21-1251 requires the paramedic to attempt to obtain a verbal order and that Section 26-20-104, C.R.S., the existing restraint law, requires paramedics to engage in telephone consultation with a physician and receive a verbal order to administer ketamine after determination that chemical restraint by ketamine is the least restrictive and most appropriate alternative available. The panel recommends that Section 26-20-104, C.R.S. as well as HB 21-1251 be revised to allow for standing orders. Until these laws are amended, however, the panel acknowledges that paramedics must comply with all verbal order requirements contained in those laws, including the recording and monitoring requirements set forth in Section 26-20-104(1)(d)-(h), C.R.S.*

B.2 Panel Recommendation: Pharmacology

Ketamine is a safe drug when used in accordance with the other recommendations described in this report regarding patient indications, dosing, monitoring, and paramedic training for chemical restraint.

B.3 Panel Recommendation: Dosing

Using a standard, fixed dose of ketamine for chemical restraint based on the patient's body stature rather than a strictly weight-based dose is preferred by the panel members. Weight estimation can be difficult and inaccurate. Using a standard dose based on the patient's body stature allows paramedics to focus their attention on the critical work of monitoring the patient for any complications associated with treatment, including signs of respiratory or cardiac depression.

The panel concludes that administration of 300/400/500 mg of ketamine IM is a safe dose for the small/average/large male patient, respectively, and administration of 250/350/450 mg of ketamine IM is a safe dose for the small/average/large female patient, respectively, assuming appropriate patient-side monitoring and trained personnel to manage any complications that may arise. Estimating a person's weight is therefore simplified to determine if a patient is of small (< 25^{th} percentile), average (25^{th} - 75^{th} percentile) or large (>75^{th} percentile).

The panel also recommends that a single IM ketamine dose should be calibrated to restrain the patient adequately to avoid repeat, or multiple, doses that can lead to patient complications. If a second ketamine dose might be required, the panel recommends that the paramedic must contact the on-line medical control physician to discuss the plan and receive a verbal order to do so.

B.4 Panel Recommendation: Monitoring

The panel concludes that the immediate monitoring of a patient who has received ketamine is of paramount importance to patient safety. Therefore, the panel recommends that paramedics should adhere to the following resuscitative efforts when ketamine is administered as a chemical restraint in the prehospital setting.

Immediately after administering ketamine, paramedics shall begin physiological monitoring, obtain peripheral vascular access, and perform a physical exam at the patient's side, in the specified following order below:

1. Waveform capnography and end-tidal carbon dioxide (CO_2) via face mask or nasal cannula to ascertain continued adequate ventilation
2. Peripheral capillary oxygen saturation (SpO_2)
3. Blood pressure assessment and monitoring
4. Cardiac monitoring
5. Intravenous (IV) or intraosseous (IO) access
6. Assess Glasgow Coma Scale (GCS). If the GCS is ≤8, do not automatically intubate. Instead, confirm adequate ventilation and oxygenation. If 1 and 2 above are adequate, then intubation is likely unnecessary. If airway obstruction is present, reposition to improve airway patency and consider other assisted airway measures (nasopharyngeal/oropharyngeal airway) prior to intubation.

C. Paramedic Education and Training

This section provides recommendations regarding paramedic education curriculum and training by medical directors or their designees.

C.1 Panel Recommendation: Changes to Paramedic Education

The panel recommends changes to the curriculum used for paramedic education, specifically, that CDPHE encourage EMS educators to augment paramedic educational curriculum to incorporate the following subjects or modalities:

- *Pharmacology:* Increased emphasis on anticipation and mitigation of complications for selected medications (*e.g.*, sedatives, anti-psychotics, opiates, dissociatives). Emphasis should be placed on structured physiological monitoring immediately following administration.
- *Clinicals:* Expanded objectives and expectations during operating room rotations beyond airway management (which is current focus) to administration and monitoring of sedatives.
- *Behavioral:* Add or create content on patient assessment, including how to identify imminent harm to self or others in ways that protect patient and provider safety, de-escalation, and safe restraint (physical and chemical).
- *Bias:* Add or create recommended content for addition to Colorado EMS education standards on bias.

C.2 Panel Recommendation: Paramedic Training on Verbal De-Escalation

The panel recommends, and the chemical restraint law requires, that paramedics must make (or, at least, attempt) verbal de-escalation efforts before deciding to administer ketamine for chemical restraint. (See Recommendation B.1) Consequently, paramedics who administer ketamine for chemical restraint should be trained in de-escalation tactics. The panel is aware that these types of training programs exist, such as the Verbal Judo training program and training offered by the Crisis Prevention Institute. The panel stresses that EMS medical directors should not assume this training will occur during paramedic training or during hospital or EMS clinicals/internships.

C.3 Panel Recommendation: Paramedic Training on Law Enforcement Interaction, Transfer of Care (Hand-off), and Medical Decisions on Scene

Law enforcement's role in the field is to protect the public, while EMS's role is to provide care for the patient. While the conditions at the scene sometimes make it difficult for these professions to conduct their respective responsibilities independently, police are not authorized to dictate medical treatment. Therefore, the panel recommends that paramedics receive mandatory training in the following areas:

- *Distinctions between the roles of EMS and law enforcement in the prehospital setting:* Law enforcement must give EMS providers access to the patient for assessment and treatment, which may include assessment for chemical restraint, as soon as possible. The hand-off process from law enforcement to the paramedic should be made clear during training. A power differential between law enforcement and paramedics can exist; therefore, both entities should be trained to understand and adhere to the parameters of their respective responsibilities. At minimum, paramedic training should give paramedics the tools to fully perform their role in the prehospital setting.
- *Paramedic authority to make medical decisions:* Clear authority to make all medical/treatment decisions at the scene lies with paramedics and not law enforcement. The authority of paramedics to refuse requests or dictates from law enforcement concerning patient and transition of care issues, and ways in which this can be done, should be incorporated into training requirements.

C.4 Panel Recommendation: Paramedic Training on Ketamine - Chemical Restraint

The panel recommends that with each chemically restrained patient, paramedics should be trained to:

- engage in verbal de-escalation and/or physical restraint first;
- have all necessary resuscitative equipment present at the patient-side;
- gather available factual information from police and bystanders while receiving the hand-off from law enforcement; and
- prior to administering chemical restraint, complete a gross neurological assessment, as is practicable.

The panel recommends that a checklist concerning appropriate dosing, monitoring and resuscitation (see Recommendations B.3 and B.4) be available in each ambulance and that paramedics be trained to follow the checklist when ketamine is used for chemical restraint.

D. EMS System Oversight

This section contains recommendations associated with oversight of EMS medical directors as well as recommendations pertaining to CDPHE and its advisory council, the Emergency Medical Practice Advisory Council (EMPAC).

In Colorado, the oversight of EMS medical directors is split among three separate entities: 1) the EMS ground ambulance agency that, as the county licensee, is required to have a medical director; 2) CDPHE, which regulates EMS medical directors as to minimum standards and medical direction oversight requirements; and 3) the Colorado Medical Board, which is authorized to oversee physician medical licensure.

This fragmented oversight system of EMS physician medical directors can, in some instances, result in inconsistent delivery of prehospital medical care and can result in a lack of EMS medical director accountability. The panel members believe that addressing this lack of standardization is an important factor in creating system-wide alignment in, and accountability for, the assessment of persons with behavioral health needs and the potential for ketamine use in the prehospital setting. Therefore, the panel recommends that CDPHE request the legislature to consider whether ground ambulance agency licensing should occur at the state, rather than county, level (see Recommendation D.5). If state regulation is authorized, the panel recommends that CDPHE supplement its regulatory requirements that govern EMS medical directors to improve accountability and to establish standardized patient care in the prehospital setting.

D.1 Panel Recommendation: EMS Medical Directors - Certification and Oversight Requirements

The panel recommends that EMS medical directors:

- Complete a CDPHE-approved training program for EMS medical directors.
- Obtain a certification from CDPHE to serve in the role of an EMS medical director. This certification may be at risk if the medical director is not in compliance with waiver requirements.
- Collaborate with other Colorado EMS medical directors regarding professional matters, including the development of protocols and standards.
- Engage with the EMS agency's Regional Emergency Medical and Trauma Services Advisory Council (RETAC), including its Regional Medical Director.

D.2 Panel Recommendation: EMS Medical Directors - Protocols

The protocols for ketamine use for chemical restraint developed by EMS medical directors should encompass, at minimum, the following recommendations established by this panel:

- Indications for Chemical Restraints (See also Recommendation B.1)
- Verbal de-escalation (See also Recommendation C.2)
- Police Interaction, Transfer of Care (Hand-off), and Medical Decisions on Scene (See also Recommendation C.3)
- Dosing consistent with Recommendation B.3
- Monitoring consistent with Recommendation B.4
- Accurate patient care reporting, including recording patient race/ethnicity (See also Recommendation D.7)

D.3 Panel Recommendation: EMS Medical Directors - Quality Assurance

The panel recommends that EMS medical directors incorporate the following quality assurance improvements in their agencies:

- Conduct chart reviews of all administrations of ketamine and perform periodic audits comparing electronic patient care reports (ePCRs) to CDPHE ketamine reporting forms.
- Regularly review and monitor data and trends in data for disproportionate impacts on marginalized communities.
- Require full compliance with data reporting requirements.
- Review video and/or audiotapes of paramedic verbal de-escalation attempts, when available.
- Collaborate with local law enforcement organizations to the extent possible to implement joint incident review with body cam footage and any other relevant information.

D.4 Panel Recommendation: CDPHE and EMPAC - Waiver Review and Waiver Requirements

To promote consistency in and sufficiency of required waiver application content, CDPHE and EMPAC should develop a standardized review tool for EMPAC members to use when reviewing ketamine waiver applications for chemical restraint, potentially including a scoring rubric.

CDPHE and EMPAC should consider shortening the waiver term for ketamine use for chemical restraint.

Whenever EMPAC issues updated material guidance concerning ketamine use for chemical restraint, CDPHE should require medical directors who hold existing ketamine waivers to supplement their waiver documents to comply with the updated guidance.

Ketamine waivers should be in compliance with the applicable components of the panel recommendations, specifically:

- Patient-side care: dosing, monitoring
- Paramedic training
- Protocols (indications, verbal de-escalation, police interaction, transfer of care [hand-off], medical decisions, dosing, and monitoring)
- Quality Assurance (QA) and Quality Improvement (QI)

CDPHE should make ketamine waivers contingent upon the requirements that EMS medical directors:

- verify that they and their providers have completed training in racial equity and explicit/implicit bias;
- prove and/or attest that guidelines/protocols for paramedics involving transfer of care, verbal de-escalation and patient hand-off training requirements for paramedics have been satisfied; and
- prove and/or attest that their agencies have conducted or, in the alternative, attempted to conduct transfer of care guidelines training with local law enforcement.

D.5 Panel Recommendation: CDPHE - Ground Ambulance Agency Licensing

In all but two states, ground ambulance agencies are licensed at the state level. Colorado is one of the two exception states since licensing occurs at the county level. CDPHE should request the legislature to consider whether ground ambulance agency licensing at the state level would allow for more uniform standards, protocols and regulatory oversight throughout the state in order to assure appropriate consumer protections.

D.6 Panel Recommendation: CDPHE - Comprehensive Investigation Process

The panel recommends that CDPHE:

- Review the current investigation process for incidents involving waivered medications or acts to ensure that this process is formalized, codified, objective, impartial, and inclusive of parameters to evaluate potential bias in outcomes.
- Ensure investigations are comprehensive and take into consideration both individual and systemic factors.
- Examine whether its existing investigation process provides the needed expertise, knowledge, and experience to address complex medical complaints, as is the case in other state regulatory arenas, e.g., Board of Nursing.
- Implement a standardized internal review process on ketamine reports it receives that indicate severe adverse outcomes or death, and require EMS medical directors to submit additional information as needed by CDPHE. CDPHE should implement a formal structured investigation process for cases warranting further review and should ensure that its review encompasses all aspects of the incident.
- Although the panel's scope of review is limited to ketamine, it also recommends that CDPHE consider extending this review and investigation process to all severe adverse outcomes or deaths resulting from sedatives that EMS providers administer in the prehospital setting.

D.7 Panel Recommendation: CDPHE - Data

The panel understands that data are essential for analyzing trends and determining whether system improvements in the ketamine waiver program are necessary. To this end, the panel recommends:

1. expanding the types of entities that should submit data;
2. establishing additional data elements;
3. making the data elements consistent with the information already submitted through ePCRs; and
4. actively monitoring trends and making trend information available to the public.

Additional entities to submit data:

- Currently only licensed transport agencies have to report patient care data to CDPHE. While unlicensed non-transport emergency responders may appear at the scene of an emergency (such as fire agencies), they are not required to submit patient care data. The legislature should consider requiring all responding agencies to submit this data to CDPHE.
- CDPHE should require all non-transport agencies that receive ketamine waivers to submit ePCR data.

Additional data elements to be submitted:

- CDPHE's data collection processes should capture race/ethnicity and zip code information in order to analyze whether there is disproportionate use of chemical restraint for marginalized persons and communities of color in Colorado.

Consistency with ePCR data set:

- CDPHE should explore transitioning the current elements collected for the waiver process to mirror the elements collected as part of the national data set for patient care reports.

System improvement activities and transparency:

- CDPHE and EMPAC should actively monitor trends in ketamine data usage for system improvement activities.
- CDPHE's statutes governing data collection and release should be reviewed and revised as necessary to allow CDPHE to provide meaningful data for system improvement while maintaining confidentiality.

D.8 Panel Recommendation: CDPHE - Referrals to the Colorado Medical Board

The panel recommends that, to the extent a CDPHE investigation of a complaint from any source about an EMS medical director raises concerns about the physician's performance as an EMS medical director, CDPHE should make a referral to the Colorado Medical Board.

D.9 Panel Recommendation: CDPHE - Written Policies and Regulations

The panel recommends that CDPHE develop written policies and regulations as applicable for the panel recommendations contained in this report, including requirements for a ketamine waiver, investigation of complaints received for alleged waiver violations, enforcement actions that may be taken, and remedies that may be imposed for violations.