COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Jeanne-Marie Bakehouse, Branch Chief, Emergency Medical and Trauma Services, Health Facilities and Emergency Medical Services Division

Through: Michelle Reese, Interim Division Director, Health Facilities and Emergency Medical Services Division ***MR***

Date: September 19, 2018

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 C.C.R. 1015-3, Chapter Four, Licensure of Ground Ambulance Services with a request for a rulemaking hearing to be set for November of 2018

Ground ambulance regulation is shared by state and county authorities. In 1978, the General Assembly established a coordinated system of emergency medical care through a comprehensive statutory scheme. See § 25-3.5-301, C.R.S., *et seq*. As part of that original coordinated scheme, the legislature determined that Colorado ground ambulance services are subject to regulation by the board of county commissioners in which the service is based, while vesting the State Board of Health with the authority to adopt rules outlining certain minimum requirements for ground ambulance service licensing. Pursuant to statute, therefore, the Board's rules adopt minimum requirements concerning ambulance equipment, staffing, medical oversight and quality improvement, an investigative complaint process, and data collection and reporting. Section 25-3.5-308, C.R.S. The Board of Health has promulgated and adopted the minimum rules as required by statute in 6 C.C.R. 1015-3, Chapter Four, Licensure of Ground Ambulance Services.

The most recent substantive revision of these rules occurred in 2008, when data reporting provisions were updated to be consistent with national standards. Given the passage of time since the last rule revision, the Department convened the EMS Chapter Four Work Group in January 2018 for the purpose of conducting a comprehensive review and update of the ground ambulance rules. The work group was comprised of representatives from the emergency medical services community, with representation from rural and metro ground ambulance services, Regional Emergency Medical and Trauma Advisory Councils (RETACs), and other affected parties. Over the past several months, the work group has worked in a collaborative and thoughtful manner to create proposed rules that reflect current industry and public safety standards but do not stray from the confines of statutory jurisdictional limits.

The Department is proposing to incorporate substantive rule revisions that:

- Add to and clarify the definition section, including ensuring it is evident that all ambulances must be licensed and that the license must be issued by the county where the ambulance is based;
- Add requirements for counties to establish a process for periodically reviewing their license requirements;
- Update vehicle safety standards references;
- Add language that clarifies the counties' responsibilities to enact a policy for complaints;

- Clarify that ambulance services are required to provide patient care information to the Department;
- Add a requirement that each ambulance service has an ongoing medical continuous quality management (CQM) program; and
- Revise language in the minimum equipment standards section as well as the advanced life support (ALS) equipment section to be more general and ensure that the rules represent true minimum standards without compromising patient care.

This set of rules has not been reviewed in its totality for a number of years. As part of its statutory obligations to review all regulations periodically, the Division sought to determine whether the existing rule continues to reflect current practice and is operationally sustainable. After conducting their review, the work group and Division concur that the proposed rule revisions are formulated in the least burdensome manner. As proposed, the revised rules ensure that the licensing of EMS services and the equipment used match practices widely accepted to be the minimum standard, are operationally viable, and assure that the level of care being given to patients is not compromised.

The Department submitted the proposed rules to the State Emergency Medical and Trauma Services Advisory Council (SEMTAC) for review and discussion on July 11, 2018. On that date, SEMTAC recommended the proposed revisions be presented by the Department to the Board for a rulemaking hearing in November 2018. (The SEMTAC letter is attached).

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 C.C.R. 1015-3, Chapter Four, Licensure of Ground Ambulance Services

Basis and Purpose.

Section 25-3.5-308, C.R.S., requires the Board of Health to promulgate rules that delineate the minimum requirements for ground ambulance service licensing by counties including, but not limited to, minimum ambulance equipment standards, staffing requirements, medical oversight and quality improvement for ambulance services, complaint investigation processes, and ambulance service data collection and reporting requirements. To implement the statutory directive for rules, the rules define pertinent terms and delineate the minimum requirements for:

- County issuance of licenses and permits;
- Complaints;
- Denial, revocation, or suspension of licensure and vehicle permits;
- Minimum data collection and reporting;
- Minimum staffing;
- Medical oversight and continuous quality management; and
- Minimum equipment.

While these rules establish minimum statutory standards, local governments retain responsibility for issuing, denying, revoking or suspending licenses and permits.

The work group conducted a comprehensive review of the rules and focused on areas requiring substantive revision to conform to current industry standards for safe patient care and transport. In addition, the work group made clarifying and grammatical changes as necessary. The rules also clarify the statutory intent that an ambulance service must be licensed in every county in which it is based. The following substantive recommended changes include:

Section 2.7: Clarifies that the licensing authority with respect to an ambulance service is the county in which the ambulance is based

Section 2.10: The definition of Medical Continuous Quality Management Program (CQM) is revised to incorporate current programmatic language

Section 2.11: The definition of “medical director” deletes outdated language and clarifies that a medical director’s responsibilities extend to EMS providers who are employed by ambulance service agencies

Deleted Sections 2.13 and 2.14—Definitions of rescue units and quick response teams--have been removed. Section 3.2.2, a county licensure exemption provision, used to refer to rescue units and quick response teams as examples of agencies that were included in the exemption. This section has been revised to delete reference to vehicles owned by specific exempt agencies to conform to the statutory intent to exempt all

privately or publicly owned vehicles that are used to evacuate patients from inaccessible areas.

Section 3.1.1 This language combines the old 3.1.1 and 3.1.2 to clarify that the General Assembly intends each ambulance service that operates in Colorado to be licensed by each county in which it is based, unless a reciprocal agreement is in place between the affected counties. The new language states:

Except as provided in Section 3.2 of these rules, no ambulance service, public or private, shall transport a sick or injured person from any point within Colorado to any point within or outside Colorado unless that ambulance service holds a valid license and permits issued by the county or counties in which the ambulance service and its ambulances are based.

Section 3.1.3: This new language contemplates situations in which counties may not license adequate types or numbers of licensed ambulances, (such as an appropriate specialty licensed ambulance), to transport and meet the needs of patients. Therefore, the rule requires every county to establish a procedure to address that circumstance.

Section 3.2.2: Besides deleting reference to rescue units and quick response team vehicles (see above), the new language permits exempted vehicles to transport patients from inaccessible areas to permitted ambulances or medical facilities (not just hospitals).

Section 3.2.3: This revised language comports with statutory language ("major catastrophe") and introduces similar language that is utilized by 6 C.C.R. 1015-3, Trauma Chapter 2 rules ("multicasualty (disaster) events).

Section 3.3.1: This provision was revised to require counties to review their adopted ground ambulance licensure processes periodically. The work group sought to correct reported problems regarding certain antiquated processes without imposing burdensome regulation.

3.3.1(G): Provision stricken because the Department has no statutory authority to impose the requirement.

3.3.1(H): The work group revised the vehicle design standards to delete specific standards in favor of imposing the requirement that all ambulances must be manufactured by an organization registered with the National Highway Traffic Safety Administration.

3.3.1(I): New language prohibits ambulance inspectors from operating under disclosed or undisclosed actual or potential conflicts of interest with the ambulance service and/or inspection process.

Section 3.3.2: This language was deleted because the revised rules no longer incorporate outside materials by reference.

Section 3.4.1: An ambulance service license shall be issued by each county in which the ambulance service is based. The county shall ensure compliance with these rules and all license requirements established by that county.

The revised language conforms to the rest of the rule and clarifies that an ambulance service must be licensed by each county in which it is based. The work group also deleted existing language concerning the maximum level of ambulance service that may be provided because it is expressly addressed in the next provision concerning ambulance permits.

Section 3.4.2.C: The work group altered the language to make the identification of ambulance service levels permissive, rather than mandatory.

Section 3.6.1: This revision permits the counties to determine their own licensing renewal process in keeping with statute.

Section 4.2.1 to 4.2.7: These sections include the components that counties must incorporate into their written complaint and investigation policies concerning licensed and unlicensed ambulance complaints. The work group modified the procedure to propose that counties must: post the complaint procedure online for public consumption/education; provide the licensee with a copy of the complaint; notify the Department and service medical director about EMS provider complaints; and notify other counties (and, if applicable, the Department of Regulatory Agencies (DORA)) about complaints concerning other ambulance service medical personnel and/or the medical director.

Section 4.3: The pre-existing language of this provision inferred that counties were required to report unknown violations. This provision proposes that counties must only notify service medical directors of any known alleged complaints or violations of individual medical providers associated with an ambulance service.

Section 6.2.2: The work group revised the vehicle design standards to delete specific standards in favor of imposing the requirement that all ambulances must be manufactured by an organization registered with the National Highway Traffic Safety Administration.

Section 7.1: Added language clarifies that ambulance staff must hold current and valid certifications and licenses, in line with the statute.

Section 7.2: The clause at the end of the rule was deleted as surplusage.

Section 8.1: The timeframe in which ambulance services must provide written notification to the county of a change to the service's medical director or medical oversight was changed from 15 calendar to 14 business days.

Sections 8.2 and 8.3: These provisions have been modified to change their order and to incorporate current terminology, *i.e.*, medical CQM program.

Section 9: The work group reviewed every provision in this section concerning minimum equipment requirements and modified certain language to comport with current equipment terminology. In addition, in some instances the group either altered specific requirements to more generic language, *i.e.*, "multiple bandages and dressings" in Section 9.2.4, or added more specific requirements, such as the child restraint system to accommodate a set weight range, as codified in Section 9.2.9. Certain new equipment requirements are also proposed. For example, the work group proposes requiring the addition of certain pharmacological agents for basic life support ambulances, as listed in Section 9.2.10.

Specific Statutory Authority.

The statute that requires or authorizes rulemaking is Section 25-3.5-308, C.R.S.

Statutes that inform or direct the rule content:

Section 25-3.5-103, C.R.S. contains definitions that apply to this set of rules.
Section 25-3.5-202, C.R.S. pertains to Rule Section 7.
The balance of the rule is informed or directed by Section 25-3.5-301, *et seq.*, C.R.S.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.
__X____ No

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library
___X___ No

Does this rulemaking create or modify fines or fees?

_____ Yes
___X___ No

Does the proposed rule create (or increase) a state mandate on local government?

___ No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

___ No. This rulemaking reduces or eliminates a state mandate on local government.

_X_ 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
_X__ Other: Imposed by the Department upon recommendation of a workgroup which was comprised of a county commissioner, local fire departments, various ground ambulance agencies, representatives from the emergency medical service association, state government and the State Emergency Medical and Trauma Services Advisory Council (SEMTAC).

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes _X__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.

A key component of the current rule is the minimum equipment list. The work group updated this list to be consistent with current medical practices and, consequently, to improve care during transport. Additionally, the work group identified gaps in the existing regulatory scheme that have resulted in inconsistent regulatory conduct among the counties and the provision of insufficient information to the public and/or Department regarding regulatory compliance and process:

3.1.3: This new language contemplates situations in which counties may not license adequate types or numbers of licensed ambulances, (such as an appropriate specialty licensed ambulance), to transport and meet the needs of patients. Therefore, the rule requires every county to establish a procedure to address that circumstance.

3.3.1: This provision has been revised to require counties to review their adopted ground ambulance licensure processes periodically. The work group sought to correct reported problems regarding certain antiquated processes without imposing burdensome regulation.

3.3.1(H): The work group revised the vehicle design standards to delete specific standards in favor of imposing the requirement that all ambulances must be manufactured by an organization registered with the National Highway Traffic Safety Administration.

3.3.1(I): New language prohibits ambulance inspectors from operating under disclosed or undisclosed actual or potential conflicts of interest with the ambulance service and/or inspection process.

4.2.1: Augments rule to require county to institute a policy that informs the public by posting how to file a complaint.

4.2.2 Complaint policy requires county to provide licensee with a copy of complaint upon filing.

4.2.6 Complaint policy must provide the method by which county notifies the Department and medical directors of complaints filed against EMS providers.

4.2.7 Complaint policy must provide a method by which county notifies other counties with jurisdiction over an ambulance service, the Department and, if applicable, DORA, about complaints against the medical director or other medical personnel.

6.3 Counties must submit a list of verified licensed ambulance services and permitted vehicles to the Department upon request.

Section 9 "Minimum Equipment Requirements," lays out the minimum on-board equipment required to be carried in licensed ALS and BLS ground ambulances. The work group has added these minimum equipment requirements that contain state mandates on local government:

For Basic Life Support Ambulances:

9.2.1.B	BBG suction catheter
9.2.2.D	pulse oximeter with adult and pediatric sensors
9.2.4	arterial tourniquet
9.2.8.E	NIOSH-approved filtering respirator of N-95 or superior particulate filtering capabilities
9.2.10.A	pharmacological agents and delivery devices as dictated by the medical director
9.2.10.B	pediatric "length-based' device for sizing drug dosage calculations and equipment
9.2.11.A	pediatric reference tool that addresses drug dosages and equipment sizing based on patient's height and weight
9.2.11.B	pediatric reference tool for vital signs

For Advanced Life Support Ambulances:

9.3.1	all equipment and supplies that must be carried in BLS ambulances
9.3.4.B	inserts intraosseous equipment requirements into Intravenous equipment section

These changes were made at the request of the work group for the purpose of updating the existing rules to reflect the current standard of practice.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1015-3, Chapter Four – Rules Pertaining to
Licensure of Ground Ambulance Services

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.

Counties,* county commissions,* privately-owned ambulance services, publicly-owned ambulance services,* ambulance service medical directors, licensed health care facilities that own and/or operate ambulance services*, emergency medical service providers, Coloradans, and the public.

A. <u>Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:#</u>

24 Privately-owned ambulance services,
142 Publicly-owned ambulance services,*
24 Licensed health care facilities that own and/or operate ambulance services*,
64 Counties and county commissions*

Although EMS and ambulance service medical providers belong in the class of individuals/entities that rely on the rule to maintain operation of ground ambulance transport, these groups were not included in this response because they are not responsible for implementing and following the rules.

Local Government Impact:

If operating a government-owned ambulance service, local government must:

- Develop and implement policies concerning the complaint process, inspector conflicts of interest, ambulance design standards, and permissible uses of unlicensed ambulance services and unpermitted vehicles;
- Review periodically their processes for licensing ambulance services;
- Submit a list of ambulance services and permitted vehicles operating in the county upon Department request; and
- Acquire new minimum equipment

B. <u>Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:</u>

Approximately 400,000 transported EMS patients per year
Approximately 210 ground ambulance agencies
18,190 EMS providers (as of June 30, 2018)
Approximately 110 ground ambulance service medical directors
Emergency Medical Services Association of Colorado (EMSAC)
Colorado Counties Inc.
Special District Association
Colorado Municipal League

Colorado State Fire Chiefs Association
Colorado Firefighters Association
Colorado Hospital Association

C. Identify each group of individuals/Entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

Individuals who require emergency medical transport in the State of Colorado will ultimately benefit because the proposed rule revisions require ground ambulances to satisfy minimum design, equipment, staffing, continuous quality management (CQM), and operational safety standards that will improve emergency medical ground ambulance services. The revised rule will also augment and clarify the complaint process for consumers of these services and their families in the event they receive, or believe they have received, deficient emergency medical ground ambulance services. Further, consumers will benefit from the proposed rule revision that now requires counties to ensure that qualified conflict-free representatives perform all annual ambulance inspections.

Counties and county commissions that regulate ground ambulance services will also benefit from clarifications to the proposed rule revisions. The modifications benefit the counties by clarifying their licensing jurisdictions. For example, the work group determined that the pre-existing rules did not adequately explain that the service area of an ambulance service is one way of determining what constitutes its "base." An ambulance service that only provides services in one county must be licensed in that county because that is where it is based. Conversely, ambulance services that provide services in multiple counties are "based" in all of those counties. Therefore, they must secure a ground ambulance license from each such county. (Rules 2.1, 2.7, 3.1.1, 3.4.1.A).

Other proposed rule revisions benefit counties by reducing their mandatory regulatory burdens. For instance, proposed Rule 3.4.1.1 deletes the county's obligation to describe the maximum amount of service that an ambulance service can provide. Likewise, proposed Rule 3.4.2.C no longer requires the county to include in its resolution or regulations requirements for identification of the level of service provided. Proposed Rule 3.6 deletes certain license renewal process requirements that are within the discretion of the counties, while proposed Rule 6.2.2 predicates the county's submission of information upon Department request, as opposed to an annual requirement. Also, proposed Rule 3.2.2 places boundaries upon the transport of patients from inaccessible areas. The new language inures to the county's benefit by clarifying that such transports must terminate at the closest point of access to a licensed ambulance, thereby limiting the county's potential liability. Finally, Section 9, "Minimum Equipment Requirements," broadly benefits counties by ensuring that all permitted ground ambulances operating within their jurisdictions will be soundly designed, possess the equipment minimally necessary to meet patients' needs, and comply with safety standards.

The work group also proposes a revision to Rule 4.3 by clarifying that counties must only report those violations or complaints about ambulance services or their medical providers about which the counties have knowledge. The existing rule infers that counties have the duty to report all violations and complaints, whether known or

unknown. Because the duty to report unknown violations and complaints is neither fair nor logical, the rule has been modified to the counties' benefit.

The work group did not receive any feedback during its rule revision process to indicate that any of the proposed rules might potentially be harmful to counties and county commissions, or impinge upon their authority to regulate ground ambulances. Certain proposed rules do impose new requirements, but these proposals are minor, only dictate processes, and are not intended to add burdensome requirements or to interfere with substantive regulatory matters.

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.

A. <u>For those that rely on the rule to maintain their own businesses, agencies or operations</u>:

24 Privately-owned ambulance services,
142 Publicly-owned ambulance services,*
24 Licensed health care facilities that own and/or operate ambulance services,[1]
64 Counties and county commissions*

<u>Health and safety standards</u>:
Describe the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

The new requirement that counties designate conflict-free representatives to conduct annual ground ambulance inspections promotes the integrity of the inspection process and ensures that licensed ground ambulances comply with minimum design safety and equipment requirements. This provision will help to eliminate or significantly reduce the risk that non-compliant ambulances are responding to emergencies and transporting patients in an unsafe environment.

A new provision (Rule 3.1.3) requires counties to establish a process by which unlicensed ground ambulances can legally transport patients, as necessary, and provides favorable benefits to the county in the short- and long-term. Typically, licensed ambulance services are able to provide safe emergency transports to address patient needs. When unanticipated events result in voluminous or rare injuries, however, that resource may not be able to provide patients with safe and adequate emergency transport services. The proposed rule provides a process to ensure that safe and adequate medical transport resources are available to respond to the needs of patients in these situations.

This provision also benefits licensed ambulance services. Rather than expecting the available licensed service to provide emergency medical transports that it is unable or

[1] Although there are approximately 210 ground ambulance services in Colorado, the Department has organizational profiles for 190 of these agencies. The data given is drawn from those Department records.

unequipped to offer, the proposed rule allows unlicensed services to provide the needed transport.

The proposed complaint process provisions should also result in collateral favorable outcomes to ambulance services and counties. By providing consumers of emergency medical ground ambulance services with a process to raise complaints about perceived substandard care, ambulance services and their medical directors can timely investigate the allegations and, if substantiated, correct and report the non-compliant violation as required. The process will result in increased transparency and accountability, and improved safety for patients.

***Unfavorable non-economic outcomes*:**

The new, more transparent complaint process provisions may impact EMS and other medical providers unfavorably if consumer complaints result in regulatory disciplinary action. Regarding all other classes, the work group was very careful to stay within the Department's statutory authority to regulate ground ambulances and the licensing process. No unfavorable non-economic outcomes are currently known.

Quantitative Economic/Financial Impact:

Ambulances services:

The proposed rules that impose additional requirements on ambulance services are minimal. The most potentially burdensome proposed rules are those that: (1) require new equipment on board ambulances (Section 9); and (2) require ambulance services that previously operated without a license in a service area to obtain a license from the county that has jurisdiction over the service area.

The Department believes that there are few, if any, ambulance services that will be impacted by the licensing service area requirement. Both the current and proposed rules contain a provision that allows counties to enter into reciprocal licensing and permitting agreements with other counties and neighboring states. (Current Rule 3.1.3) Therefore, those ambulance services operating within a multi-county area with reciprocity agreements will not suffer any economic or financial impact normally associated with additional licensing requirements.

With respect to the minimum equipment additions and modifications, the working group noted that most basic life support and advance life support ambulances already have this equipment. This change is simply the proposed rules reflecting the current state of practice.

EMS Providers and other Medical Personnel:

The Department believes that there are no imminent economic impacts to emergency medical service providers (EMTs, Paramedics) or other medical personnel that work for an ambulance service. However, it is possible that the revised complaint reporting requirements to the Department of Regulatory Affairs and to the Department could impact those professionals' licenses or certifications to work.

***Anticipated financial impact*:**

Anticipated Costs:	Anticipated Benefits:
Description of costs that must be incurred. Some ambulance services already have the minimum equipment required in the proposed rule. To the extent equipment needs to be procured: • <u>New Equipment For Each BLS Ground Ambulance</u>: BBG suction catheter: $3.12 – $7.33 per unit Arterial tourniquet#: $10.95 – $37.48 per unit Adult and Pediatric pulse oximeter: $98.85 - $169.95 per unit Pediatric pulse oximeter sensor*: $17.88 - $54.95 per unit Pediatric length-based measuring device: $24.00 - $34.88 per unit Pediatric reference guide: $1525 per unit plus $395 set-up fee (N.B. It may be possible to comply by carrying Children's Hospital pediatric guide that is provided at no cost annually) #Already required for City and County of Denver, Jefferson, Adams, Arapahoe, Douglas, and City and County of Broomfield *If ambulance already has electronic monitor for adults, only the pediatric sensor is needed to convert for use with pediatric patient	Description of financial benefit. • As noted above, some counties may be the recipients of additional licensing fee revenues that are generated by ambulance services that are based in more than one county. • Consistency across ambulance services as to equipment, increasing the competitiveness of all services.

TOTAL BLS EXPENSE RANGE: With Pediatric reference guide: $1697.68 + $395 set up fee to $1829.59 + $395 set up fee Without Pediatric reference guide/with free Children's Hospital pediatric guide: $172.68 to $304.59 • New Equipment for Each ALS Ground Ambulance: Intraosseous access and administration equipment: $65.98-$68.88 per unit TOTAL ALS EXPENSE RANGE:* With Pediatric reference guide: $65.98 for IO equipment, plus BLS equipment $1697.68 + $395 set up fee (Totaling $2158.66) to $68.88 for IO equipment plus BLS equipment $1829.59 + $395 set up fee plus (Totaling $2293.47) Without Pediatric reference guide/with free Children's Hospital pediatric guide: $65.98 for IO equipment, plus $172.64 BLS equipment (Totaling $238.62) To $68.88 for IO equipment plus BLS equipment $304.59 (Totaling $393.47) *ALS ground ambulances must be equipped with minimum equipment required for BLS and ALS categories.	

Description of costs that may be incurred. • Ambulance services that do not currently carry the additional mandated equipment will incur some or all of the foregoing costs necessary to update their equipment. The Department anticipates that a number of permitted ambulance service vehicles are already so equipped; therefore, in that circumstance, no additional costs will be incurred to the ambulance service. • Concerning the additional policy-making requirements imposed by the proposed rules discussed above, the Department does not anticipate that counties will incur additional cost, FTE, or fiscal impact.	
Cost or cost range. Enter "none" if there are no costs. For BLS ambulances that do not currently carry any newly-required minimum equipment: $172.68 to $1829.59 + $395 set up fee For ALS ambulances that do not currently carry any newly-required ALS and BLS minimum equipment: <u>Without Pediatric reference guide/with free Children's Hospital pediatric guide</u>: $393.47 To <u>With Pediatric reference guide</u>:	Savings or range of savings. $_____ or _X__ No data available.

$2158.66	
Dollar amounts that have not been captured and why: • None	Dollar amounts that have not been captured and why: • None

B. <u>For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.</u>

Approximately 400,000 transported EMS patients
Approximately 190 EMS agencies
18,190 EMS providers (as of June 30, 2018)
Approximately 110 ambulance service medical directors
Emergency Medical Services Association of Colorado (EMSAC)
Colorado Counties Inc.
Special District Association
Colorado Municipal League
Colorado State Fire Chiefs Association
Colorado Firefighters Association
Colorado Hospital Association

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

For ambulance service medical directors, the new complaint process laid out in Proposed Rule 4.2.6 ensures that the counties will adopt a policy and procedure concerning the method by which medical directors will be notified of complaints involving EMS providers. Medical directors will therefore see a favorable outcome from the rule revision because they will receive notice of any alleged regulatory violation or breached standard of practice committed by an ambulance service EMS and/or medical provider, and be able to institute necessary personnel and/or operational improvements.

For EMS patients, see response to Question 1(C), above. Individuals who require emergency medical transport in the State of Colorado will ultimately benefit because the proposed rule revisions require ground ambulances to satisfy minimum design, equipment, staffing, CQM, and operational safety standards that will improve emergency medical ground ambulance services. The revised rule will also augment and clarify the complaint process for consumers of these services and their families in the event they receive, or believe they have received, deficient emergency medical ground ambulance services. Further, consumers will benefit from the proposed rule revision that now requires counties to ensure that qualified conflict-free representatives perform all annual ambulance inspections, thereby protecting the safety of the public who are medically transported.

For EMS agencies, see response to Question 2(A), above**.** This provision also benefits licensed ambulance services because it recognizes that, in some circumstances, certain permitted ground ambulances cannot adequately respond to emergency transport demands, even if they are available. The new provision institutes a process to accommodate these circumstances, rather than expecting the licensed service to provide emergency medical transports that it is unable or unequipped to offer.

The proposed complaint process provisions should also result in collateral favorable outcome to ambulance services and counties. By providing consumers of emergency medical ground ambulance services with a process by which to raise complaints about perceived substandard care, ambulance services and their medical directors can timely investigate the allegations and, if substantiated, correct and report the non-compliant violation as required. The process will result in increased transparency and accountability, and improved safety for patients.

For EMS Providers, the proposed design safety, inspection, and equipment rules ensure that these medical professionals will be operating in a safe environment and providing emergency medical care with updated equipment.

Unfavorable non-economic outcomes:

As previously noted, the new, more transparent complaint process provisions may impact EMS and other medical providers unfavorably if consumer complaints result in regulatory disciplinary action. Regarding all other classes, the work group was very careful to stay within the Department's statutory authority to regulate ground ambulances and the licensing process. Consequently, the Department is currently unaware of other unfavorable non-economic outcomes.

Anticipated financial costs:

Ambulance services that do not currently carry the additional mandated equipment will incur costs necessary to update their equipment. However, the Department anticipates that a number of ambulance services already maintain this equipment. Therefore, no additional costs will be incurred by these entities.

The Department is unaware of any anticipated financial costs the other individuals or entities might incur.

Anticipated financial benefits:

The Department is unaware of any anticipated financial benefits these individuals or entities might receive.

C. <u>For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.</u>

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

The Department does not foresee any potential harm resulting from the proposed rules. The proposed regulation balances the interests of the counties and patients with the interests of regulated ambulance services.

Financial costs to these individuals/entities:

For individuals affected by this rule, the cost is unknown. However, the Department anticipates that any such costs, if incurred, will be minimal.

For entities affected by this rule, see Sections (2)(a) and (3)(a), infra.

Financial benefits to or cost avoidance for these individuals/entities:

N/A as to individuals.

Unknown at this time as to entities.

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:

There will be no additional cost to CDPHE associated with this proposed rule.

Anticipated CDPHE Revenues:

No additional revenues are anticipated because of the proposed regulation. The proposed rules do not increase fees.

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

N/A

Anticipated Revenues for 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.

Check mark all that apply:
_x_ Inaction is not an option because the statute requires rules be promulgated.

___ The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and Department funding obligations.

_x__ The proposed revisions appropriately maintain alignment with other states or national standards.

_x__ The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.

_x__ The proposed revisions implement stakeholder feedback.

_x__ The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities Goal 2, Increase Efficiency, Effectiveness and Elegance Goal 3, Improve Employee Engagement Goal 4, Promote health equity and environmental justice Goal 5, Prepare and respond to emerging issues, and Comply with statutory mandates and funding obligations

Strategies to support these goals:
___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
_X__ Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
___ Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
___ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
_X__ Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

_x__ Other favorable and unfavorable consequences of inaction:

Unfavorable consequences of inaction include:

- Ambulances may not be carrying the necessary equipment to respond to the needs of EMS and trauma patients,
- The existing rules do not clearly state that ambulance services must be licensed in each county in which they are based,
- The public does not have the necessary information to report complaints concerning ambulance services and/or their providers, and
- The Department may not receive accurate data or necessary regulatory data to assess and monitor the EMS and trauma system effectively.

The Department does not believe that inaction results in any favorable consequences.

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 conjunction with stakeholders. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, and are the minimum necessary to achieve compliance with statute.

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

Rulemaking is expressly mandated by statute. The only alternative was to leave the rules as they currently stand, which would not reflect current practice or the standard of care. Consequently, no alternatives to rulemaking were considered. The Department provided stakeholders and the public with the opportunity to contribute substantively throughout the entire rule development process.

The work group was mindful throughout the process not to impose unnecessary requirements on ambulance services or local government. During the course of its discussions, the work group did consider and reject certain rule proposals. For example, there was robust conversation concerning the need versus desirability of requiring ambulances to carry certain pieces of equipment. In one instance, the work group reasoned that it makes more sense to require counties to develop a process to allow extra-jurisdictional (unlicensed) specialty ambulances to transport patients under certain circumstances rather than to require every licensed ambulance to purchase seldom-used specialized equipment.

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

The gaps in the current rules were identified by subject matter experts and practitioners. They contributed their ideas for regulatory improvement to the work group, and this proposal is a product of those suggestions.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1015-3, Chapter Four – Rules Pertaining to
Licensure of Ground Ambulance Services

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
County Commissioners	Commissioner Sean Wood, Clear Creek County
For-Profit Ground Ambulance	Shawn Howe, American Medical Response
Hospital-Based Ground Ambulance	Dave Bressler, Banner Northern Colorado
EMS for Children	Sean Caffrey
Emergency Medical Services Association of Colorado	Tim Nowak
State Emergency Medical and Trauma Services Advisory Council (SEMTAC)	Commissioner Sean Wood, Clear Creek County, and Rich Martin, Castle Rock Fire Department
Regional Emergency Medical and Trauma Advisory Councils (RETACs)	Brandon Chambers, and Kim Schallenberger, Plains to Peaks RETAC
Fire-Based Ground Ambulance	Rich Martin, Castle Rock Fire Department

The work group met six times over a period of seven months in 2018. Draft rule proposals were distributed throughout the process. All work group meetings were publicly noticed and available through teleconferencing to any interested person.

Local Government Impact:

A county commissioner was a participating member of the work group and therefore was aware of all discussions and outcomes of local government mandates or provisions. Additionally, Department staff consulted with staff of Colorado Counties Inc. concerning all provisions involving local government requirements.

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).

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

____ 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.

The proposed rules are the product of the work group's consensus. Other than the issues noted below, no major factual or policy issues were encountered. The work group was mindful throughout the rule development process not to impose unnecessary requirements on ambulance services or local government.

During the course of its discussions, the work group and the Department considered and rejected certain rule modifications. For example, there were significant conversations concerning the need versus desirability of requiring ambulances to carry certain pieces of equipment. In one instance, the work group reasoned that it was more sensible to require counties to develop a process whereby extra-jurisdictional (unlicensed) specialty ambulances are able to transport patients under certain circumstances rather than to require every licensed ambulance to purchase seldom-used specialized equipment.

Another policy issue that arose was whether ground ambulance personnel should be required to leave patient care assessments and reports at the receiving facility in real time. After discussion, the work group wished to incorporate such a practice into rule. However, the Department rejected the suggestion because it was outside the scope of the Board of Health's rulemaking authority.

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

By standardizing the minimum equipment that an ambulance must carry and requiring counties to improve their complaint policies and processes, the proposed regulation helps set a standard of service by licensed ambulance services and an expectation of sensitivity and responsiveness to customer/patient concerns.

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.
x	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	x	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.
x	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.	X	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.	x	Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

If the rulemaking implements new legislation or you have supplemental information such as a letter of support or a study, insert the legislation (an excerpt may be appropriate) or the supplemental information here in the .doc or in the PDF.

N/A.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

EMERGENCY MEDICAL SERVICES

6 CCR 1015-3

___ Adopted by the Board of Health on _____, 2018. Effective _____, 2018.

CHAPTER FOUR – RULES PERTAINING TO LICENSURE OF GROUND AMBULANCE SERVICES

Section 1 – Purpose and Scope

1.1 These rules are promulgated pursuant to § 25-3.5-308, CRS. They are consistent with § 25-3.5-301, 302, and 304 -306, CRS. Each county may adopt rules that exceed these rules adopted herein.

Section 2 – Definitions

2.1 Based: an ambulance service headquartered, having a substation, office, ambulance post, SERVICE AREA or other permanent location in a county.

2.2 County: county or city and county government within Colorado.

2.3 Department: the Colorado Department of Public Health and Environment.

2.4 Ambulance: any public or privately owned ~~land~~ LICENSED GROUND vehicle especially constructed or modified and equipped, intended to be used and maintained or operated by, ambulance services for the transportation, upon the ~~roads,~~ streets and highways of this state, of individuals who are sick, injured, or otherwise incapacitated or helpless.

2.5 Ambulance-advanced life support: a type of permit issued by a county to ~~a vehicle~~ AN AMBULANCE equipped in accordance with Section 9 of these rules and operated by an ambulance service authorizing the vehicle to be used to provide ambulance service limited to the scope of practice of the advanced emergency medical technician, emergency medical technician-intermediate or paramedic as defined in the EMS Practice and Medical Director Oversight Rules at 6 CCR 1015-3 Chapter Two.

2.6 Ambulance-basic life support: a type of permit issued by a county to ~~a vehicle~~ AN AMBULANCE equipped in accordance with Section 9 of these rules and authorized to be used to provide ambulance service limited to the scope of practice of the emergency medical technician as defined in the EMS Practice and Medical Director Oversight Rules at 6 CCR 1015-3 Chapter Two.

2.7 Ambulance service license: a legal document issued to an ambulance service by a county IN WHICH THE AMBULANCE IS BASED as evidence that the applicant meets the requirements for licensure to operate an ambulance service as defined by county resolution or regulations.

2.8 Ambulance service: the furnishing, operating, conducting, maintaining, advertising, or otherwise engaging in or professing to be engaged in the transportation of patients by ambulance. Taken in context, it also means the person so engaged or professing to be so engaged. ~~and the~~ THE vehicles used for the emergency transportation of persons injured at a mine are excluded from this definition when the personnel utilized in the operation of said vehicles are subject to the

mandatory safety standards of the federal mine safety and health administration, or its successor agency.

2.9 EMS Provider: refers to all levels of ~~E~~ emergency ~~M~~ medical SERVICE PROVIDER ~~Technician~~ certification issued by the department, including Emergency Medical Technician, Advanced Emergency Medical Technician, Emergency Medical Technician Intermediate and Paramedic.

2.10 MEDICAL CONTINUOUS QUALITY MANAGEMENT (CQM) PROGRAM: A PROCESS CONSISTENT WITH THE EMS PRACTICE AND MEDICAL DIRECTOR OVERSIGHT RULES AT 6 CCR 1015-3, CHAPTER TWO, USED TO OBJECTIVELY, SYSTEMATICALLY AND CONTINUOUSLY MONITOR, ASSESS AND IMPROVE THE QUALITY AND APPROPRIATENESS OF CARE PROVIDED BY THE MEDICAL CARE PROVIDERS OPERATING ON AN AMBULANCE SERVICE.

2.~~10~~11 Medical Director: a Colorado licensed physician who establishes protocols and standing orders for medical acts performed by EMS Providers of ~~a prehospital EMS service agency~~ AN AMBULANCE SERVICE AGENCY and who is specifically identified as being responsible to assure the competency of the performance of those acts by such EMS Providers as described in the physician's medical ~~continuous quality improvement~~ CQM program. ~~Any reference to a "physician advisor" in any previously adopted rules shall apply to a "medical director" as defined in these rules.~~

2.~~11~~12 Patient Care Report: a medical record of an encounter between any patient and a provider of medical care.

2.~~12~~13 Permit: the authorization issued by the governing body of a local government with respect to an ambulance used or to be used to provide ambulance service in this state.

~~2.13 Medical quality improvement program: a process consistent with the EMS Practice and Medical Director Oversight Rules at 6 CCR 1015-3 Chapter Two, used to objectively, systematically and continuously monitor, assess and improve the quality and appropriateness of care provided by the medical care providers operating on an ambulance service.~~

~~2.14 Rescue Unit: any organized group chartered by this state as a corporation not for profit or otherwise existing as a nonprofit organization whose purpose is the search for and the rescue of lost or injured persons and includes, but is not limited to, such groups as search and rescue, mountain rescue, ski patrols, (either volunteer or professional), law enforcement posses, civil defense units, or other organizations of governmental designation responsible for search and rescue.~~

~~2.15 Quick Response Teams: provides initial care to a patient prior to the arrival of an ambulance.~~

Section 3 – County Issuance of Licenses and Permit

3.1 License Required

~~3.1.1 Within one year following adoption of these rules, no person or agency, private or public, shall transport a patient from any point within Colorado in an ambulance, to any point within or outside Colorado unless that person or agency holds a valid license and permits issued by the county where the service is based and by the county where the patient originates, except as provided in Section 3.2 of these rules.~~

3.1.1 EXCEPT AS PROVIDED IN SECTION 3.2 OF THESE RULES, NO AMBULANCE SERVICE, PUBLIC OR PRIVATE, SHALL TRANSPORT A SICK OR INJURED PERSON FROM ANY POINT WITHIN COLORADO TO ANY POINT WITHIN OR OUTSIDE COLORADO UNLESS THAT AMBULANCE SERVICE HOLDS A VALID LICENSE AND

PERMITS ISSUED BY THE COUNTY OR COUNTIES IN WHICH THE AMBULANCE SERVICE IS BASED.

~~3.1.2 Ambulance services that are based outside Colorado, but respond within Colorado and transport patients originating in Colorado are required to be licensed in Colorado by the county in which they provide service.~~

~~3.1.3~~ 3.1.2 Counties may enter into reciprocal licensing and permitting agreements with other counties and neighboring states.

3.2 County Exemptions From Licensure or Permit Requirements

3.2.1 Vehicles used for the transportation of persons injured at a mine when the personnel used on the vehicles are subject to the mandatory safety standards of the federal mine safety and health administration, or its successor agency.

3.2.2 Vehicles used TO EVACUATE PATIENTS FROM AREAS INACCESSIBLE TO A PERMITTED AMBULANCE. VEHICLES USED IN THIS CAPACITY MAY ONLY TRANSPORT PATIENTS TO THE CLOSEST PRACTICAL POINT OF ACCESS TO A PERMITTED AMBULANCE OR MEDICAL FACILITY. ~~by other agencies including quick response teams and rescue units that do not routinely transport patients or vehicles used to transport patients for extrication from areas inaccessible to a permitted ambulance. Vehicles used in this capacity may only transport patients to the closest practical point for access to a permitted ambulance or hospital.~~

3.2.3 Vehicles, including ambulances from another state, used during major catastrophe or ~~mass casualty incident~~ MULTICASUALTY (DISASTER) EVENTS, rendering services when permitted ambulances are insufficient.

3.2.4 An ambulance service that does not transport patients from points originating in Colorado, or transporting a patient originating outside the borders of Colorado.

3.2.5 Vehicles used or designed for the scheduled transportation of convalescent patients, individuals with disabilities, or persons who would not be expected to require skilled treatment or care while in the vehicle.

3.2.6 Vehicles used solely for the transportation of intoxicated persons or persons incapacitated by alcohol as defined in § ~~25-1-302,~~ 25-81-102(11), ~~CRS~~ C.R.S. but who are not otherwise disabled or seriously injured and who would not be expected to require skilled treatment or care while in the vehicle.

3.2.7 Ambulances operated by a department or an agency of the federal government, originating from a federal reservation for the purpose of responding to, or transporting patients under federal responsibility.

3.3 General Requirements For County Licensure Of Ambulance Services AND PERMITTING OF AMBULANCE VEHICLES

3.3.1 Counties shall adopt by resolution or regulations, AND PERIODICALLY REVIEW, a process for licensure of ambulance services. The process shall include, but not be limited to:

A~~).~~ Compliance with ALL applicable ~~federal, state, and local~~ laws and regulations to operate an ambulance service in Colorado.

B~~).~~ An application form adopted by the county.

C). An application fee, as defined in county resolution or regulations.

D). Submission to the county, upon request, of copies of the ambulance service's written policy and procedure manual, operational or medical protocols, or other documentation the county may deem necessary.

E). Demonstration by the applicant of minimum vehicle insurance coverage as defined by § 10-4-609, ~~CRS~~ C.R.S. and § 42-7-103 (2), ~~CRS~~ C.R.S. with the county(s) identified as the certificate holder.

F). Demonstration by the applicant of proof of any additional insurance as identified in county resolution or regulations. In making a decision about additional insurance requirements at any time it deems necessary to promote the public health, safety and welfare, the county shall require a minimum level of worker's compensation consistent with the Colorado worker's compensation act of Colorado Revised Statutes title 8, article 40-47.

~~G. Documentation from the applicant that information regarding the amount of professional liability insurance the ambulance service carries was provided to employees.~~

~~H.~~G) Prior to beginning operations and upon change of ownership of an ambulance service, the new owner or operator must file for and obtain an ambulance license and ambulance permit.

~~I.~~ H) IN ORDER TO ASSURE PATIENT AND CREW SAFETY, THE ~~The~~ county ~~may~~ SHALL REQUIRE THAT ALL AMBULANCES BE MANUFACTURED BY AN ORGANIZATION REGISTERED WITH THE NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION (NHSTA) AS A FINAL STAGE MANUFACTURER. THE COUNTY MAY adopt minimum ~~acceptable~~ vehicle design standards for ambulances. ~~In doing so, the county shall consider vehicle design standards such as those established by the US General Services Administration: federal specifications for ambulances KKK-A-1822 (e), 2003.~~

~~J.~~ I) The county shall verify that each ambulance is inspected annually by qualified representatives, as defined and appointed by the county commissioners, to assure compliance with these rules. COUNTIES SHALL ENSURE THAT ALL SUCH REPRESENTATIVES DO NOT HAVE ANY DISCLOSED OR UNDISCLOSED ACTUAL OR POTENTIAL CONFLICTS OF INTEREST WITH THE AMBULANCE SERVICE OR INSPECTION PROCESS.

~~K.~~ J) Counties shall verify that all equipment on the ambulance is properly secured, and medications and supplies are maintained and stored according to the manufacturer's recommendations and ~~any federal, state or local~~ ALL APPLICABLE requirements.

~~L.~~K) A county may delegate or contract the ambulance inspection process but not the responsibility of licensure as set forth in § 25-3.5-301, *et seq.*, ~~CRS.~~ C.R.S.

~~M.~~L) An ambulance service license or vehicle permit may not be assigned, sold or otherwise transferred.

3.3.2 ~~These rules incorporate by reference vehicle design standards by the US General Services Administration: federal specifications for ambulances KKK-A-1822 (e), 2003 (Section 3.3.1I). These rules do not include later amendments to or editions of the incorporated materials. The Department of Public Health and Environment maintains copies of the complete text of the incorporated materials for public inspection during~~

~~regular business hours, and shall provide certified copies of any non-copyrighted material to the public at cost upon request. The incorporated material may be examined at any state publications depository library.~~

~~A. Information regarding how the incorporated materials may be obtained or examined is available from:~~

~~Emergency Medical and Trauma Services Section Chief~~
~~Health Facilities and Emergency Medical Services Division~~
~~Colorado Department of Public Health and Environment~~
~~4300 Cherry Creek Drive South, Denver, Colorado 80246~~

EVERY COUNTY SHALL ESTABLISH A PROCESS BY WHICH AMBULANCE SERVICES NOT LICENSED WITHIN THE COUNTY'S JURISDICTION MAY PROVIDE TRANSPORT IN THE EVENT THAT ALL LICENSED AMBULANCE SERVICES ARE UNABLE TO MEET THE NEEDS OF THE PATIENT.

3.4 Licensure Process

3.4.1 Ambulance Service License

~~A.~~

An ambulance service license shall be issued by EACH county IN WHICH THE AMBULANCE SERVICE IS BASED. ~~upon~~ THE COUNTY SHALL ENSURE compliance with these rules and all license requirements ~~duly~~ established by that county. ~~The type of license issued shall describe the maximum level of ambulance service that could be provided at any time by the service.~~

3.4.2 Permits Of Vehicles

A)~~.~~ The county shall create a process and procedure for the issuing of permits for each AMBULANCE ~~vehicle~~ used by the ambulance service.

B)~~.~~ The type of permit issued will describe the ~~maximum~~ level of service that could be provided at any time by that ~~vehicle~~ AMBULANCE and appropriate staff. Types of permissible permits are limited to:

1)~~.~~ Ambulance basic life support

2). Ambulance advanced life support.

~~3.~~

C) Each county ~~shall~~ MAY include in ~~their~~ ITS resolution or regulations the requirements for identification of the permitted level of service on each vehicle issued a permit.

3.5 Licensure Period

3.5.1 The licensure period for all ambulance services shall be for twelve months.

3.6 License Renewal

3.6.1 Counties shall create an annual license renewal process. ~~The license renewal process shall require the ambulance service to submit a completed renewal application form and the required licensure fee, as defined in county resolution or regulations.~~ The licensure renewal process shall require the receipt of applications for renewal no less than 30 days before the date of license expiration.

Section 4 – Complaints

4.1 Each county SHALL ~~must~~ have a written complaint and investigation policy and procedure to address:

4.1.1 complaints against any ambulance service licensed in the county.

4.1.2 allegations of unlicensed ambulance services or vehicles without a valid permit operating within the county.

4.2 The policy shall include, but not be limited to:~~,~~

4.2.1 ~~t~~The procedures ~~associated with~~ CONCERNING complaint intake, INCLUDING POSTED INFORMATION TO THE PUBLIC CONCERNING HOW TO FILE A COMPLAINT;

4.2.2 THE COUNTY'S DUTY TO PROVIDE THE LICENSEE WITH A COPY OF THE COMPLAINT AT THE TIME IT IS FILED;

4.2.3 complaint validation;

4.2.4. THE criteria for initiating an investigation;

4.2.5 ~~a~~ THE method for ~~notification to~~ NOTIFYING the complainant about the resolution of the investigation;

4.2.6 THE METHOD FOR NOTIFYING THE DEPARTMENT AND MEDICAL DIRECTORS REGARDING COMPLAINTS INVOLVING EMS PROVIDERS; and

4.2.7 ~~a~~ THE method for ~~the notification of other local entities~~ NOTIFYING OTHER COUNTIES with jurisdiction over ambulance services, the department ~~and/or the Colorado Medical Board for~~ AND, IF APPLICABLE, THE COLORADO DEPARTMENT OF REGULATORY AGENCIES ABOUT complaints regarding ~~EMS Providers or~~ other medical personnel associated with the AMBULANCE service or the medical director.

4.3 The county shall notify the primary medical director of the ambulance service, in writing, of any KNOWN violation of the ambulance licensing regulations by the ambulance service or KNOWN alleged complaints or violations OF THE AMBULANCE LICENSING REGULATIONS by individual medical providers operating on an ambulance service.

Section 5 – Denial, Revocation, Or Suspension Of Licensure And Vehicle Permits

5.1 Each county shall develop policies and procedures for the denial, suspension or revocation of an ambulance service license or ambulance permit consistent with § 25-3.5-304, ~~CRS.~~C.R.S.

Section 6 – Minimum Data Collection And Reporting Requirements

6.1 The county shall require that licensed ambulance services ~~complete a patient care report~~ PROVIDE PATIENT CARE INFORMATION INCLUDING ~~for each patient that is assessed. The patient care report shall include~~ the minimum pre-hospital care data set ~~as set forth in~~ TO THE

DEPARTMENT PURSUANT TO the Rules Pertaining to Emergency Medical Services Data and Information Collection and Record Keeping at 6 CCR 1015-3, Chapter Three.

6.2 ~~The county shall require that the ambulance service provide patient care information to the department pursuant to the Rules Pertaining to Emergency Medical Services Data and Information Collection and Record Keeping at 6 CCR 1015-3, Chapter Three.~~

THE COUNTY SHALL REQUIRE THAT EACH LICENSED AMBULANCE SERVICE COMPLETE AND SUBMIT TO THE DEPARTMENT AN ORGANIZATIONAL PROFILE PURSUANT TO THE RULES PERTAINING TO EMERGENY MEDICAL SERVICES DATA AND INFORMATION COLLECTION AND RECORDKEEPING AT 6 CCR 1015-3, CHAPTER THREE.

6.3 ~~The county shall require that each licensed ambulance service complete and submit to the department an agency profile as defined by the State Emergency Medical and Trauma Services Advisory Council and approved by the department to provide information on resources available for planning and coordination of statewide emergency medical and trauma services on an annual basis.~~

UPON DEPARTMENT REQUEST, THE COUNTY SHALL VERIFY THE LIST OF LICENSED AMBULANCE SERVICES AND THE VEHICLES PERMITTED BY SUCH SERVICES TO PROVIDE EMERGENCY MEDICAL AND TRAUMA SERVICES.

Section 7 – Minimum Staffing Requirements

7.1 AT MINIMUM, ~~T~~the county shall establish by resolution or regulations THE FOLLOWING ambulance staffing requirements ~~to include, but not be limited to~~:

7.1.1 ~~The minimum requirement for~~ FOR the person responsible for providing direct emergency medical care to patients transported in an ambulance, A CURRENT AND VALID ~~is~~ certification as an EMS Provider as defined in the Rules Pertaining to EMS Education and Certification at 6 CCR 1015-3, Chapter One.

7.1.2 ~~The minimum requirement for~~ FOR the ambulance driver, ~~shall be~~ a CURRENT AND valid driver's license.

7.2 Consistent with § 25-3.5-202, ~~CRS~~ C.R.S., in the case of an emergency in any ambulance service area where no person possessing the qualifications required by this section is present or available to respond to a call for the emergency treatment and transportation of patients by ambulance, any person may operate such ambulance to transport any sick, injured, or otherwise incapacitated or helpless person in order to stabilize the medical condition of such person. ~~pending the availability of personnel meeting these minimum qualifications.~~

Section 8 – Medical Oversight and CONTINUOUS Quality ~~Improvement~~ MANAGEMENT

8.1 The county shall require each ambulance service operating within ~~their~~ ITS jurisdiction to have a primary medical director meeting the requirements as defined in the EMS Practice and Medical Director Oversight Rules at 6 CCR 1015-3, Chapter Two to supervise the medical acts performed by ~~all personnel on~~ EMS PROVIDERS OF the ambulance service AGENCY. The county shall require a licensee to inform the county within ~~15 calendar~~ 14 BUSINESS days, in writing, of changes in medical oversight of the ambulance service and/or the medical director of record.

8.2 THE COUNTY SHALL REQUIRE EACH LICENSED AMBULANCE SERVICE OPERATING WITHIN ITS JURISDICTION TO HAVE AN ONGOING MEDICAL CQM PROGRAM CONSISTENT WITH THE REQUIREMENTS AS DEFINED IN THE EMS PRACTICE AND MEDICAL DIRECTOR OVERSIGHT RULES AT 6 CCR 1015-3, CHAPTER TWO.

~~The county ambulance service licensure application shall include an attestation by the medical director of willingness to provide medical oversight and a medical continuous quality improvement program for the ambulance service~~.

8.3 THE COUNTY AMBULANCE SERVICE LICENSURE APPLICATION SHALL INCLUDE AN ATTESTATION BY THE MEDICAL DIRECTOR OF WILLINGNESS TO PROVIDE MEDICAL OVERSIGHT AND THE MEDICAL CQM PROGRAM FOR THE AMBULANCE SERVICE.

~~The county shall require each licensed ambulance service operating within their jurisdiction to have an ongoing medical continuous quality improvement program consistent with the requirements as defined in the EMS Practice and Medical Director Oversight Rules at 6 CCR 1015-3, Chapter Two.~~

Section 9 – Minimum Equipment Requirements

9.1 Counties shall ensure that permitted ambulances are in compliance with the minimum equipment list for the type of service defined by their permitS as defined in 9.2 and 9.3 of these rules.

9.2 Minimum Equipment For Basic Life Support Ambulances

9.2.1 Ventilation And Airway Equipment

A)~~.~~ ~~portable~~ PORTABLE suction unit, and a house (fixed system) or backup suction unit, with wide bore tubing, rigid pharyngeal curved suction tip, and soft catheter suction tips to include ADULT AND pediatric sizes~~. 6 fr. through 14 fr.~~

B)~~.~~ ~~bulb~~ BULB syringe AND BBG SUCTION CATHETER.

C)~~.~~ FIXED (house) oxygen and portable oxygen bottle, each with a variable flow regulator.

D)~~.~~ ~~transparent~~ TRANSPARENT, non-rebreather oxygen masks and nasal cannula in adult sizes, and transparent, non-rebreather oxygen masks in pediatric sizes.

E)~~.~~ ~~hand~~ HAND operated, self-inflating bag-valve mask resuscitators with oxygen reservoirs and standard 15mm /21mm fittings in the following sizes:

1)~~.~~ ~~500cc bag~~ for infant and neonate

2)~~.~~ ~~750cc bag~~ for children

3)~~.~~ ~~1000cc~~ bag for adult

4)~~.~~ ~~Transparent~~ TRANSPARENT masks for infants, neonate patients, children and adults.

F)~~.~~ ~~nasopharyngeal~~ NASOPHARYNGEAL airways in adult sizes 24 FR. ~~fr.~~ through 32 FR. ~~fr.~~

G)~~.~~ ~~o~~Oropharyngeal airways in adult and pediatric sizes to include: infant, child, small adult, adult and large adult.

9.2.2 Patient Assessment Equipment

A)~~.~~ ~~b~~ Blood pressure cuffs to include large adult, regular adult, child and infant sizes.

B). s Stethoscope.

C). penlight AN ILLUMINATION DEVICE CAPABLE OF APPROPRIATELY TESTING FOR PUPILLARY REACTION.

D). PULSE OXIMETER WITH ADULT AND PEDIATRIC SENSORS.

9.2.3 Splinting Equipment

A). l Lower extremity traction splint.

B). u Upper and lower extremity splints.

C). l Long board, scoop TM STRETCHER, vacuum mattress or equivalent with appropriate accessories to immobilize SECURE the patient from head to heels.

D). s Short board, K.E.D. EXTRICATION DEVICE or equivalent, with the ability to immobilize SECURE the patient from head to pelvis.

E). p Pediatric spine LONG board or adult spine LONG board that can be adapted for pediatric use.

F). a Adult and pediatric head immobilization equipment.

G). a Adult and pediatric cervical spine immobilization equipment. per medical director protocol.

9.2.4 Dressing Materials

A). MULTIPLE bandages —AND DRESSINGS OF various types and sizes, INCLUDING OCCLUSIVE DRESSINGS. per agency needs and medical director protocol.

B). multiple dressings (including occlusive dressings), various sizes per ambulance service requirements, needs and medical director protocol.

BC). S Sterile burn sheets.

D C) a Adhesive tape. per ambulance service requirements, needs and medical director protocol.

D) ARTERIAL TOURNIQUET.

9.2.5 Obstetrical Supplies

A). sterile ob OB kit to include: towels, 4x4 dressings, umbilical tape or cord clamps, scissors, bulb syringe, sterile gloves and thermal absorbent blanket.; AND

B). nNeonate stocking cap or equivalent.

9.2.6 Miscellaneous Equipment

A). h Heavy bandage scissors, shears or equivalent capable of cutting clothing, belts, boots, etc.

B). AT LEAST ONE two working flashlights.

C). b Blankets. and appropriate heat source for the ambulance patient compartment.

9.2.7 Ambulance Service Medical Treatment Protocols.

9.2.87 Communications Equipment

A. All communications equipment shall be maintained in good working order. The communications equipment must be capable of transmitting and receiving clear voice communications.

B.A) Two-way communications IN GOOD WORKING ORDER that will enable the CLEAR VOICE COMMUNICATIONS BETWEEN ambulance personnel to communicate with AND THE:

1) ambulance service's dispatch.

2). medical control facility or a THE MEDICAL CONTROL physician

3). receiving facilities

4). mutual aid agencies.

9.2.9 Extrication Equipment

A. Each ambulance should carry extrication equipment appropriate for the level of extrication the ambulance service provides and in accordance with the requirements established by the county in which the ambulance is licensed.

9.2.10 8 Body Substance Isolation (BSI) Equipment Properly Sized To Fit All Personnel

A). nNon-sterile disposable LATEX FREE gloves, to include a minimum 1 box of latex free gloves.

B). p Protective eyewear.

C). n Non-sterile surgical masks.

D. safety protection gear for extrication consistent with the ambulance service extrication capabilities.

ED). S Sharps containers AND RECEPTACLES for the appropriate disposal and storage of medical waste and biohazards.

F.E) NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH (NIOSH) APPROVED N-95 OR SUPERIOR PARTICULATE FILTERING RESPIRATOR (MASK), HEPA masks, which can be of universal size.

9.2.119 Safety Equipment

A). a A set of three (3) warning reflectors.

B). o0ne (1) ten pound (10 lb.) or two (2) five pound (5 lb.) ABC fire extinguishers, with a minimum of one extinguisher accessible from the patient compartment and vehicle exterior.

C)~~.~~ ~~c~~ Child PROTECTIVE RESTRAINT SYSTEM THAT ACCOMMODATES A WEIGHT RANGE BETWEEN 5 AND 99 LBS. ~~safety seat or appropriate protective restraints for patients, crew, accompanying family members and other vehicle occupants.~~

D) APPROPRIATE PROTECTIVE RESTRAINTS FOR PATIENTS, CREW, ACCOMPANYING FAMILY MEMBERS AND OTHER VEHICLE OCCUPANTS.

~~D~~ E)~~.~~ ~~p~~ Properly secured patient transport system (i.e. wheeled stretcher).

~~E~~F)~~.~~ DEPARTMENT APPROVED triage tags ~~as approved by the department~~.

9.2.10 PHARMACALOGICAL AGENTS

A) PHARMACALOGICAL AGENTS AND DELIVERY DEVICES PER MEDICAL DIRECTOR APPROVAL.

B) PEDIATRIC “LENGTH BASED” DEVICE FOR SIZING DRUG DOSAGE CALCULATIONS AND SIZING EQUIPMENT.

9.2.11 PEDIATRIC REFERENCE TOOL

A) ONE (1) PEDIATRIC DRUG DOSAGE CHART OR TAPE: THIS MAY INCLUDE CHARTS LISTING THE DRUG DOSAGES IN MILLILITERS PER KILOGRAM. PRE-CALCULATED DOSES BASED ON WEIGHT, OR A TAPE THAT GENERATES APPROPRIATE EQUIPMENT SIZES AND DRUG DOSES BASED ON THE PATIENT’S HEIGHT OR WEIGHT.

B) VITAL SIGNS.

9.3 Minimum Equipment Requirement for Advanced Life Support Ambulances

9.3.1 All Equipment AND SUPPLIES ~~Listed~~ LISTED In Section 9.2

9.3.2 Ventilation Equipment

A)~~.~~ ~~a~~ Adult and pediatric ADVANCED AIRWAY ~~endotracheal intubation~~ equipment ~~to include stylets and an endotracheal tube stabilization device and endotracheal tubes uncuffed range from 2/5 - 5/5, and cuffed size range from 6.0-8.0~~ per medical director ~~protocol~~ APPROVAL.

~~B. laryngoscope and blades, straight and/or curved of sizes 0-4.~~

~~C~~B)~~.~~ ~~adult~~ ADULT and pediatric ~~m~~Magill forceps.

~~D~~C)~~.~~ ~~e~~End tidal ~~co~~ CO_2 MONITOR OR DETECTION DEVICE FOR DETERMINING ADVANCED AIRWAY DEVICE ~~detector or alternative device, approved by the FDA, for determining end tube~~ placement.

9.3.3 Patient Assessment Equipment

A)~~.~~ ~~p~~Portable, battery operated cardiac monitor-defibrillator with strip chart recorder and adult and pediatric EKG electrodes and defibrillation capabilities.

B). pulse oximeter with adult and pediatric probes.

CB). e Electronic blood glucose measuring device.

9.3.4 Intravenous Equipment

A). a Adult and pediatric:

1) intravenous solutions: AND and

2) administration equipment. per medical director protocol.

B). INTRAOSSEOUS:

1) ACCESS DEVICE; AND

2) ADMINISTRATION EQUIPMENT.

C) adult ADULT and pediatric intravenous arm boards.

9.3.5 Pharmacological Agents

A). p Pharmacological agents and delivery devices per medical director protocol APPROVAL.

B). p Pediatric “length based” device for sizing drug dosage calculations and sizing equipment.