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: Michelle Reese, Deputy Director, Health Facilities and Emergency Medical Services Division

Through: Randy Kuykendall, Director, Health Facilities and Emergency Medical Services Division, DRK

Date: October 19 2017

Subject: **Rulemaking Hearing**
Proposed New Part to 6 CCR 1011-3, Standards for Community Integrated Health Care Service Agencies**,** for the rulemaking hearing to occur in October of 2017

The Department is proposing rules to implement Senate Bill 16-069, which authorizes the Department to license Community Integrated Health Care Service (CIHCS) Agencies. The Department will be requesting a January 1, 2018 effective date for the proposed rules.

Over the last several years the delivery of health care has undergone significant changes. As a result, new and innovative programs have emerged that are referred to as "community paramedicine," (CP) "mobile integrated health care," (MIH) and now, CIHCS. In general, these programs address the needs of "gap" patients within a community, those who lack the resources, financial or otherwise, to receive appropriate care in the most effective manner. Currently these gap patients are using emergency medical service agencies and departments to address medical needs that do not require those levels of resources. By providing a coordinated and holistic assessment of the patient's needs, these programs can provide more effective, appropriate and targeted care and navigation to appropriate resources.

In the mid-2000's a few Colorado emergency medical service agencies developed various CP programs to serve their communities. The Department was aware of the programs; however, because the Department does not license EMS agencies (EMS agencies are licensed by counties), no existing regulatory framework clearly applied to EMS agencies that utilized their personnel to provide non-emergent services in the home. In 2012, the Department convened a group of interested stakeholders to discuss issues surrounding the practice, but their robust discussion did not result in an agreed-upon path forward. In January 2015 the Department concluded that the existing EMS and home care agency laws required EMS agencies providing non-emergency, skilled home health or personal care services to be licensed by the department as a home care agency.

That same month, the State Emergency Medical and Trauma Services Advisory Council (SEMTAC) created a CP/MIH Task Force with representatives from various stakeholder groups to address questions concerning the role of CP programs in Colorado. Among other things, the task force was charged with defining the scope of work to be performed by CP versus those provided by traditional "emergency" services, and to determine whether CP and home health service providers could collaborate to address the needs of medically underserved patients without overlap. Moreover, the task force sought to determine whether local CP programs could more effectively promote collaboration and innovation, and avoid excessive regulatory burdens, by focusing on the community's underserviced medical needs. Its resulting recommendation forms the building block for the CIHCS health care services program that utilizes CPs and other types of health care business entities and providers in a more broad-based and inclusive model.

Senate Bill 16-069 is a bill that was based, in part, on the 2015 task force recommendation. After extensive negotiations among many interested parties, the bill was passed by the General Assembly and signed into law on June 8, 2016. The bill, now codified within Title 25, Part 3.5 of the Colorado Revised Statutes, creates three new community health care constructs.

First, Senate Bill 16-069 creates a CP endorsement for emergency medical service providers who meet required educational and credentialing requirements. The Department formed a separate CP endorsement task force to develop these rules, which will be presented to the Board of Health and Executive Director and Chief Medical Officer, Dr. Larry Wolk, for hearings in October under a separate rulemaking.

Second, the statute creates Community Assistance Referral and Education Services ("CARES") programs to provide consumers with medical resource navigation and referral information as alternatives to 911 and emergency medical services. The statute does not allow regulation of CARES programs, but does require annual reporting requirements for new programs.

Third, it creates a new licensing category and pathway for agencies to offer out-of-hospital medical services as licensed CIHCS Agencies. By law, the Board's rules must become effective on or before January 1, 2018. Consequently, in September 2016, the Department convened a task force to develop implementing rules. The rules now before the Board apply to the newly-created licensure category, and address CIHCS agency licensure standards. Under the law, the rules must address: (1) CIHCS agency medical direction requirements; (2) Department inspection of agencies; (3) Minimum educational training and experience standards for administrator and staff; (4) License fees from applicants, including governmental entities; (5) Insurance requirements; (6) Occurrence reporting; and (7) Record retention and agency reporting requirements. In addition to addressing these requirements, the rules set forth necessary definitions such as "out-of-hospital medical services" and standards governing CIHCS Agency operations, including consumer eligibility, types of services CIHCS Agencies may provide, and required service plan, assessment, and discharge procedures. The rules also restrict currently-regulated CIHCS Agency providers to their existing scopes of practice, and follow the CP endorsement task force's recommendation regarding CP scope of practice by prohibiting unendorsed EMS providers from performing direct non-emergent medical care to CIHCS Agency consumers.

During its eleven-month tenure, the CIHCS task force worked to identify and reach consensus concerning: (1) the defined categories of eligible CIHCS service recipients; (2) the characteristics distinguishing CIHCS agencies and providers from other health facility agencies and providers; and (3) the level of medical direction necessary in a CIHCS agency. The task force ultimately reached consensus regarding all these issues.

The Colorado State Fire Chiefs Association (CSFCA) representative raised an objection concerning the statutory limitations on CIHCS services that non-endorsed EMS providers may perform. The new law permits CIHCS Agencies to provide services, "as determined by rule,that a community paramedic may provide." The statute defines "community paramedic" as an EMS provider who obtains the newly-created endorsement. Toward the beginning of the task force process, the Department interpreted the totality of Senate Bill 16-069's plain language to require EMS personnel who provide direct medical CIHCS services to obtain the CP endorsement. The CP endorsement task force concurred; therefore, its proposed rules require these credentials to provide direct medical services as a CIHCS provider. The CIHCS task force developed congruent rules that limit unendorsed EMS personnel to providing ancillary non-medical CIHCS and CARES services, as provided in Section 25-3.5-1203(3), C.R.S.

The statute further requires all EMS providers who wish to obtain a CP endorsement to pass a national test certifying competency to practice community paramedicine. Currently the only nationally offered community paramedicine test available is for individuals at the paramedic level (versus the EMT, Advanced EMT and Intermediate EMT levels). Consequently, EMS providers who

are not certified paramedics cannot take the test at this time.[1] The Department understands the rule will impact EMS programs that utilize unendorsed EMS personnel, but believes the situation will be remedied when the national testing agency develops additional tests for other EMS personnel. The Department believes that the rule, as developed, is necessary because of the plain statutory language. The CSFCA stakeholder acknowledges that the statutory CP endorsement requirement will necessarily limit unendorsed EMS providers from performing certain out-of-hospital medical services on behalf of a CIHCS Agency, but reiterated his concern that the requirement may disrupt existing CIHCS-type programs.

Senate Bill 16-069 is included in this rulemaking packet for reference.

[1] The International Board of Specialty Certification (IBSC) testing agency anticipates developing national CP competency tests for other non-paramedic EMS providers in the future.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for new rule
6 CCR 1011-3 Standards for Community Integrated Health Care Service Agencies

Basis and Purpose.

Senate Bill 16-069 was signed into law on June 8, 2016. The legislation creates a new licensing category for agencies to offer out-of-hospital medical services as licensed Community Integrated Health Care Service (CIHCS) Agencies.

The Board of Health is directed to promulgate rules that establish the minimum licensing requirements for CIHCS Agencies. The proposed CIHCS Agency rules were developed collaboratively by the Department and a task force consisting of representatives of affected entities and interested parties. These rules address the CIHCS Agency licensure standards.

The rules establish definitions necessary to implement the law, such as "out-of-hospital medical services," and "community integrated health care services provider."[2] The rules also delineate the requirements for:

- License applications, including:
    - The applicant's submission of a community needs assessment that identifies the medical service gaps in the community to be served,
    - Provision of written notice to the board of county commissioners in any jurisdictions in which the applicant plans to operate as a CIHCS Agency,
    - Criminal background checks--including fingerprint checks--of the Agency owner[s] and administrator[s],
    - Required Colorado Adult Protective Services Data System ("CAPS") check for all Agency employees providing direct consumer care, beginning January 1, 2019,
    - Liability insurance for injuries to persons, in amounts determined by the board, and as required by Colorado law,
    - Establishing reasonable fees for licensure and for on-site inspections, investigations, changes of ownership, and other activities related to licensure, and
    - Issuance of initial, renewal, and provisional licenses, and other necessary licenses;
- Minimum qualifications, training, and roles and responsibilities for CIHCS administrators, endorsed Community Paramedics, other CIHCS providers and administrative staff;
- Minimum qualifications, training, and roles and responsibilities for CIHCS Agency medical directors who supervise Community Paramedics and/or other CIHCS providers;

[2] Rule 2.9 defines a CIHCS provider as "A person who, through employment or under contract, performs certain out-of-hospital medical services, as determined by rule, on behalf of a CIHCS Agency . . . ." CIHCS providers include: (1) CPs; (2) health care providers who are licensed, registered, or certified by the Department of Regulatory Agencies (DORA) and are supervised and directed by a CIHCS medical director; (3) unlicensed individuals who lawfully engage in practices not regulated by DORA and are supervised and directed by a CIHCS medical director; (4) individuals who fulfill a consumer's CIHCS service plan while employed by or contracted with a CIHCS Agency; and (5) unendorsed EMS providers, who may perform ancillary non-medical services for non-emergent conditions and any services that may be provided through a CARES Program as set forth in Section 25-3.5-1203(3), C.R.S.

- Eligibility requirements for CIHCS consumers;
- Standards applying to single CIHCS visits;
- Standards and procedures applying to recurrent Agency services, including assessment and discharge standards;
- Minimum standards, policies, and procedures governing CIHCS Agency operations, including consumer rights, staffing, training, service planning, care coordination, access to Agency services and consumer records, complaints, required reporting requirements, agency quality management program, and record retention requirements;
- Standards governing CIHCS Agency provision of CARES program services; and
- The procedure and grounds for the suspension, revocation, or denial of a license.

The legislation requires the rules to be promulgated on or before January 1, 2018; therefore, the Department requests an effective date of January 1, 2018.

Senate Bill 16-069 also required the creation of a Community Paramedic endorsement for emergency medical service providers who meet certain educational and credentialing requirements, which mandates changes to 6 CCR 1015-3, Chapter One and Chapter Two. A hearing on the proposed changes to Chapter One, Rules Pertaining to EMS and EMR Education, EMCS Certification and EMR Registration will be held by the Board of Health in October 2017. Under a separate rulemaking, proposed changes to Chapter Two, Rules Pertaining to EMS Practice and Medical Director Oversight, will be heard by the Executive Director/Chief Medical Officer at the same time.

The statute also creates Community Assistance Referral and Education Services programs ("CARES") for the purpose of providing consumers with medical resource navigation and referral information as alternatives to 911 and emergency medical services. Any entity that provided services prior to January 1, 2015 that now qualifies as a CARES program is exempt from complying with the statutory reporting requirements of Sections 25-3.5-1201 through 1204, C.R.S. until June 20, 2021. The proposed rules do not include any regulation of CARES programs.

Specific Statutory Authority.
These rules are promulgated pursuant to the following statutes:

Sections 25-3.5-1302, 25-3.5-1303 and 25-3.5-1305, C.R.S. and Section 25-3.5-103(4.3), C.R.S.

Sections 25-3.5-1301 *et seq.*, and 26-3.1-111, C.R.S. (SB 17-1284)

Is this rulemaking due to a change in state statute?

X Yes, the bill number is SB 16-069. Rules are required.

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

_____ Yes
X No

Does this rulemaking incorporate materials by reference?

_____ Yes
X No

If "Yes," the rule needs to provide the URL of where the material is available on the internet (CDPHE website recommended) or the Division needs to provide one print or

electronic copy of the incorporated material to the State Publications Library. § 24-4-103(12.5)(c), C.R.S.

Does this rulemaking create or modify fines or fees?

X Yes
_____ No

REGULATORY ANALYSIS
for new rule
6 CCR 1011-3 Standards for Community Integrated Health Care Service Agencies

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

   By statute the proposed new rules affect any qualified applicant[3] who seeks to manage and offer, directly or by contract, community integrated health care services in the state of Colorado. In addition, the proposed new rules benefit any individual who is a recipient of community integrated health care services within the state of Colorado. The proposed rules should reduce the burden on emergency services such as 911 and emergency departments by decreasing unnecessary utilization of their resources.

   To the extent that current EMS programs are performing out-of-hospital medical services upon patients with non-emergent conditions, these programs will need to make a determination whether they will require a CIHCS Agency license or will limit their services with CARES program requirements.

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.

   The proposed rules create a new agency licensing category that permit a community-based team of qualified CIHCS providers to provide non-duplicative out-of-hospital medical services to individuals who are experiencing intermittent health care issues.

   CIHCS Agency services are intended to address the unmet medical needs of individuals in the community in which it operates who fall within primary and public health care system gaps. Once the CIHCS Agency identifies its community gap consumers, the Agency will assess and treat them outside of the hospital for the purposes of preventing or improving a particular medical condition.

   As noted, the rules are intended to decrease the unnecessary utilization of 911 and emergency department medical services, which, in turn, will benefit those resources and decrease costs to the health care system. However, entities who apply for a CIHCS Agency license to provide these services will incur licensing fees and attendant compliance costs. Likewise, entities currently providing these types of services will be required to obtain a license to continue to provide these services.

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

   The Department received General Fund monies to support the stakeholder and rulemaking processes. The allocated funds will be eliminated as of June 30, 2018. On July 1, 2018 all agencies will need to be licensed and at that point the program will become funded solely on cash funds generated from application fees. The new rule proposes a fee structure that covers costs related to the applicant CIHCS Agency's licensing and inspection costs, costs relative to changes in ownership, travel costs, and legal costs associated with complaints and adverse licensing actions. The Colorado Bureau of Investigations (CBI) and Federal Bureau of Investigations (FBI) will also incur costs associated with the processing of owner

[3] "Any individual, sole proprietorship, partnership, corporation, non-profit entity, special district, governmental unit or agency, or licensed or certified health care facility that is subject to regulation under Article 1.5 or Article 3 of Title 25 that manages and offers, directly or by contact, community integrated health care services within the state of Colorado." Section 25-3.5-301(1), C.R.S.

and administrator criminal background checks. Payment for criminal background checks will be paid by the applicant directly to the CBI and/or FBI.

The fiscal note to SB 16-069 estimated an initial license fee. This estimate was evaluated during the stakeholder process and the rule now proposes a $3,000 initial license fee. The Department will monitor the fee and return to the board with a request to adjust the fee when appropriate. The fiscal note to SB 16-069 also anticipated 25 CIHCS Agencies will be licensed in FY 2018-2019. Based on working with stakeholders through the stakeholder process, this assumption has changed. The Department anticipates that the new licensing category will attract ten initial license applications in year one of operation (FY18-19). During year two, the Department projects that another five applicants will seek initial CIHCS Agency licensure.

For licenses other than provisional, the license is valid for one year. On-site inspections are on a three-year renewal cycle after the initial inspection has occurred, unless complaints, occurrences, or other events necessitate Department action. The three-year cycle recognizes the state resources needed for a site visit and balances this cost with the need for reasonable fees so Coloradans can receive services. The complaint process enables the Department to investigate and take appropriate measures to ensure public health and safety between inspections.

The Department anticipates it will collect state revenue in the amount of $30,000 in the first year of licensure. It will incur expenses from initial inspections and complaint investigations in the amount of $22,160.

Estimated Cash Fund Revenues			
Type of Revenue	**Year 1**	**Year 2**	**2-year Total**
Initial Agency Licenses*	$30,000	$15,000	$45,000
Renewal Licenses	$0	$17,000	$17,000
Total	$30,000	$32,000	**$62,000**
Estimated Expenditures			
Type of Expenditure	**Year 1**	**Year 2****	**2-year Total**
Initial Survey	($13,339)	($6,669)	($20,008)
Renewal Survey	$0	($9,142)	($9,142)
Complaint Survey	($8,822)	($13,232)	($22,054)
Total	($22,161)	($29,043)	**($51,204)**

* The Department also assumes 10 initial licenses in Year 1; 5 initial licenses in Year 2.
**The Department assumes a complaint rate of 40%.

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

Inaction is not an option. Senate Bill 16-069 requires promulgation of rules by January 1, 2018.

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

There is no less costly or intrusive method for achieving the purpose of the proposed rules. Senate Bill 16-069 requires rules to be promulgated by the Board of Health, as well as fees

to be set to cover all costs incurred by the Department to implement the new licensing program. The proposed rules were created through a collaborative process between the Department and a task force consisting of interested and potentially affected entities.

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

The statute mandates the rules. Therefore, no alternative methods were considered. Senate Bill 16-069 requires promulgation of rules by January 1, 2018. The task force has been meeting at least once a month from September 2016 through June 2017 to reach consensus on the proposed rule language.

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

The Department surveyed a majority of jurisdictions across the U.S. that operate community paramedicine and/or mobile integrated health care programs in other states and presented the information to the task force. After consideration, the task force and department determined which elements were congruent with the Colorado law and compatible with existing facility licensing. As Senate Bill 16-069 creates a unique health care business model in the United States, it is difficult to quantify short and long-term consequences at this time.

Recently several governmental entities, including states, counties, and municipalities, have created mobile integrated /community paramedicine programs through statute or code, or pilot programs to provide out-of-hospital non-emergent medical services to gap patients who have little access to medical services, or who otherwise access emergency medical services or emergency departments for their medical needs. The Department conducted an extensive survey of these programs and found that numerous community paramedicine programs solely and exclusively utilize EMS providers from EMS agencies. Colorado's statutory program is unique in that it does not confine either the agency, or the provision of community integrated health care services, to an EMS model. Instead, the legislation directs the Department to license any qualified applicant and allows licensed CIHCS agencies to employ or contract with many different types of providers to serve the out-of-hospital medical needs of eligible CIHCS consumers.

Over the course of several months, the task force considered these various models. Within the boundaries of Colorado's law and existing regulatory structure, the task force then integrated some of these components into a new framework of regulatory requirements to meet the needs of Coloradans.

In the short-term, the proposed rules will require entities that are already providing these types of services to comply with uniform minimum requirements through the licensure process and, consequently, to protect the health and safety of Colorado consumers.

In the long term, the Department anticipates that the rule's implementation will encourage local community providers to collaborate and assess the needs of the consumers they serve, address those needs responsively and without redundancy, and reduce the demands made upon emergency and 911 providers by people who require non-urgent medical attention.

The rules intend to tailor the needs of the gap consumer with an appropriate medical response, thereby advancing and protecting the health, safety, and welfare of Colorado citizens. At the same time, the Department anticipates that licensed CIHCS agencies may become eligible for reimbursement from governmental or private payer sources for their community integrated health care services in the future.

STAKEHOLDER COMMENTS
for new rule
6 CCR 1011-3 Standards for Community Integrated Health Care Service Agencies

State law requires agencies to establish a representative group of participants when considering whether 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: The Department formed a task force comprised of a broad cross-section of interested stakeholders. Membership included:

Organization	**Representative**
Colorado Association of Local Public Health Officials	Yvonne Long
Center for Health Progress-fka Colorado Coalition of Medically Underserved	Aubrey Hill
Colorado Counties, Inc.	Cindy Dicken, Gini Pingenot
Colorado Hospital Association	Gail Finley, Amber Burkhart
Colorado Municipal League	Meghan Dollar
Colorado Nurses Association	Colleen Casper, Lauren Snyder
Colorado State Fire Chiefs Association	Rick Lewis, Gordie Olson, Ralph Vickrey
Emergency Medical Services Association of Colorado	Tim Dienst, Chris Montera
Home Care Association	Cathy Kaufmann, Sarah Engels
Home Care Advisory Committee	Sonya Neumann, David Bolin
International Association of Fire fighters	Dennis Eulberg, Thomas Breyer
State Emergency Medical and Trauma Services Advisory Council[4]	Thomas Davidson, Stephanie Eveatt

All task force meetings were appropriately noticed and open to the public.

Draft rules were posted on Health Facilities website for review since July 2017, with notice being sent to all facilities types that comments were being collected until August 31, 2017. During that two month period, the Department received a handful of comments, all of which were seeking some sort of clarification as to the rules' effect on their particular facility. Information was received from the X-Ray Certification and Mammography program within the Department that the requirements put forth in the rule previously were not accurate. They have now been updated. With this change, the Department has updated the rules on the Health Facilities website for review and provided notice to all facilities of the rulemaking hearing scheduled for October 19, 2017. The CIHCS Task Force was also notified via email of the changes on September 7, 2017.

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).

[4] The State Emergency Medical and Trauma Services Advisory Council (SEMTAC) includes: fire chiefs, emergency medical service providers, and county commissioners, among others.

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

X 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.

By the end of the task force process consensus was reached regarding the general policy issues encountered. While the task force unanimously recommended that the proposed rules proceed to a rulemaking hearing, the Colorado State Fire Chiefs Association (CSFCA) representative voiced objection to the part of the rules that prohibits non-Community Paramedic endorsed EMS providers from directly providing out-of-hospital medical services as part of a CIHCS Agency. However, the Department notes, and the CSFCA representative did not dispute, that this result is mandated by Senate Bill 16-069.

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

This program is directed at underserved communities and is intended to serve gap patients, those who lack access to adequate health care services. Early in the process, the task force agreed that CIHCS Agency applicants must identify the needs of gap patients within their service areas by conducting a community needs assessment. Based on the community needs assessment, the CIHCS Agency will be able to identify health equity concerns and work to address those concerns. The Department anticipates that the proposed rules will advance health equity for all Coloradans.

SENATE BILL 16-069

BY SENATOR(S) Garcia, Newell, Donovan, Lambert, Lundberg, Guzman, Kerr, Merrifield, Ulibarri, Aguilar, Carroll, Crowder, Heath, Hodge, Johnston, Kefalas, Todd;
also REPRESENTATIVE(S) Pabon, Williams, Esgar, Hamner, Lebsock, Salazar, Young, Duran, Ginal, Kraft-Tharp, Lee, Lontine, Melton, Mitsch Bush, Primavera, Ryden, Vigil, Winter, Hullinghorst.

CONCERNING MEASURES TO PROVIDE COMMUNITY-BASED OUT-OF-HOSPITAL MEDICAL SERVICES, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

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

SECTION 1. In Colorado Revised Statutes, 25-3.5-103, **add** (4.3) and (4.5) as follows:

25-3.5-103. Definitions. As used in this article, unless the context otherwise requires:

(4.3) "COMMUNITY INTEGRATED HEALTH CARE SERVICE" MEANS THE PROVISION OF CERTAIN OUT-OF-HOSPITAL MEDICAL SERVICES, AS DETERMINED BY RULE, THAT A COMMUNITY PARAMEDIC MAY PROVIDE.

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

(4.5) "COMMUNITY PARAMEDIC" MEANS AN EMERGENCY MEDICAL SERVICE PROVIDER WHO OBTAINS AN ENDORSEMENT IN COMMUNITY PARAMEDICINE PURSUANT TO SECTION 25-3.5-206.

SECTION 2. In Colorado Revised Statutes, **add** 25-3.5-203.5 as follows:

25-3.5-203.5. Community paramedic endorsement - rules. (1) ON OR BEFORE JANUARY 1, 2018, THE BOARD SHALL ADOPT RULES IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24, C.R.S., FOR COMMUNITY PARAMEDICS INCLUDING STANDARDS FOR:

(a) THE DEPARTMENT'S ISSUANCE OF AN ENDORSEMENT IN COMMUNITY PARAMEDICINE TO AN EMERGENCY MEDICAL SERVICE PROVIDER;

(b) VERIFYING AN EMERGENCY MEDICAL SERVICE PROVIDER'S COMPETENCY TO BE ENDORSED AS A COMMUNITY PARAMEDIC. THE STANDARDS MUST INCLUDE A REQUIREMENT THAT THE EMERGENCY MEDICAL SERVICE PROVIDER HAS OBTAINED FROM AN ACCREDITED PARAMEDIC TRAINING CENTER OR AN ACCREDITED COLLEGE OR UNIVERSITY A CERTIFICATE OF COMPLETION FOR A COURSE IN COMMUNITY PARAMEDICINE WITH COMPETENCY VERIFIED BY A PASSING SCORE ON AN EXAMINATION OFFERED NATIONALLY AND RECOGNIZED IN COLORADO FOR CERTIFYING COMPETENCY TO SERVE AS A COMMUNITY PARAMEDIC; AND

(c) CONTINUING COMPETENCY TO MAINTAIN A COMMUNITY PARAMEDIC ENDORSEMENT.

(2) RULES ADOPTED UNDER THIS SECTION SUPERSEDE ANY RULES OF THE COLORADO MEDICAL BOARD REGARDING THE MATTERS SET FORTH IN THIS PART 2.

SECTION 3. In Colorado Revised Statutes, 25-3.5-206, **add** (4) (a.5) as follows:

25-3.5-206. Emergency medical practice advisory council - creation - powers and duties - emergency medical service provider scope of practice - rules. (4) (a.5) (I) ON OR BEFORE JANUARY 1, 2018, THE DIRECTOR, OR, IF THE DIRECTOR IS NOT A PHYSICIAN, THE CHIEF

MEDICAL OFFICER SHALL ADOPT RULES IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24, C.R.S., CONCERNING THE SCOPE OF PRACTICE OF A COMMUNITY PARAMEDIC. AN EMERGENCY MEDICAL SERVICE PROVIDER'S ENDORSEMENT AS A COMMUNITY PARAMEDIC, ISSUED PURSUANT TO THE RULES ADOPTED UNDER SECTION 25-3.5-203.5, IS VALID FOR AS LONG AS THE EMERGENCY MEDICAL SERVICE PROVIDER MAINTAINS HIS OR HER CERTIFICATION BY THE DEPARTMENT.

(II) THE RULES MUST ESTABLISH THE TASKS AND PROCEDURES THAT AN EMERGENCY MEDICAL SERVICE PROVIDER WITH A COMMUNITY PARAMEDIC ENDORSEMENT IS AUTHORIZED TO PERFORM IN ADDITION TO AN EMERGENCY MEDICAL SERVICE PROVIDER'S SCOPE OF PRACTICE, INCLUDING:

(A) AN INITIAL ASSESSMENT OF THE PATIENT AND ANY SUBSEQUENT ASSESSMENTS, AS NEEDED;

(B) MEDICAL INTERVENTIONS;

(C) CARE COORDINATION;

(D) RESOURCE NAVIGATION;

(E) PATIENT EDUCATION;

(F) INVENTORY, COMPLIANCE, AND ADMINISTRATION OF MEDICATIONS; AND

(G) GATHERING OF LABORATORY AND DIAGNOSTIC DATA.

SECTION 4. In Colorado Revised Statutes, **add** parts 12 and 13 to article 3.5 of title 25 as follows:

PART 12
COMMUNITY ASSISTANCE REFERRAL AND EDUCATION SERVICES (CARES) PROGRAM

25-3.5-1201. Short title. THE SHORT TITLE OF THIS PART 12 IS THE "COMMUNITY ASSISTANCE REFERRAL AND EDUCATION SERVICES (CARES) PROGRAM ACT".

25-3.5-1202. Definitions. AS USED IN THIS PART 12, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "AUTHORIZED ENTITY" MEANS:

(a) A LICENSED AMBULANCE SERVICE;

(b) A FIRE DEPARTMENT OF A TOWN, CITY, OR CITY AND COUNTY;

(c) A FIRE PROTECTION DISTRICT, AMBULANCE DISTRICT, HEALTH ASSURANCE DISTRICT, HEALTH SERVICE DISTRICT, OR METROPOLITAN DISTRICT, OR SPECIAL DISTRICT AUTHORITY; OR

(d) A HEALTH CARE BUSINESS ENTITY, INCLUDING A LICENSED OR CERTIFIED HEALTH CARE FACILITY THAT IS SUBJECT TO REGULATION UNDER ARTICLE 3 OF THIS TITLE.

(2) "MEDICAL DIRECTION" MEANS THE SUPERVISION OVER AND DIRECTION OF INDIVIDUALS WHO PERFORM ACTS ON BEHALF OF A CARES PROGRAM BY A PHYSICIAN OR ADVANCED PRACTICE REGISTERED NURSE WHO IS LICENSED IN COLORADO AND IN GOOD STANDING AND WHO IS IDENTIFIED AS BEING RESPONSIBLE FOR ASSURING THE COMPETENCY OF THOSE INDIVIDUALS IN THE PERFORMANCE OF ACTS ON BEHALF OF THE CARES PROGRAM.

(3) "PROGRAM" OR "CARES PROGRAM" MEANS A COMMUNITY ASSISTANCE REFERRAL AND EDUCATION SERVICES PROGRAM ESTABLISHED IN ACCORDANCE WITH THIS PART 12.

25-3.5-1203. Community assistance referral and education services programs - authorization - scope - repeal. (1) TO IMPROVE THE HEALTH OF RESIDENTS WITHIN ITS JURISDICTION, PREVENT ILLNESS AND INJURY, OR REDUCE THE INCIDENCE OF 911 CALLS AND HOSPITAL EMERGENCY DEPARTMENT VISITS MADE FOR THE PURPOSE OF OBTAINING NONEMERGENCY, NONURGENT MEDICAL CARE OR SERVICES, AN AUTHORIZED ENTITY MAY ESTABLISH A COMMUNITY ASSISTANCE REFERRAL AND EDUCATION SERVICES PROGRAM TO PROVIDE COMMUNITY OUTREACH AND HEALTH EDUCATION TO RESIDENTS WITHIN THE AUTHORIZED ENTITY'S JURISDICTION.

(2) (a) ON OR AFTER JULY 1, 2018, AN AUTHORIZED ENTITY THAT OPERATES OR PLANS TO OPERATE A CARES PROGRAM IN COLORADO SHALL NOTIFY THE DEPARTMENT OF ITS CARES PROGRAM IN THE FORM AND MANNER REQUIRED BY THE DEPARTMENT.

(b) THE DEPARTMENT SHALL MAINTAIN A LIST OF ALL AUTHORIZED ENTITIES THAT OPERATE A CARES PROGRAM AND MAKE THE LIST ACCESSIBLE TO THE PUBLIC.

(c) AN AUTHORIZED ENTITY OPERATING A CARES PROGRAM SHALL NOT ASSERT THAT IT IS LICENSED OR CERTIFIED BY THE DEPARTMENT.

(3) SUBJECT TO MEDICAL DIRECTION, AN AUTHORIZED ENTITY OPERATING A PROGRAM MAY, WITHIN THE SCOPE OF PRACTICE OF ITS PRACTITIONERS:

(a) PROVIDE THE FOLLOWING SERVICES:

(I) HEALTH EDUCATION AND INFORMATION AVAILABLE ON RELEVANT SERVICES; AND

(II) REFERRALS FOR AND INFORMATION CONCERNING LOW-COST MEDICATION PROGRAMS AND ALTERNATIVE RESOURCES TO THE 911 SYSTEM;

(b) TO PROVIDE SERVICES IN ACCORDANCE WITH PARAGRAPH (a) OF THIS SUBSECTION (3) AND TO ENSURE NONDUPLICATION OF THE SERVICES, COLLABORATE WITH APPROPRIATE COMMUNITY RESOURCES, INCLUDING:

(I) HEALTH CARE FACILITIES LICENSED OR ISSUED A CERTIFICATE OF COMPLIANCE PURSUANT TO SECTION 25-1.5-103 OR SUBJECT TO REGULATION BY THE DEPARTMENT PURSUANT TO ARTICLE 1 OR 3 OF THIS TITLE;

(II) PRIMARY CARE PROVIDERS;

(III) OTHER HEALTH CARE PROFESSIONALS; OR

(IV) SOCIAL SERVICES AGENCIES.

(4) (a) AN AUTHORIZED ENTITY OPERATING A CARES PROGRAM SHALL NOT PROVIDE SERVICES THAT WOULD REQUIRE A LICENSE OR CERTIFICATION PURSUANT TO PART 13 OF THIS ARTICLE OR ARTICLE 3 OR 3.5 OF THIS TITLE.

(b) IN THE FORM AND MANNER PRESCRIBED BY THE DEPARTMENT AND BEFORE REFERRING A SERVICE OR PROVIDER TO A RECIPIENT OF A CARES PROGRAM SERVICE, AN AUTHORIZED ENTITY OPERATING A CARES PROGRAM SHALL DISCLOSE, AT A MINIMUM, IN WRITING, THE FOLLOWING INFORMATION TO THE RECIPIENT:

(I) ANY RELATIONSHIP THAT THE CARES PROGRAM HAS WITH AN INDIVIDUAL OR ENTITY TO WHICH IT REFERS A RECIPIENT OF CARES PROGRAM SERVICE; AND

(II) WHETHER THE AUTHORIZED ENTITY DIRECTS, CONTROLS, SCHEDULES, OR TRAINS ANY PROVIDER TO WHICH IT REFERS A RECIPIENT OF CARES PROGRAM SERVICES.

(5) THE DEPARTMENT MAY INVESTIGATE AN AUTHORIZED ENTITY AS IT DEEMS NECESSARY TO ENSURE:

(a) THE PROTECTION OF THE HEALTH, SAFETY, AND WELFARE OF A RECIPIENT OF CARES PROGRAM SERVICES; AND

(b) THAT THE AUTHORIZED ENTITY IS NOT PROVIDING SERVICES THROUGH ITS CARES PROGRAM THAT REQUIRE A LICENSE OR CERTIFICATION PURSUANT TO PART 13 OF THIS ARTICLE OR ARTICLE 3 OR 3.5 OF THIS TITLE.

(6) A PERSON WORKING DIRECTLY OR INDIRECTLY FOR A CARES PROGRAM, WHETHER AS AN EMPLOYEE OR A CONTRACTOR, MAY ONLY PROVIDE SERVICES CONSISTENT WITH THE REQUIREMENTS OF SUBSECTION (3) OF THIS SECTION; EXCEPT THAT NOTHING IN THIS SECTION PROHIBITS A LICENSED, CERTIFIED, OR REGISTERED HEALTH CARE OR MENTAL HEALTH PROVIDER OR CERTIFIED EMERGENCY MEDICAL SERVICE PROVIDER FROM ACTING OR PROVIDING SERVICES WITHIN HIS OR HER SCOPE OF PRACTICE IF NECESSARY TO RESPOND TO AN EMERGENT SITUATION.

(7) (a) IF AN ENTITY OFFERED COMMUNITY OUTREACH AND HEALTH

EDUCATION BEFORE JANUARY 1, 2015, THE ENTITY MAY CONTINUE AND NEED NOT COMPLY WITH THE REQUIREMENTS OF THIS PART 12. THE ENTITY MAY VOLUNTARILY PROVIDE REPORTS CONSISTENT WITH THE REQUIREMENTS OF SECTION 25-3.5-1204.

(b) THIS SUBSECTION (7) IS REPEALED, EFFECTIVE JULY 1, 2021.

25-3.5-1204. Reports. (1) (a) IF AN AUTHORIZED ENTITY DEVELOPS A PROGRAM UNDER THIS ARTICLE, THE AUTHORIZED ENTITY SHALL REPORT TO THE DEPARTMENT, IN THE FORM AND MANNER DETERMINED BY THE DEPARTMENT, ON THE PROGRESS OF THE PROGRAM ON OR BEFORE DECEMBER 31 IN THE YEAR FOLLOWING THE YEAR IN WHICH THE PROGRAM COMMENCED AND ON OR BEFORE DECEMBER 31 OF EACH SUBSEQUENT YEAR IN WHICH THE PROGRAM CONTINUES TO OPERATE.

(b) AN AUTHORIZED ENTITY'S REPORT MUST INCLUDE:

(I) THE NUMBER OF RESIDENTS WHO HAVE USED PROGRAM SERVICES AND THE TYPES OF PROGRAM SERVICES USED;

(II) A MEASUREMENT OF ANY REDUCTION IN THE USE OF THE 911 SYSTEM FOR NONEMERGENCY, NONURGENT MEDICAL ASSISTANCE BY RESIDENTS WITHIN THE AUTHORIZED ENTITY'S JURISDICTION; AND

(III) A MEASUREMENT OF ANY REDUCTION IN VISITS TO THE EMERGENCY DEPARTMENT IN A HOSPITAL FOR NONEMERGENCY, NONURGENT MEDICAL ASSISTANCE BY RESIDENTS WITHIN THE AUTHORIZED ENTITY'S JURISDICTION.

(c) AN AUTHORIZED ENTITY'S REPORT PURSUANT TO THIS SECTION MUST NOT INCLUDE ANY PERSONALLY IDENTIFIABLE INFORMATION CONCERNING A PROGRAM CLIENT OR PROSPECTIVE CLIENT.

(2) ON OR BEFORE MARCH 31 OF EACH YEAR, THE DEPARTMENT SHALL COMPILE ANNUAL REPORTS RECEIVED FROM AUTHORIZED ENTITIES IN THE PREVIOUS YEAR INTO A SINGLE REPORT AND POST THE REPORT ON ITS WEBSITE.

PART 13
COMMUNITY INTEGRATED

HEALTH CARE SERVICE AGENCIES

25-3.5-1301. Definitions. AS USED IN THIS PART 13, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY" OR "AGENCY" MEANS A SOLE PROPRIETORSHIP, PARTNERSHIP, CORPORATION, NONPROFIT ENTITY, SPECIAL DISTRICT, GOVERNMENTAL UNIT OR AGENCY, OR LICENSED OR CERTIFIED HEALTH CARE FACILITY THAT IS SUBJECT TO REGULATION UNDER ARTICLE 1.5 OR 3 OF THIS TITLE THAT MANAGES AND OFFERS, DIRECTLY OR BY CONTRACT, COMMUNITY INTEGRATED HEALTH CARE SERVICES.

(2) "MANAGER" OR "ADMINISTRATOR" MEANS ANY PERSON WHO CONTROLS AND SUPERVISES OR OFFERS OR ATTEMPTS TO CONTROL AND SUPERVISE THE DAY-TO-DAY OPERATIONS OF A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY.

(3) "MEDICAL DIRECTION" MEANS THE SUPERVISION OVER AND DIRECTION OF INDIVIDUALS WHO PERFORM ACTS ON BEHALF OF AN AGENCY BY A PHYSICIAN OR ADVANCED PRACTICE REGISTERED NURSE WHO IS LICENSED IN COLORADO, IS IN GOOD STANDING, AND IS IDENTIFIED AS BEING RESPONSIBLE FOR ASSURING THE COMPETENCY OF THOSE INDIVIDUALS IN THE PERFORMANCE OF ACTS ON BEHALF OF THE AGENCY; EXCEPT THAT, IF THE AGENCY HIRES OR CONTRACTS WITH A COMMUNITY PARAMEDIC, ONLY A LICENSED PHYSICIAN IN GOOD STANDING MAY PROVIDE MEDICAL DIRECTION.

(4) "OWNER" MEANS AN OFFICER, DIRECTOR, GENERAL PARTNER, LIMITED PARTNER, OR OTHER PERSON HAVING A FINANCIAL OR EQUITY INTEREST OF TWENTY-FIVE PERCENT OR GREATER.

25-3.5-1302. Community integrated health care service agency license required - rules - civil and criminal penalties - liability insurance. (1) ON OR AFTER JULY 1, 2018, A PERSON SHALL NOT OPERATE OR MAINTAIN A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY UNLESS THE PERSON HAS SUBMITTED TO THE DEPARTMENT A COMPLETED APPLICATION FOR LICENSURE AS A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY. ON OR AFTER DECEMBER 31, 2018, A PERSON SHALL NOT OPERATE OR MAINTAIN AN AGENCY WITHOUT A COMMUNITY INTEGRATED

HEALTH CARE SERVICE AGENCY LICENSE ISSUED BY THE DEPARTMENT.

(2) (a) A PERSON WHO VIOLATES SUBSECTION (1):

(I) IS GUILTY OF A MISDEMEANOR AND, UPON CONVICTION THEREOF, SHALL BE PUNISHED BY A FINE OF NOT LESS THAN FIFTY DOLLARS NOR MORE THAN FIVE HUNDRED DOLLARS; AND

(II) MAY BE SUBJECT TO A CIVIL PENALTY ASSESSED BY THE DEPARTMENT, AFTER CONDUCTING A HEARING IN ACCORDANCE WITH SECTION 24-4-105, C.R.S., OF UP TO TEN THOUSAND DOLLARS FOR EACH VIOLATION OF THIS SECTION. THE DEPARTMENT SHALL TRANSMIT ALL FINES COLLECTED PURSUANT TO THIS SUBPARAGRAPH (II) TO THE STATE TREASURER, WHO SHALL CREDIT THE MONEYS TO THE GENERAL FUND.

(b) AN OWNER, MANAGER, OR ADMINISTRATOR OF AN AGENCY IS SUBJECT TO THE PENALTIES IN THIS SUBSECTION (2) FOR ANY VIOLATION OF SUBSECTION (1).

(3) A LICENSE APPLICANT SHALL SUBMIT TO THE DEPARTMENT, IN THE MANNER DETERMINED BY THE BOARD BY RULE, PROOF THAT THE AGENCY AND ANY STAFF THAT IT EMPLOYS OR CONTRACTS IS COVERED BY GENERAL LIABILITY INSURANCE IN AN AMOUNT DETERMINED BY THE BOARD BY RULE, BUT NOT LESS THAN THE AMOUNT CALCULATED IN ACCORDANCE WITH SECTION 24-10-114 (1) (a) (I) AND (1) (b), C.R.S.

25-3.5-1303. Minimum standards for community integrated health care service agencies - rules. (1) IN ADDITION TO THE SERVICES THAT THE BOARD, BY RULE, AUTHORIZES A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY TO PERFORM, AN AGENCY MAY PERFORM ANY OF THE SERVICES THAT MAY BE PROVIDED THROUGH A CARES PROGRAM PURSUANT TO SECTION 25-3.5-1203 (3) AND THE TASKS AND PROCEDURES THAT A COMMUNITY PARAMEDIC IS AUTHORIZED TO PERFORM WITHIN HIS OR HER SCOPE OF PRACTICE IN ACCORDANCE WITH SECTION 25-3.5-206 AND RULES PROMULGATED PURSUANT TO THAT SECTION. ON OR BEFORE JANUARY 1, 2018, THE BOARD SHALL PROMULGATE RULES PROVIDING MINIMUM STANDARDS FOR THE OPERATION OF AN AGENCY WITHIN THE STATE. THE RULES MUST INCLUDE THE FOLLOWING:

(a) A REQUIREMENT THAT THE AGENCY HAVE MEDICAL DIRECTION;

(b) INSPECTION OF AGENCIES BY THE DEPARTMENT OR THE DEPARTMENT'S DESIGNATED REPRESENTATIVE;

(c) MINIMUM EDUCATIONAL, TRAINING, AND EXPERIENCE STANDARDS FOR THE ADMINISTRATOR AND STAFF OF AN AGENCY, INCLUDING A REQUIREMENT THAT THE ADMINISTRATOR AND STAFF BE OF GOOD MORAL CHARACTER;

(d) (I) FEES FOR AGENCY APPLICATIONS AND LICENSURE BASED ON THE DEPARTMENT'S DIRECT AND INDIRECT COSTS IN IMPLEMENTING THIS PART 13. THE DEPARTMENT SHALL TRANSMIT THE FEES TO THE STATE TREASURER, WHO SHALL CREDIT THE FEES TO THE COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCIES CASH FUND CREATED IN SECTION 25-3.5-1304.

(II) THE DEPARTMENT SHALL COLLECT FEES FROM ANY ENTITY THAT APPLIES TO OPERATE A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY, INCLUDING AN AGENCY WHOLLY OWNED AND OPERATED BY A GOVERNMENTAL UNIT OR AGENCY. THE DEPARTMENT SHALL TRANSMIT THE FEES TO THE STATE TREASURER WHO SHALL CREDIT THE FEES TO THE COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCIES CASH FUND CREATED IN SECTION 25-3.5-1304.

(e) THE AMOUNT OF GENERAL LIABILITY INSURANCE COVERAGE THAT AN AGENCY SHALL MAINTAIN AND THE MANNER IN WHICH AN AGENCY SHALL DEMONSTRATE PROOF OF INSURANCE TO THE DEPARTMENT. THE BOARD MAY ESTABLISH BY RULE THAT AN AGENCY MAY OBTAIN A SURETY BOND IN LIEU OF LIABILITY INSURANCE COVERAGE.

(f) ESTABLISHING OCCURRENCE REPORTING REQUIREMENTS PURSUANT TO SECTION 25-1-124;

(g) REQUIREMENTS FOR RETAINING RECORDS, INCLUDING THE TIME THAT AGENCIES MUST MAINTAIN RECORDS FOR INSPECTION BY THE DEPARTMENT; AND

(h) A REQUIREMENT THAT AGENCIES REPORT TO THE DEPARTMENT ON AN ANNUAL BASIS.

25-3.5-1304. Community integrated health care service agencies

cash fund - created. THERE IS CREATED THE COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCIES CASH FUND, REFERRED TO IN THIS SECTION AS THE "FUND". THE DEPARTMENT SHALL TRANSMIT FEES COLLECTED PURSUANT TO THIS PART 13 TO THE STATE TREASURER FOR DEPOSIT IN THE FUND. THE MONEY IN THE FUND IS SUBJECT TO ANNUAL APPROPRIATION BY THE GENERAL ASSEMBLY TO THE DEPARTMENT FOR THE DEPARTMENT'S DIRECT AND INDIRECT COSTS IN IMPLEMENTING AND ADMINISTERING THIS PART 13. ANY UNENCUMBERED OR UNEXPENDED MONEY IN THE FUND AT THE END OF A FISCAL YEAR REMAINS IN THE FUND AND SHALL NOT BE CREDITED OR TRANSFERRED TO THE GENERAL FUND OR ANY OTHER FUND.

25-3.5-1305. License - application - inspection - criminal history records check - issuance. (1) A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY LICENSE EXPIRES AFTER ONE YEAR. THE DEPARTMENT SHALL DETERMINE THE FORM AND MANNER OF INITIAL AND RENEWAL LICENSE APPLICATIONS.

(2) (a) THE DEPARTMENT SHALL INSPECT AN AGENCY AS IT DEEMS NECESSARY TO ENSURE THE HEALTH, SAFETY, AND WELFARE OF AGENCY CONSUMERS. AN AGENCY SHALL SUBMIT IN WRITING, IN A FORM AND MANNER PRESCRIBED BY THE DEPARTMENT, A PLAN DETAILING THE MEASURES THAT THE AGENCY WILL TAKE TO CORRECT ANY VIOLATIONS FOUND BY THE DEPARTMENT AS A RESULT OF AN INSPECTION.

(b) THE DEPARTMENT SHALL KEEP ALL MEDICAL RECORDS AND PERSONALLY IDENTIFYING INFORMATION OBTAINED DURING AN INSPECTION OF AN AGENCY CONFIDENTIAL. ALL RECORDS AND INFORMATION OBTAINED BY THE DEPARTMENT THROUGH AN INSPECTION ARE EXEMPT FROM DISCLOSURE PURSUANT TO SECTIONS 24-72-204, C.R.S., AND 25-1-124.

(3) (a) (I) WITH THE SUBMISSION OF AN APPLICATION FOR A LICENSE PURSUANT TO THIS SECTION, EACH OWNER, MANAGER, AND ADMINISTRATOR OF AN AGENCY APPLYING FOR AN INITIAL OR RENEWAL LICENSE SHALL SUBMIT A COMPLETE SET OF HIS OR HER FINGERPRINTS TO THE COLORADO BUREAU OF INVESTIGATION FOR THE PURPOSE OF CONDUCTING A STATE AND NATIONAL FINGERPRINT-BASED CRIMINAL HISTORY RECORD CHECK UTILIZING THE RECORDS OF THE COLORADO BUREAU OF INVESTIGATION AND THE FEDERAL BUREAU OF INVESTIGATION. THE COLORADO BUREAU OF INVESTIGATION SHALL FORWARD THE RESULTS OF A CRIMINAL HISTORY RECORD CHECK TO THE DEPARTMENT.

(II) EACH OWNER, MANAGER, OR ADMINISTRATOR OF AN AGENCY IS RESPONSIBLE FOR PAYING THE FEE ESTABLISHED BY THE COLORADO BUREAU OF INVESTIGATION FOR CONDUCTING THE FINGERPRINT-BASED CRIMINAL HISTORY RECORD CHECK TO THE BUREAU.

(III) THE DEPARTMENT MAY ACQUIRE A NAME-BASED CRIMINAL HISTORY RECORD CHECK FOR AN OWNER, MANAGER, OR ADMINISTRATOR WHO HAS TWICE SUBMITTED TO A FINGERPRINT-BASED CRIMINAL HISTORY RECORD CHECK AND WHOSE FINGERPRINTS ARE UNCLASSIFIABLE.

(b) THE DEPARTMENT MAY DENY A LICENSE OR RENEWAL OF A LICENSE IF THE RESULTS OF A CRIMINAL HISTORY RECORD CHECK OF AN OWNER, MANAGER, OR ADMINISTRATOR DEMONSTRATES THAT THE OWNER, MANAGER, OR ADMINISTRATOR HAS BEEN CONVICTED OF A FELONY OR A MISDEMEANOR INVOLVING CONDUCT THAT THE DEPARTMENT DETERMINES COULD POSE A RISK TO THE HEALTH, SAFETY, OR WELFARE OF COMMUNITY INTEGRATED HEALTH CARE SERVICE CONSUMERS.

(c) IF AN AGENCY APPLYING FOR AN INITIAL LICENSE IS TEMPORARILY UNABLE TO SATISFY ALL OF THE REQUIREMENTS FOR LICENSURE, THE DEPARTMENT MAY ISSUE A PROVISIONAL LICENSE TO THE AGENCY; EXCEPT THAT THE DEPARTMENT SHALL NOT ISSUE A PROVISIONAL LICENSE TO AN AGENCY IF OPERATION OF THE AGENCY WILL ADVERSELY AFFECT THE HEALTH, SAFETY, OR WELFARE OF THE AGENCY'S CONSUMERS. THE DEPARTMENT MAY REQUIRE AN AGENCY APPLYING FOR A PROVISIONAL LICENSE TO DEMONSTRATE TO THE DEPARTMENT'S SATISFACTION THAT THE AGENCY IS TAKING SUFFICIENT STEPS TO SATISFY ALL OF THE REQUIREMENTS FOR FULL LICENSURE. A PROVISIONAL LICENSE IS VALID FOR NINETY DAYS AND MAY BE RENEWED ONE TIME AT THE DEPARTMENT'S DISCRETION.

25-3.5-1306. License denial - suspension - revocation. (1) UPON DENIAL OF AN APPLICATION FOR AN INITIAL LICENSE, THE DEPARTMENT SHALL NOTIFY THE APPLICANT IN WRITING OF THE DENIAL BY MAILING A NOTICE TO THE APPLICANT AT THE ADDRESS SHOWN ON THE APPLICATION. IF AN APPLICANT, WITHIN SIXTY DAYS AFTER RECEIVING THE NOTICE OF DENIAL, PETITIONS THE DEPARTMENT TO SET A DATE AND PLACE FOR A HEARING, THE DEPARTMENT SHALL GRANT THE APPLICANT A HEARING TO REVIEW THE DENIAL IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24, C.R.S.

(2) THE DEPARTMENT MAY SUSPEND, REVOKE, OR REFUSE TO RENEW THE LICENSE OF A COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCY THAT IS OUT OF COMPLIANCE WITH THE REQUIREMENTS OF THIS PART 13 OR RULES PROMULGATED PURSUANT TO THIS PART 13. BEFORE TAKING FINAL ACTION TO SUSPEND, REVOKE, OR REFUSE TO RENEW A LICENSE, THE DEPARTMENT SHALL CONDUCT A HEARING ON THE MATTER IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24, C.R.S. THE DEPARTMENT MAY IMPLEMENT A SUMMARY SUSPENSION BEFORE A HEARING IN ACCORDANCE WITH SECTION 24-4-104 (4) (a), C.R.S.

(3) AFTER CONDUCTING A HEARING ON THE MATTER IN ACCORDANCE WITH ARTICLE 4 OF TITLE 24, C.R.S., THE DEPARTMENT MAY REVOKE OR REFUSE TO RENEW AN AGENCY LICENSE WHERE THE OWNER, MANAGER, OR ADMINISTRATOR OF THE AGENCY HAS BEEN CONVICTED OF A FELONY OR MISDEMEANOR INVOLVING CONDUCT THAT THE DEPARTMENT DETERMINES COULD POSE A RISK TO THE HEALTH, SAFETY, OR WELFARE OF THE AGENCY'S CONSUMERS.

(4) THE DEPARTMENT MAY IMPOSE INTERMEDIATE RESTRICTIONS OR CONDITIONS ON AN AGENCY THAT MAY REQUIRE THE AGENCY TO:

(a) RETAIN A CONSULTANT TO ADDRESS CORRECTIVE MEASURES;

(b) BE MONITORED BY THE DEPARTMENT FOR A SPECIFIC PERIOD;

(c) PROVIDE ADDITIONAL TRAINING TO ITS EMPLOYEES, OWNERS, MANAGERS, OR ADMINISTRATORS;

(d) COMPLY WITH A DIRECTED WRITTEN PLAN TO CORRECT THE VIOLATION, IN ACCORDANCE WITH THE PROCEDURES ESTABLISHED UNDER SECTION 25-27.5-108 (2) (b); OR

(e) PAY A CIVIL PENALTY OF UP TO TEN THOUSAND DOLLARS PER VIOLATION. THE DEPARTMENT, AFTER PROVIDING THE AGENCY WITH THE OPPORTUNITY FOR A HEARING IN ACCORDANCE WITH SECTION 24-4-105, C.R.S., ON ANY PENALTIES ASSESSED, SHALL TRANSMIT ALL PENALTIES COLLECTED PURSUANT TO THIS PARAGRAPH (e) TO THE STATE TREASURER, WHO SHALL CREDIT THE MONEY TO THE GENERAL FUND. THE AGENCY MAY REQUEST, AND THE DEPARTMENT SHALL GRANT, A STAY IN PAYMENT OF A CIVIL PENALTY UNTIL FINAL DISPOSITION OF THE RESTRICTION OR

CONDITION.

25-3.5-1307. Repeal of article - review of functions. THIS PART 13 IS REPEALED, EFFECTIVE SEPTEMBER 1, 2025. BEFORE THE REPEAL, THE DEPARTMENT'S FUNCTIONS UNDER THIS PART 13 SHALL BE REVIEWED AS PROVIDED FOR IN SECTION 24-34-104, C.R.S.

SECTION 5. In Colorado Revised Statutes, 24-34-104, **add** (56) (d) as follows:

24-34-104. General assembly review of regulatory agencies and functions for termination, continuation, or reestablishment. (56) The following agencies, functions, or both, terminate on September 1, 2025:

(d) THE FUNCTIONS OF THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT REGARDING COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCIES PURSUANT TO PART 13 OF ARTICLE 3.5 OF TITLE 25, C.R.S.

SECTION 6. Appropriation. (1) For the 2016-17 state fiscal year, $73,986 is appropriated to the department of public health and environment. This appropriation is from the general fund. To implement this act, the department may use this appropriation as follows:

(a) $70,184 for use by the health facilities and emergency medical services division for the state EMS coordination, planning and certification program, which amount is based on an assumption that the division will require an additional 1.0 FTE; and

(b) $3,802 for the purchase of legal services.

(2) For the 2016-17 state fiscal year, $3,802 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of public health and environment under paragraph (b) of subsection (1) of this section. To implement this act, the department of law may use this appropriation to provide legal services for the department of public health and environment.

SECTION 7. Safety clause. The general assembly hereby finds,

determines, and declares that this act is necessary for the immediate preservation of the public peace, health, and safety.

Bill L. Cadman
PRESIDENT OF
THE SENATE

Dickey Lee Hullinghorst
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Effie Ameen
SECRETARY OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED 3:56 Pm 6/8/16

John W. Hickenlooper
GOVERNOR OF THE STATE OF COLORADO

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR COMMUNITY INTEGRATED HEALTH CARE SERVICE AGENCIES

6 CCR 1011-3

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

SECTION 1. STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in Section 25-3.5-1301, *et seq*.

1.2 An Agency that performs the services set forth in Section 25-3.5-1303(1), C.R.S., must comply with the requirements set forth in Section 25-3.5-1301, C.R.S. *et seq*., and these rules.

1.3 Any entity that performed the services provided through a Community Assistance Referral and Education Services Program ("CARES Program") pursuant to Section 25-3.5-1203(3), C.R.S. before January 1, 2015 may continue to offer such services and are exempt from complying with the requirements of Sections 25-3.5-1201 through 1204, C.R.S. prior to June 30, 2021.

1.3.1 Effective July 1, 2021, the exemption in section 1.3 of these rules is repealed, pursuant to Section 25-3.5-1203(7)(b), C.R.S.

SECTION 2. DEFINITIONS

2.1 Administrator: The term "Administrator" is synonymous with the term "Manager" pursuant to Section 25-3.5-1301(2), C.R.S. For purposes of these rules, the term "Administrator" shall be used and means a person who controls and supervises or offers or attempts to control and supervise the day-to-day operations of a Community Integrated Health Care Service agency.

2.2 Advanced Practice Nurse (APN): An Advanced Practice Registered Nurse who is a professional nurse and is licensed to practice pursuant to Title 12, Article 38, who obtains specialized education or training as provided in Sections 12-38-103 (8.5), and 12-38-111.5, C.R.S. and who applies to and is accepted by the State Board of Nursing for inclusion in the advanced practice registry.

2.3 At-Risk Adult: An individual eighteen years of age or older who is susceptible to mistreatment or self-neglect because the individual is unable to perform or obtain services necessary for his or her health, safety, or welfare, or lacks sufficient understanding or capacity to make or communicate responsible decisions concerning his or her person or affairs.

2.4 Authorized Entity: A licensed ambulance service; a fire department of a town, city, or city and county, a fire protection district, ambulance district, health assurance district, health service district, or metropolitan district, or special district authority; or a health care business entity, including a licensed or certified health care facility that is subject to regulation under Article 3

of Title 25 that performs any of the services that may be provided through a Community Assistance Referral and Education Services Program pursuant to Section 25-3.5-1203(3), C.R.S.

2.5 Care Coordination: The deliberative organization of consumer care activities between two or more participants, including the consumer, involved in a consumer's care to facilitate the delivery of out-of-hospital medical services.

2.6 Care Provider: For the purposes of these rules, a Care Provider is a person who, under state law, has the authority to provide, coordinate, or order out-of-hospital medical services for his or her patients to be provided by CIHCS Providers, and who collaborates with CIHCS agencies on the patient's behalf.

2.7 CIHCS Medical Director (Medical Director): A Colorado licensed physician and/or APN in good standing who is identified as being responsible for supervising, directing, and assuring the competency of those individuals who are employed by or contracted with the CIHCS agency to perform community integrated health care services on behalf of the agency; except that if the agency hires or contracts with a Community Paramedic, only a licensed physician in good standing may supervise, direct, and assure the competency of Community Paramedics.

2.8 Community Assistance Referral and Education Services Program (CARES Program) : A program established by an authorized entity as defined in Section 25-3.5-1202(1), C.R.S. to provide community outreach and health education to residents within the authorized entity's jurisdiction for the purposes of preventing illness and injury, or reducing the incidence of 911 calls and hospital emergency department visits made for nonemergency, non-urgent medical care or services.

2.9 Community Integrated Health Care Services Provider (CIHCS provider): A person who, through employment or under contract, performs certain out-of-hospital medical services, as determined by rule, on behalf of a CIHCS Agency:

2.9.1 A Community Paramedic as defined in Section 2.11 of these rules acting within his or her scope of practice.

2.9.2 An individual who:

A) Is a health care provider who holds a valid Colorado license, registration, or certification by the Colorado Department Of Regulatory Agencies (DORA) and is in good standing; and

B) While acting within the scope of his or her license or certificate is supervised and directed by a CIHCS agency medical director.

2.9.3 An individual who is employed by or contracted with the CIHCS agency who is not licensed, certified, or registered by DORA but who otherwise lawfully engages in practice, including but not limited to, dietetics, nutrition counseling, X-ray technology or phlebotomy while under the supervision and direction of a CIHCS Agency medical director to furnish community integrated health care services as defined in Section 25-3.5-103(4.3), C.R.S. and as defined in these rules.

2.9.4 Anyone employed by or contracted with the CIHCS Agency who is involved in the fulfillment of a consumer's service plan.

2.9.5 Except as provided in Section 5.3.4(C), EMS Providers who are not endorsed Community Paramedics are prohibited from providing out-of-hospital medical services to a consumer when employed by or contracting with a CIHCS Agency.

2.10 Community Integrated Health Care Services (CIHCS): The provision of certain out-of-hospital medical services as determined by these rules that a Community Paramedic and other qualified CIHCS Providers may provide and may include:

2.10.1 Services authorized pursuant to Section 25-3.5-1203(3) C.R.S. and as set forth in this rule;

2.10.2 Services authorized under the scope of practice as set forth in 6 CCR 1015-3, Chapter Two for a currently certified Colorado paramedic in good standing who is endorsed as a Community Paramedic; and

2.10.3 Services authorized pursuant to Section 25-3.5-206(4)(a.5)(II), C.R.S.

2.11 Community Integrated Health Care Service Agency (CIHCS Agency or Agency): A sole proprietorship, partnership, corporation, nonprofit entity, special district, governmental unit or agency, or licensed or certified health care facility that is subject to regulation under Article 1.5 or Article 3 of Title 25 that manages and offers, directly or by contract, community integrated health care services.

2.12 Community Paramedic: An emergency medical service provider as defined in Section 25-3.5-103(8), C.R.S. who obtains an endorsement in community paramedicine pursuant to Sections 25-3.5-203.5 and 206, C.R.S. and performs, in addition to a paramedic's scope of practice, authorized tasks and procedures and acts within the scope of practice as established in these rules, and 6 CCR 1015-3, Chapter Two including:

2.12.1 An initial assessment of the patient and any subsequent assessments, as needed;

2.12.2 Medical interventions;

2.12.3 Care coordination;

2.12.4 Resource navigation;

2.12.5 Patient education;

2.12.6 Inventory, compliance, and administration of medications; and

2.12.7 Gathering of laboratory and diagnostic data.

2.13 Consumer (CIHCS Consumer or Consumer): An individual receiving community integrated health care services.

2.14 Department: The Colorado Department of Public Health and Environment.

2.15 DORA: The Colorado Department of Regulatory Agencies.

2.16 Initial Assessment: As used in these rules, means the Agency's evaluation of the consumer's immediate needs.

2.17 Licensed in Good Standing: As used in these rules, means any individual providing services pursuant to these rules who holds a current and valid Colorado license, registration, or certification to provide services under the applicable licensing, registration, or certification authority and who is not subject to any restrictions.

2.18 Medical Direction: For purposes of these rules means the supervision and direction of individuals who perform acts on behalf of an Agency by a physician and/or advanced practice registered nurse (APN) who is licensed in Colorado and is in good standing, and who is identified as being responsible for assuring the competency of those individuals in the performance of acts on behalf of the Agency. If the Agency hires or contracts with a Community Paramedic, only a Colorado-licensed physician in good standing may provide medical direction for a Community Paramedic provider.

2.19 Out-of-Hospital Medical Services: For purposes of these rules means performing the initial assessment of the consumer and any subsequent assessments, as needed, furnishing of medical treatment and interventions, care coordination, resource navigation, patient education, medication inventory, compliance, and administration, and gathering of laboratory and diagnostic data. Such services also include nursing services, rehabilitative services, complementary health services, and behavioral health services that may be provided out-of-hospital, as well as the furnishing of other necessary out-of-hospital services and goods for the purpose of preventing, alleviating, curing or healing human illness, physical disability, physical injury, or alcohol, drug, or controlled substance abuse. All out-of-hospital medical services must be performed within each CIHCS Provider's scope of practice.

2.20 Owner: An officer, director, general partner, limited partner, or other person having a financial or equity interest of twenty-five percent or greater.

2.21 Service Plan: The approved written plan specific to each consumer receiving CIHCS in a series of visits that identifies the consumer's physical, medical, social, mental health, and/or environmental needs, as necessary; sets forth the out-of-hospital medical services the CIHCS Agency agrees to provide to the consumer; and, is overseen by the CIHCS Agency medical director.

SECTION 3. REQUIRED POLICIES AND PROCEDURES

All policies and procedures shall be documented in writing and available for Department inspection.

3.1 Related to Consumer Rights

3.1.1 The Agency shall develop and implement policies and procedures regarding rights of the consumer. These policies and procedures shall be made available in writing to the consumer at the initiation of community integrated health care services. At a minimum, the policies and procedures shall include:

A) The right of the consumer to participate in the development of the service plan;

B) The right of the consumer and his or her property to be treated with respect;

C) The right of the consumer to be free from discrimination in the provision of services;

D) The right of the consumer to consent to receive and to discontinue Agency services at any time;

E) The right of the consumer to have personally identifying health information protected from unnecessary disclosure;

F) The right of the consumer or his or her representative to file a complaint with the Agency and/or Department concerning services or care that is or is not furnished, and receive documentation of the existence of the investigation and resolution of the complaint, including providing the complainant with the results of the investigation and the Agency's plan to resolve any identified issues;

G) The right of the consumer to file a complaint with the Agency and/or Department without fear of discrimination or retaliation by the CIHCS Agency owner, administrator, or any CIHCS provider or Agency staff; and

H) The right of the consumer to formulate an advanced directive.

3.2 Related to Staffing

3.2.1 The Agency shall develop and implement policies and procedures establishing that each employee and contracted staff possesses, at a minimum:

A) The education, experience, and training, including adequate clinical knowledge of and competence in performing medical skills and acts within the CIHCS provider's scope of practice, to provide services in the homes of consumers, in compliance with Sections 5.3.1 through 5.3.5 of these rules; and

B) Good moral character. If the Agency employs or contracts with any individual convicted of a felony or misdemeanor, the Agency shall develop policies and procedures to ensure that the individual does not pose a risk to the health, safety and welfare of the consumer.

3.2.2 The Agency shall also develop and implement policies and procedures:

A) Ensuring adequate staffing and resources to meet each consumer's needs;

B) Concerning the supervision of CIHCS providers, and the evaluation of their performance, to comport with the requirements of Sections 5.1.1(C)(i) and 5.2.3(A)(i) and (ii) of these rules;

C) Establishing that any on-call medical director[s], administrator and/or CIHCS provider[s] will have access to all pertinent current consumer information;

D) Ensuring proper staff utilization and availability, in compliance with these rules;

E) Designating medical direction back-up, in accordance with the requirements of Sections 5.1.1(C)(ii) and 5.2.3(A)(vii) of these rules, for when the Agency medical director is unavailable;

F) Designating administrative back-up when the Agency administrator is unavailable, in accordance with the requirements of Section 5.1.1(B)(iv) of these rules;

G) Ensuring that the Agency complies with the requirements of Section 26-3.1-111, C.R.S, on and after January 1, 2019.

3.2.3 The Agency shall also develop and implement training policies and procedures that:

A) Ensure the Agency's oversight of training is specific to the community integrated health care services provided to the community and to the equipment used by the Agency;

B) Establish the minimum amount of training its providers must receive annually;

C) Promote consumer dignity, independence, self-determination, privacy, choice and rights; and

D) Without limitation, address the following items:

i) Abuse and neglect prevention and reporting requirements;

ii) Behavior management techniques;

iii) Disaster and emergency procedures;

iv) Infection control, including standard universal precautions; and

v) Topics and subject matter that educate providers on community resources and other available services.

3.3 Related to Initial and Subsequent Assessments, Service Planning, and Care Coordination

3.3.1 The Agency shall develop and implement policies and procedures concerning the assessment, service planning, and care coordination services it conducts when providing out-of-hospital medical services to the consumer. At a minimum, such policies and procedures shall establish how the Agency will:

A) Secure consent to obtain the consumer's medical records;

B) Determine the consumer's eligibility for recurrent services, in compliance with Section 6.1 of these rules;

C) Comply with the initial and subsequent consumer assessments requirements set forth in Section 8.4 of these rules;

D) Develop and execute consumer service plans in accordance with Sections 8.3 and 8.5 of these rules;

E) Determine and document the appropriate CIHCS provider[s] who are necessary to fulfill the consumer's service plan goals;

F) Coordinate care across multiple providers, as applicable;

G) Require providers to document every consumer visit in compliance with Section 7.1.5 of these rules;

H) Refer consumers to a higher level of medical care and/or to other appropriate resources that may assist in the resolution of other issues identified in the initial and any subsequent assessments, in compliance with Section 7.1.1 of these rules; and

I) Under circumstances in which the Agency has co-medical directors, delineate the line of authority and medical oversight each medical director must exercise with respect to each consumer.

3.4 Related to Access to Services and Consumer Records

3.4.1 The Agency shall develop and implement policies and procedures describing, at minimum:

A) How consumers may contact the CIHCS Agency;

B) That the consumer's documentation of diagnostic and therapeutic procedures, treatments, tests and their results, if applicable, are available upon request; and

C) That all releases of personally identifying health information are consistent with applicable state and federal law.

3.5 Related to Discharge

3.5.1 The Agency shall develop and implement policies and procedures concerning the consumer's discharge in accordance with Section 8.6 of these rules that, at minimum, shall require that:

A) Discharge planning be initiated in a timely manner to allow for the arrangement of any other appropriate and necessary care;

B) A discharge plan and summary be included in the consumer's CIHCS Agency record; and

C) The Agency solicit consumer input regarding his or her satisfaction with the CIHCS provider and services received for quality management purposes.

3.6 Related to Complaints

The CIHCS Agency shall develop and implement policies and procedures that address, at a minimum, the following:

3.6.1 The CIHCS Agency's duty to provide consumers with contact information for the Department and Agency staff responsible for complaint intake and problem resolution;

3.6.2 The process by which consumers or others can submit verbal or written complaints to the Department and/or directly to the Agency about services or care;

3.6.3 How the Agency will document investigation of, and resolution process for, any complaint made concerning Agency services and providers, including the Agency's mandatory notification to the complainant about the results of the investigation and the agency's plan to resolve the identified issue(s);

3.6.4 The Agency's incorporation of the substantiated findings of any complaint into its quality management program for the purpose of evaluating and implementing systematic changes where needed; and

3.6.5 The Agency's explicit statement that it does not discriminate or retaliate against a consumer for expressing a complaint or multiple complaints.

3.7 Related to Required Reporting

3.7.1 The Agency shall develop and implement policies and procedures regarding occurrences and other reporting requirements in Sections 10.1 and 10.2 of these rules.

3.7.2 Every CIHCS Agency shall develop and implement a policy and procedure regarding its duty to define deaths reportable to the local county coroner under Section 30-10-606(1), C.R.S., in a manner consistent with the local coroner's reporting policy.

3.8 Related to Quality Management Program

3.8.1 The Agency shall develop and implement policies and procedures that require and document that the quality management program complies with Section 7.2 of these rules.

3.9 Related to Records

3.9.1 The Agency shall develop and implement policies and procedures that establish and document its record retention requirements, including the length of time the Agency must retain records for Department inspection in compliance with Section 4.6.3 of these rules.

3.9.2 The Agency shall develop and implement policies and procedures that establish and document its personnel file retention requirements for all employees.

A) Personnel records for all employees shall include references, dates of employment and separation from the Agency, and the reason for separation.

B) Personnel records for all employees shall also include:

i) Current documentation of qualifications and any licenses, certifications, endorsements, or registrations. Qualifications include confirmation of type and depth of experience, advanced skills, training and education, and appropriate, detailed and observed competency evaluation and written testing overseen by a person with the same or higher validated qualifications;

ii) Documentation of the employees orientation to the Agency;

iii) Job descriptions for all positions assigned by the Agency; and

iv) Annual performance evaluation for each employee.

SECTION 4. LICENSING

4.1 License Required

4.1.1 On or after July 1, 2018, a person, sole proprietorship, partnership, corporation, nonprofit entity, special district, governmental unit or agency, or licensed or certified health care facility that is subject to regulation under Article 1.5 or Article 3 of Title 25, C.R.S. shall not manage and offer, directly or by contract, community integrated health care services or operate or maintain a CIHCS Agency without having submitted a completed application for licensure as a Community Integrated Health Care Service Agency.

4.1.2 On or after December 31, 2018, a person, sole proprietorship, partnership, corporation, nonprofit entity, special district, governmental unit or agency, or licensed or certified health care facility that is subject to regulation under Article 1.5 or Article 3 of Title 25, C.R.S. shall not operate or maintain a CIHCS Agency without a community integrated health care services license issued by the Department.

4.1.3 A license as a Community Integrated Health Care Service Agency is not required for an entity that only provides the following services:

A) Health education and information available on relevant services; and/or

B) Referrals for and information concerning low-cost medication programs and alternative resources to the 911 system.

4.1.4 A person, including an owner or administrator of a CIHCS Agency, who violates Sections 4.1.1 and 4.1.2 of these rules shall be guilty of a misdemeanor and, upon conviction thereof:

A) Shall be punished by a fine of not less than fifty dollars nor more than five hundred dollars; and

B) May be subject, pursuant to Section 25-3.5-1302(2)(a)(II), C.R.S., to a civil penalty assessed by the Department for an amount of up to $10,000 per violation of Sections 4.1.1 and 4.1.2.

4.2 License Procedure

4.2.1 No later than July 1, 2018, an applicant as described in Section 4.1.1 of these rules that provides or intends to provide, directly or by contract, community integrated health care services must submit a completed application in the manner and form required by the Department.

4.2.2 An applicant for an initial license, or a licensee holding a Community Integrated Health Care Service Agency license, shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Section 2.7 regarding the process for change of ownership.

4.2.3 When applying for an initial or renewal license, the applicant Agency shall include evidence of either general liability insurance coverage or a surety bond in lieu of

general liability insurance coverage. Such coverage shall be maintained for the duration of the license period and shall include coverage for the Agency and any staff that the Agency employs or contracts with.

A) An applicant Agency that is not granted qualified immunity under Section 24-10-101, C.R.S., *et seq*., shall provide proof of either general liability insurance or a surety bond. The minimum amount of general liability insurance coverage or surety bond shall be as set forth in Section 24-10-114(1)(a), C.R.S.

B) An applicant Agency that is granted qualified immunity under the Colorado Governmental Immunity Act, Sections 24-10-101, C.R.S. *et seq*., shall provide proof of general liability insurance in an amount not less than the amount calculated in accordance with Section 24-10-114(1) (a)(1) and (1)(b)**,** C.R.S.

4.2.4 Fingerprints

A) With the submission of an application for an Agency license, or within ten (10) calendar days after a change in the Agency owner and/or Agency administrator, each owner and administrator of an Agency applying for a license shall submit a complete set of his or her fingerprints to the Colorado Bureau of Investigation for the purpose of conducting a state and national fingerprint-based criminal history record check utilizing the records of the Colorado Bureau of Investigation and the Federal Bureau of Investigation.

B) Each owner and administrator is responsible for paying the fee established by the Colorado Bureau of Investigation for conducting the criminal history record check.

C) If an owner or administrator has twice submitted to a fingerprint-based criminal history record check to either the Federal Bureau of Investigation or the Colorado Bureau of Investigation, and the fingerprints are deemed unclassifiable, then the department may acquire a Colorado Bureau of Investigation and/or Federal Bureau of Investigation name-based criminal history report.

4.2.5 The Department may deny a license or renewal of a license if the applicant or Agency owner or administrator has been convicted of a felony or misdemeanor which involves conduct that the Department determines could pose a risk to the health, safety, or welfare of community integrated health care services consumers.

4.2.6 The Department may review and investigate each initial and renewal license application to ensure the applicant's compliance with these rules. The licensing determination shall be based on one or more of the following:

A) An on-site investigation of the Agency;

B) A review of the application and associated documents;

C) A review of the Agency's compliance history, including the results of complaint investigations and occurrence reports;

D) Interviews with consumers and/or staff;

E) A review of required Agency policies and procedures; and

F) Any other information the Department determines is necessary to make a licensing determination.

4.2.7 Except as otherwise specified in these or other applicable rules, the Department shall issue or renew a license when it is satisfied that the applicant or licensee complies with these rules. The Department may refuse to issue or renew the license of an applicant or Agency that is out of compliance with the requirements of Section 25-3.5-1301, *et seq,* C.R.S. or these rules.

4.2.8 A license issued or renewed pursuant to this Section 4 shall expire after one (1) year.

4.2.9 A Community Integrated Health Care Service Agency license is not transferable. The license is only valid while in the possession of the licensee to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a license be valid for any purposes other than those for which it was originally issued.

4.2.10 If the Department denies an application for an initial or renewal license, the Department shall notify the applicant in writing of such denial by mailing a notice to the applicant at the address shown on the application.

4.2.11 Denial of a license may be appealed within 60 days of receipt of the written notice of denial. Requests for the Department to set a hearing must be in writing.

4.2.12 All hearings on license denials shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, C.R.S**.,** *et seq.*

4.3 Required License Information

The applicant shall provide the following:

4.3.1 Community Needs Assessment

A) Any applicant for a Community Integrated Health Care Services Agency license shall submit the following information:

i) A description of the program, population to be served, and types of services the applicant intends to provide;

ii) A description of the geographic area that it intends to serve and a list of the contiguous counties that it plans to serve within the declared geographical area;

iii) A description of how the applicant intends to coordinate with existing resources and programs, including licensed health care facilities;

iv) A description or plan of how the applicant will identify the needs of the community that it will serve;

v) Identification of:

a) Any partners the applicant intends to work and collaborate with, if any, to achieve program goals, and the groups or organizations within the community that support the program, if any; and

b) A community's specific needs, such as communication or language barriers, social support systems, environmental concerns, transportation accessibility issues, and any other appropriate information regarding barriers to meeting a consumer's non-medical goal and/or health related outcomes within the community.

B) If the licensee modifies its community needs assessment, it shall notify the Department in writing at the time it submits its license renewal application to the Department.

C) The Department may request supplemental information for clarification of any information submitted for the community needs assessment prior to initial or ongoing licensing approval.

4.3.2 Other required information

A) Proof of general liability insurance or surety bond as specified in Section 4.2.3 of these rules;

B) Identification of the Agency's medical director(s);

C) Identification of the Agency's administrator;

D) The CIHCS Agency shall make available copies of its policies and procedures required by Section 4.2.4 of these rules;

E) Compliance with fingerprint requirements in Section 4.2.4 of these rules;

F) After January 1, 2019, compliance with the Colorado Adult Protective Services Data System (CAPS Check) requirements set forth in Section 26-3.1-111, C.R.S.;

G) The CIHCS Agency shall make available the quality management program to the Department for review during the initial licensure survey and all subsequent surveys; and

H) Any other information the Department determines is necessary to make a licensing determination.

4.3.3 In addition to the information required by Sections 4.3.1 and 4.3.2 of these rules, an applicant shall provide written notification to the Board of County Commissioners of the jurisdictions in which it plans to operate that the applicant intends to obtain a Community Integrated Health Care Service license. The applicant shall also provide a copy of the written notification to the Department.

4.3.4 The appropriate fee(s) shall accompany the initial or renewal license application.

4.4 Provisional License

4.4.1 Circumstances warranting a provisional license

A) The Department may issue a provisional license to any applicant for an initial license to operate a Community Integrated Health Care Service Agency for a period of ninety (90) days if the applicant is temporarily unable to conform to all the minimum standards required by this chapter. However, no provisional license shall be issued to an applicant if the operation of the applicant's CIHCS Agency will adversely affect the health, safety, or welfare of the CIHCS consumers.

B) The Department may issue a second provisional license for the same duration if the Department determines substantial compliance with these requirements is occurring and shall charge the same fee as for the first provisional license. If the licensee has made a timely and sufficient application for renewal of the provisional license, the existing license shall not expire until the Department has acted upon the renewal application. The Department may not issue a third or subsequent provisional license to the applicant, and in no event shall an Agency be provisionally licensed for a period to exceed one hundred eighty (180) calendar days.

C) As a condition of obtaining a provisional license, the applicant shall show proof to the Department that attempts are being made to conform and comply with applicable standards.

4.5 License Fees

All fees shall be based on the Department's direct and indirect cost of implementing the program. Any entity, including an Agency wholly owned and operated by a governmental unit or agency, which applies to operate a CIHCS Agency shall pay the applicable fees.

Initial Licensure Fee	$3000
Renewal Licensure Fee	$1700
Provisional Licensure Fee	$750
Change Of Ownership Fee	$3000
Change Of Name And Change Of Address Fee	$75
Revisit Fee	$1700
Late Fee	$1700

4.6 Inspections

4.6.1 The Department may conduct an inspection or re-inspection of the Agency and all aspects of its operations, including policies and procedures, equipment, consumer records, staffing records, and other documentation, at any time it deems necessary to ensure compliance with these rules and to protect the health, safety and welfare of the Agency's consumers. Additionally, the Department may conduct complaint and other investigations as needed.

4.6.2 Inspections may include evaluation of care and services at the consumer's home with the consumer's consent.

4.6.3 The CIHCS Agency shall retain its consumer records in accordance with state and federal requirements, but for no less than four (4) years, and those records shall be readily available to the Department during inspection and/or investigation. The Department will keep medical records and personally identifying health information obtained during an inspection confidential, and those records are exempt from disclosure.

4.6.4 Consumer records kept in the home or individual consumer documents not included in the CIHCS Agency permanent record shall be made available to the Department within two hours of request if the visit occurred 14 or more days prior to the request. The time for production may be extended at the Department's discretion.

4.6.5 The consumer file and administrative records, including, but not limited to, census and demographic information, complaint and incident reports, meeting minutes, quality management and annual program review documents , shall be provided to the Department commencing within 30 minutes of request. The time for production may be extended at the Department's discretion.

4.7 Plan of Correction

4.7.1 After any Department inspection or complaint investigation, the Department may request a plan of correction from a CIHCS Agency. A plan of correction shall be in the format prescribed by the Department and shall address, at minimum, the following:

A) Corrective action that will be accomplished for those consumers who have been affected by the deficient practice;

B) Identification of other consumers having the potential to be affected by the same deficient practice and the corrective action implemented;

C) Root cause(s) that led to the deficient practice and any measures and systematic changes the Agency will implement to ensure the deficient practice will not recur;

D) Monitoring procedure to ensure that the plan of correction is effective and that the specific deficiency(ies) cited remains corrected and/or in compliance with the regulatory requirements; and

E) Overall date when corrective action will be completed.

4.7.2 Completed plans of correction shall be:

A) Submitted within ten (10) calendar days after the date of the Department's mailing of the written notice of deficiencies to the Agency, unless otherwise required or approved by the Department; and

B) Signed by the Agency administrator.

4.7.3 The Department has the discretion to approve, modify or reject plans of correction.

A) If the plan of correction is accepted, the Department shall notify the Agency by issuing a written notice of acceptance within thirty (30) calendar days of receipt of the plan.

B) If the plan of correction is unacceptable, the Department shall notify the Agency in writing, and the Agency shall submit a revised plan of correction to the Department within fifteen (15) calendar days of the date of the written notice.

C) If the Agency fails to comply with the requirements or deadlines for submission of a plan or fails to submit a revised plan of correction, the Department may reject the plan of correction and impose intermediate restrictions or conditions as set forth in Section 4.8 of these rules.

D) If the Agency fails to timely implement the actions agreed to in the plan of correction, the Department may impose intermediate restrictions or conditions as set forth in Section 4.8 of these rules.

4.8 Intermediate Restrictions or Conditions

4.8.1 The Department may impose intermediate restrictions or conditions on an Agency for violation of these rules that may include at least one of the following:

A) Retaining a consultant to address corrective measures;

B) Monitoring by the Department for a specific period;

C) Providing additional training to employees, owners, or administrators of the Agency;

D) Complying with a directed written plan to correct the violation; or

E) Paying a civil penalty of up to $10,000 per violation.

4.8.2 If the Department imposes an intermediate restriction or condition that is not the result of a serious and immediate threat to health or welfare, the Department shall provide the Agency with written notice of the restriction or condition. No later than ten (10) calendar days after receipt of the notice, the Agency shall submit a written plan to the Department setting forth the time frame in which it will complete the directed plan of correction.

4.8.3 If the Department imposes an intermediate restriction or condition that is the result of a serious and immediate threat to health, safety or welfare, the Department shall notify the Agency in writing, by telephone, or in person during an on-site visit.

A) The Agency shall remedy the circumstances creating the harm or potential harm immediately upon receiving notice of the restriction or condition.

B) If the Department provides notice of a restriction or condition by telephone or in person, the Department shall send written confirmation of the restriction or condition to the Agency within two (2) business days.

C) If the Department imposes an intermediate restriction or condition that requires payment of a civil penalty, the Agency may request and the Department shall grant a stay in payment of the penalty until final disposition of the restriction or condition. Additionally, the Department shall provide the Agency with an opportunity for a hearing in accordance with Section 24-4-105, C.R.S. on any civil penalty assessed.

4.9 Revocation or Suspension of License or Refusal to Renew License

4.9.1 The Department may revoke, suspend or refuse to renew the license of a Community Integrated Health Care Service Agency that is out of compliance with the requirements of Section 25-3.5-1301 *et seq*., C.R.S., other applicable laws, or these rules.

4.9.2 Revocation or suspension of an existing license or refusal to renew a license shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, *et seq*., C.R.S.

4.10 Summary Suspension

4.10.1 The Department may summarily suspend an Agency's license if it finds, after full investigation, that the Agency has engaged in deliberate and willful violation of Section 25-3.5-1301, *et seq*., C.R.S., other applicable laws, or these rules, or that the public health, safety, or welfare immediately requires emergency action.

4.10.2 If the Department summarily suspends an Agency's license, it shall provide the Agency with notice explaining the basis for the summary suspension. Additionally, the notice shall inform the Agency of its right to appeal the action and that it is entitled to a prompt hearing concerning the revocation or suspension of the Agency license.

4.10.3 Appeals of a summary suspension shall be conducted in accordance with the State Administrative Procedure Act, Section 24-4-101, *et seq.,* C.R.S.

4.11 Annual Reporting to the Department

4.11.1 Within forty-five (45) days after an Agency's annual license expiration, the Agency shall submit, in the format determined by the Department, the following information:

A) The number of persons served by the CIHCS Agency for the annual reporting period;

B) The types of CIHCS services provided;

C) The types of providers utilized by the Agency, including whether the CIHCS providers hold any licenses, registrations, or certifications;

D) The number of visits performed by each CIHCS provider type;

E) The number of consumers who received community integrated health care services from a single visit;

F) The number of consumers who received community integrated health care services from recurrent visits;

G) An evaluation and determination of whether the Agency meets the needs it identified in its community needs assessment;

H) A measurement of any reduction in visits to an emergency department for nonemergency, non-urgent medical assistance by persons served by the CIHCS Agency; and

I) The results of any Agency performance reviews received from consumers and collaborative partners.

SECTION 5. ADMINISTRATOR, MEDICAL DIRECTOR AND OTHER STAFF

5.1 Administrator

5.1.1 Minimum Qualifications

A) The administrator shall:

i) Be at least 21 years of age and of good moral character;

ii) Be qualified by education, knowledge and experience to oversee the community integrated health care services provided; and

iii) Have at least two (2) years health care, emergency medical service agency or health service administration experience with at least one (1) year of supervisory experience in home care, emergency medical services, or a closely related health program.

B) Responsibilities

The administrator shall assume authority for the CIHCS Agency's business operations including, but not limited to:

i) Managing the business affairs and the overall operation of the CIHCS Agency;

ii) Organizing and directing the Agency's ongoing functions;

iii) Overseeing a budgeting and accounting system;

iv) Designating in writing a qualified back up administrator to act in the administrator's absence;

v) Maintaining availability of a qualified administrator at all hours employees are providing services;

vi) Ensuring the Agency's community integrated health care services are in compliance with all applicable federal, state and local laws;

vii) Ensuring the completion, maintenance and submission of such reports and records as required by the Department;

viii) Providing ongoing liaison with the CIHCS providers, Agency staff members and the community;

ix) Establishing a current organizational chart to show lines of authority down to the consumer level;

x) Maintaining appropriate personnel records, financial and administrative records, and all policies and procedures of the Agency;

xi) Ensuring that marketing, advertising and promotional information accurately represents the CIHCS Agency, and addresses the care, treatment and services that the Agency can provide directly or through contractual arrangement; and

xii) Hiring and employing or contracting with sufficient qualified personnel to operate the Agency's services in accordance with:

a) Written job descriptions;

b) Applicable licensing, certification or registration requirements in compliance with state laws and regulations;

c) Each CIHCS provider's scope of practice, if applicable; and

d) The provisions of Sections 26-3.1-111(6), C.R.S., on or after January 1, 2019. Prior to hiring or contracting with a person who will provide direct care to an at-risk adult as defined in Section 2.3 of these rules, the administrator shall ensure that it has required each prospective Agency employee and contractor to submit to a CAPS Check, as defined in Section 26-3.1-101(1.8), C.R.S.

C) The administrator shall, in collaboration with the Agency's medical director:

i) Ensure appropriate education, supervision and evaluation of Agency staff;

ii) Designate through policy a backup for medical direction when the Agency medical director is unavailable in accordance with the requirements of Section 5.2.3(A)(vii) of these rules; and

iii) Develop and implement a quality management program for the Agency and CIHCS provider services.

5.2 Medical Director's Qualifications, Duties and Training

5.2.1 Nothing in these rules prohibits a CIHCS Agency from employing or contracting with an APN and physician medical director to serve as co-medical directors for the Agency. The Agency shall clearly delineate and document those CIHCS providers over whom each co-medical director retains supervisory and medical direction oversight as defined in Section 2.18 of these rules.

5.2.2 Qualifications**.** A CIHCS Agency's medical director, as defined in Section 2.7 of these rules, must possess the following minimum qualifications:

A) Physician medical directors must:

i) Be a physician currently licensed in good standing to practice medicine in the State of Colorado;

ii) Possess authority under their licensure to perform all medical acts to which they extend their authority to CIHCS providers; and

iii) Satisfy all requirements mandated in 6 CCR 1015-3, Chapter Two if the medical director also serves as an EMS Agency medical director.

B) Advanced Practice Registered Nurse (APN) medical directors:

i) Must be currently licensed in good standing to practice advanced practice nursing in the State of Colorado;

ii) Must possess authority under their licensure to perform all nursing functions and delegated medical functions in accordance with accepted practice standards for which they extend their authority to non-Community Paramedic-endorsed CIHCS providers;

iii) Must not be a medical director for any Community Paramedic-endorsed provider delivering medical services; and

iv) May only issue standing orders and protocols as authorized by law.

5.2.3 Responsibilities

A) A CIHCS Agency shall ensure that all CIHCS Agency medical directors perform the following responsibilities and duties:

i) Be actively involved in the provision of community integrated health care services within the community served by the CIHCS Agency. Involvement does not require that a physician or APN have such community involvement prior to becoming a medical director, but does require active involvement as the medical director. Community involvement could include, by way of example and not limitation, those inherent, reasonable and appropriate responsibilities of a medical director to interact, and, as necessary, collaborate with the community served by the CIHCS Agency, the hospital community, the public safety agencies, home care, hospice, and the medical community, and should include other aspects of liaison oversight and communication expected in the supervision of CIHCS providers;

ii) Be actively involved on a regular basis with the CIHCS Agency providers. Such involvement shall include, at minimum, overseeing continuing education, provider supervision, care and service audits, developing protocols and/or treatment policies and procedures;

iii) In collaboration with the administrator, develop a quality management program for the Agency and CIHCS provider services;

iv) In accordance with Agency policy, participate in the supervision and evaluation of the performance of CIHCS providers. This includes ensuring that CIHCS providers have adequate clinical knowledge of, and are competent in performing medical skills and acts performed on behalf of the CIHCS Agency within the CIHCS provider's scope of practice and in accordance with state licensure, certification or registration requirements as applicable;

v) In collaboration with the administrator, oversee training and education programs for CIHCS Agency personnel regarding the provision of out-of-hospital medical services;

vi) Notify the Department within fourteen (14) business days of changes to the medical director's position, including cessation of duties as the Agency's medical director;

vii) In collaboration with the Agency administrator, designate through policy a backup for medical direction in accordance with the requirements of Section 3.2.2(E) of these rules for when the agency medical director is unavailable;

viii) Establish standards governing the CIHCS Agency services that can be provided to consumers during a single visit, pursuant to Section 8.2 of these rules;

ix) In conjunction with the CIHCS consumer's care provider, if applicable, develop, monitor, and evaluate service plans as required by Section 8.5.1 of these rules;

x) When implementing the consumer service plan, ensure that consumer chart reviews are performed in compliance with the quality management plan to determine if appropriate assessments, referrals, documentations, and communications are occurring between the care provider(s), CIHCS providers, and the consumer; and

xi) In conjunction with the consumer's care provider(s), if applicable, and CIHCS provider(s), develop and implement discharge summaries as part of each consumer's service plan.

5.2.4 Additional physician medical director responsibilities for Community Paramedic oversight.

A) In addition to the responsibilities set forth in Section 5.2.3(A) of these rules, all physician medical directors shall:

i) Develop protocols and standing orders which are appropriate for the care and services offered by the Agency and conform to the certification, skill level and scope of practice of each CIHCS provider type;

ii) Conduct a review of the protocols and standing orders on an annual basis; and

iii) Retain ultimate authority for establishing all protocols and standing orders pertaining to community integrated health care services provided by Community Paramedics.

B) In addition to the responsibilities set forth in Section 5.2.3(A) of these rules, a physician medical director who oversees Community Paramedics shall:

i) Oversee the training, knowledge and competency of endorsed Community Paramedics under his or her supervision and ensure that Community Paramedics are appropriately trained and demonstrate ongoing competency in all skills, procedures and medication administration and management as authorized in accordance with Section 6 CCR 1015-3, Chapter 2;

ii) Ensure that appropriate additional education and training is provided to supervised Community Paramedics and understand that certain skills, procedures and medications authorized in accordance with Section 6 CCR 1015-3, Chapter 2 (and as identified by the Department) may not be included in the education and training of Community Paramedics; and

iii) Retain ultimate authority and responsibility for monitoring, supervising, evaluating and ensuring the competency of Community Paramedics in the delivery of care and services and the performance of authorized medical acts.

5.3 Staff and CIHCS Providers

5.3.1 General Requirements

A) The Agency shall ensure that each employee or contracted staff possesses the education, good moral character and experience to provide services in the homes of consumers in accordance with Agency policy, these regulatory requirements, state practice acts, and professional standards of practice.

B) The Agency shall ensure its providers and other relevant staff receive appropriate training.

i) The CIHCS Agency shall develop and implement a provider training policy that requires its CIHCS providers to undergo a minimum amount of annual training specific to the CIHCS Agency services provided to the community and the equipment used.

ii) The CIHCS Agency shall establish by policy the minimum annual amount of continuing education required of each CIHCS provider and, as applicable, administrative staff.

a) The minimum amount of required continuing education shall not be less than twelve (12) hours or twelve (12) educational sessions per year.

b) Continuing education requirements that CIHCS providers complete to maintain certification, license, or registration may apply to

satisfy the annual minimum twelve (12) hour mandatory continuing education requirement.

C) All training and continuing education records shall be documented and retained by the Agency.

5.3.2 Responsibilities of all CIHCS Providers

A) CIHCS providers**,** acting within the scope of their relevant certification, license or registration, shall:

i) Participate as part of a community based team to provide integrated out-of-hospital medical services to address a consumer's particular non-urgent medical condition; and

ii) Provide information to CIHCS Agency consumers about relevant local community resources and other collaborative services.

B) As required by these regulations and in accordance with Agency policy and procedures, the duties of a CIHCS provider shall at a minimum include:

i) Preparing clinical notes;

ii) Coordinating services;

iii) Communicating appropriate medical status and treatment information to the consumer and/or designated representative and, if applicable, the consumer's care provider; and

iv) Comply with all Agency reporting requirements set forth in Agency policy and these rules.

5.3.3 Requirements Applicable To Specific CIHCS Providers

A) CIHCS providers who are not regulated under DORA shall, at a minimum, meet the following requirements:

i) A registered dietician shall have successfully completed a program of formal training in nutrition with successful completion of the registration examination for dieticians.

ii) An X-ray technician:

a) Shall meet the requirements of 6 CCR 1007-1, Part Two (Appendix 2D—X-ray System Operator Adequate Radiation Safety Training And Experience, Including Limited Scope X-ray Machine Operator); or

b) Who operates an X-ray machine for dental, podiatric, and chiropractic diagnosis purposes must meet the minimum standard for qualifications, education, and training under Sections 12-32-201 and 202, C.R.S. (podiatrist X-ray technician); Sections 12-33-

201 and 202, C.R.S. (chiropractic X-ray technician); or Sections 12-35-201 and 202, C.R.S. (dental X-ray technicians).

iii) A phlebotomist shall:

a) Have successfully completed an approved phlebotomy training course or have equivalent experience through previous employment; and

b) Have two (2) years of verifiable phlebotomy experience.

5.3.4 CIHCS Agency Provider Scopes of Practice

A) Community Paramedic scope of practice when providing out-of-hospital medical services on behalf of a CIHCS Agency.

i) Under the supervision and direction of the Agency's physician medical director, an endorsed Community Paramedic may, in addition to performing his or her other authorized activities within the paramedic scope of practice, perform the following medical tasks and procedures:

a) An initial assessment of the consumer and any subsequent assessments, as needed, within the rules as promulgated in 6 CCR 1015-3, Chapter Two;

b) Medical interventions that are deemed permissible tasks and procedures as promulgated in 6 CCR 1015-3, Chapter Two, and are conducted within the rules set forth therein;

c) Care coordination;

d) Resource navigation;

e) Patient education;

f) Inventory, compliance, and administration of medications conducted within the rules promulgated in 6 CCR 1015-3, Chapter Two;

g) Gathering of laboratory and diagnostic data conducted within the rules promulgated in 6 CCR 1015-3, Chapter Two; and

h) Other community paramedic tasks and procedures as promulgated within the rules of 6 CCR 1015-3, Chapter Two.

B) Any services provided must not exceed the scope of practice of the Community Paramedic.

C) EMS Providers who are not endorsed Community Paramedics are prohibited from providing out-of-hospital medical services to a consumer when employed by or contracting with a CIHCS Agency; except that, in their capacity as CIHCS Agency providers, unendorsed EMS providers may perform:

i) Ancillary non-medical services with respect to non-emergent conditions (i.e. driving); and

ii) Any of the services that may be provided through a CARES Program as set forth in Section 25-3.5-1203(3), C.R.S.

5.3.5 Other CIHCS Agency Providers When Performing Out-Of-Hospital Medical Services On Behalf Of a CIHCS Agency.

A) Under the supervision and direction of the Agency's medical director, a CIHCS Agency provider who holds a license, registration or certificate to practice a profession in good standing may perform the authorized activities and skills listed for the provider's license, registration, or certificate level on behalf of a CIHCS Agency within the applicable scope of practice as described in statute and rule.

SECTION 6. ELIGIBILITY STANDARDS

6.1 Standards Governing Eligibility for CIHCS Agency Services

6.1.1 Licensed CIHCS Agencies may provide out-of-hospital medical services to consumers who:

A) Over-utilize the 911 system; or

B) i) Do not qualify for home care or hospice services; or

ii) Have been rejected from, or have declined, or are unable to utilize home care or hospice services.

6.1.2 If a CIHCS Agency is going to provide continuing services to a particular consumer, the CIHCS Agency shall confirm and document that the consumer has been rejected from or is not appropriate for home care or hospice services, has declined home care or hospice services, or is otherwise unable to utilize home care or hospice services.

SECTION 7. STANDARDS GOVERNING CIHCS AGENCY OPERATIONS

7.1 A CIHCS Agency shall:

7.1.1. As necessary, refer consumers to a higher level of medical care and/or to other appropriate resources that may assist in the resolution of other issues identified in the initial and subsequent assessments;

7.1.2 Not utilize its license to circumvent licensing requirements of other facility or agency services;

7.1.3 Only enroll consumers with the reasonable expectation their needs can be met.

A) The Agency and consumer shall agree to the tasks to be provided and the frequency of visits.

B) If the consumer's service plan requires care or services to be delivered at specific times, the Agency shall ensure it either employs qualified staff in sufficient quantity or has other effective back-up plans to ensure the needs of the consumer are met.

C) If applicable, to ensure the needs of the consumer are met, the Agency shall provide the consumer with its after-hours contact information and/or with contact information for the Agency's back-up provider.

D) In the event of the need to alter the consumer's agreed-upon schedule of visits, the consumer shall be notified as soon as practicable. If the consumer has time-sensitive needs, the Agency shall initiate effective back-up plans to ensure patient safety.

E) If there is a missed visit, services shall be provided as agreed upon by the consumer and Agency.

7.1.4 Ensure that its operation and staff utilization will not place CIHCS consumers at risk of harm or disrupt any other Agency services, including emergency services, the Agency may be authorized to provide.

7.1.5 Ensure that its providers document each consumer visit/contact and include such documentation in the consumer's records.

7.1.6 Document evidence of the minimum qualifications and competencies of the Agency's medical director(s) and the administrator and his/her qualified substitutes.

7.1.7 Ensure that its CIHCS providers that are licensed, certified or registered meet the requirements for their practice or profession.

7.2 Standards for Quality Management Program

7.2.1. Every CIHCS Agency applicant or licensee shall establish and implement a quality management program that is appropriate to the size and type of the agency, evaluates the quality of consumer care and safety, and complies with the requirements of this section.

7.2.2 The program shall include, at minimum:

A) A general description of the types of cases, problems, or risks to be reviewed and criteria for identifying potential risks, including without limitation any incidents that may be required by Department regulations to be reported to the Department;

B) Identification of the personnel responsible for coordinating quality management activities, the means of reporting to the Agency administrator, and the prescribed time within which the reporting must occur;

C) A description of the method(s) for:

i) Investigating and analyzing the frequency and causes of individual problems and patterns of problems;

ii) Taking corrective action to address the problems, including prevention and minimizing problems or risks;

iii) Evaluating corrective action[s] to determine the effectiveness of such action[s];

iv) Coordinating all pertinent case, problem, or risk review information with other applicable quality assurance and/or risk management activities, such as review of consumer care; review of staff or CIHCS provider conduct; the consumer complaint system; and education and training programs;

D) Documentation of required quality management activities, including cases, problems, or risks identified for review; findings of investigations; and any actions taken to address problems or risks; and

E) A schedule for program implementation not to exceed 90 days after the date of the initial inspection.

7.2.3 The CIHCS Agency shall evaluate the discharge planning process periodically for effectiveness.

7.2.4 The CIHCS Agency shall periodically review treatment protocols and compliance with such protocols.

SECTION 8. PERMISSIBLE CIHCS AGENCY SERVICES

8.1 Purpose

The activities of licensed CIHCS Agencies are directed towards integrating the services of a community-based team of qualified CIHCS providers, based on local need, to address gaps in a community's primary and public health care systems, to assess and treat consumers outside of the hospital setting for the purpose of preventing or improving a particular medical condition, and to reduce the burden of patients with non-emergent conditions who access the larger health care system through the emergency medical services system. CIHCS Agency services are intended to address the unmet needs of individuals who are experiencing intermittent health care issues and to prevent duplication of out-of-hospital medical care and services.

8.2 Standards Governing CIHCS Agency Evaluation and Treatment Services for Single Visits

8.2.1 A CIHCS Agency, under medical direction and within the applicable scope of the provider's practice, may utilize its appropriate personnel to assess, provide, and/or coordinate out-of-hospital medical services during single visits.

8.2.2 A CIHCS Agency that is also an emergency medical services agency or that has contracted with an emergency medical services agency may utilize its appropriate personnel to:

A) Treat and release consumers with non-emergent conditions instead of transporting the consumer to a hospital or emergency department;

B) Treat and transport, as authorized by law, consumers with non-emergent conditions to appropriate destinations other than a hospital or an emergency department;

C) Treat and refer consumers with non-emergent conditions to a primary care or urgent care facility; or

D) Assess the consumer with a non-emergent condition and communicate with a care provider to determine an appropriate course of action.

8.3 Standards Governing Recurrent CIHCS Agency Services

8.3.1 If the eligible consumer's care provider, as defined in Section 2.6 of these rules, orders a CIHCS Agency to provide services specific to the consumer's needs in a series of visits, the CIHCS Agency shall approve a service plan before providing services to the consumer. For purposes of these rules, "approval" of the service plan means, at minimum, that the Agency must review the service plan and, pursuant to these rules and the Agency's policies and procedures, confirm that its providers can supply the ordered services within their scopes of practice.

8.3.2 If the Agency determines the consumer lacks adequate resources to obtain or access necessary out-of-hospital medical services, the CIHCS Agency may provide the consumer with such necessary services through a series of visits established in the consumer service plan that the CIHCS medical director shall approve.

8.3.3 The Agency will provide the services in accordance with the consumer's service plan within the scope of services of the Agency, and will ensure continuous oversight of the consumer's care up to and until the consumer's discharge.

8.3.4 Evaluations of the consumer's progress based on the goals established in the service plan shall be conducted as set forth in Sections 8.4.2 and 8.5.2 and documented in the consumer's service records. CIHCS providers shall notify the Agency and/or the care provider regarding any changes that suggest a need to alter the service plan.

8.3.5 Each consumer service plan shall incorporate a defined discharge summary, as required in Sections 8.5.1(H) and 8.6 of these rules.

8.4 Standards Governing Initial and Subsequent Assessments

8.4.1 Initial Consumer Assessment

A) The CIHCS Agency shall ensure a qualified CIHCS provider conducts an assessment of the consumer's immediate needs at the initial encounter.

B) The CIHCS Agency assessment shall:

i) Evaluate the consumer's physical and psychological status, if applicable, including but not limited to the consumer's special needs, communication or language barriers, capabilities, limitations, and short-term and long-term goals;

ii) Evaluate or screen the consumer for medical, therapeutic, social, nursing, and dietary service needs;

iii) Obtain a list of the consumer's current medications and medication schedules;

iv) Identify social support systems, evaluate environment and discuss any transportation accessibility issues and barriers; and

v) Assess, obtain and identify other systems, situations, and information as deemed appropriate to improve the consumer's life and/or health related outcomes.

8.4.2 Subsequent Assessments

A) CIHCS providers shall document and submit an individualized subsequent assessment that:

i) Accurately reflects the consumer's current health status, goals, and timeframes for meeting the goals;

ii) Includes information that may be used to demonstrate the consumer's progress toward achievement of the desired outcomes; and

iii) Identifies whether the consumer requires continuing CIHCS services or may be discharged.

B) Subsequent assessments shall occur when there is a significant change of condition.

C) Each subsequent assessment shall be submitted to the Agency for evaluation and use during the Agency's preparation of periodic service plan reviews, as required in Section 8.5.2 of these rules.

8.5 Standards Governing CIHCS Agency Service Plans for Recurrent Services

8.5.1 This Section shall not apply to single visits described in Section 8.2 of these rules. Based on the initial assessment described in Section 8.4.1 of these rules, the CIHCS Agency shall ensure that a written service plan is developed or amended as needed to address the consumer's pertinent diagnoses and needs. The service plan must include at minimum information on:

A) The consumer's physical and mental status;

B) The consumer's short and long-term health care needs and any goals, and time-frames for meeting those needs and goals;

C) A description of the out-of-hospital medical service[s] needed to address and satisfy the consumer's health-care needs and any non-medical goals;

D) The frequency of visits along with the projected number of visits that may be required to address the consumer's health care needs and any non-medical goals;

E) Identification of and written documentation setting forth the CIHCS Agency's coordination of services provided to the consumer, including non-medical related goal outcomes;

F) A description of any equipment needed;

G) Limitations on the consumer's activities; and

H) A goal for the consumer's discharge.

8.5.2 For recurrent services provided pursuant to Sections 8.3 and 8.5 of these rules the CIHCS Agency shall ensure that either the Agency medical director or the consumer's care provider evaluates the subsequent assessments submitted by the CIHCS providers pursuant to Section 8.4.2 of these rules, and shall re-review the service plan when there is a significant change of condition.

8.6 Standards Governing Discharge

8.6.1 The Agency shall establish and follow a discharge planning process as set forth in Section 8.3.5 of these rules.

8.6.2 The CIHCS Agency shall develop a discharge summary for each consumer.

8.6.3 The discharge summary shall be discussed with the consumer or designated representative prior to discharge and shall include:

A) An evaluation of the post-CIHCS care needs and goals as outlined in the service plan, and a summary of the services the consumer received.

B) Contact information for the consumer to call in case the consumer has questions after discharge.

C) Written instructions about self-care, follow-up care, modified diet, medications, and signs and symptoms to be reported to the consumer's care provider(s).

SECTION 9. COMPLAINTS

9.1 When services commence, the Agency shall provide each consumer with:

9.1.1 Contact information for the Department and the Agency staff responsible for complaint intake and problem resolution;

9.1.2 Information regarding how to initiate a complaint; and

9.1.3 Information regarding the Agency's investigation and resolution process.

9.2 Complaints may be reported to the CIHCS Agency and/or the Department.

9.3 Complaints in writing against medical directors for violations of these rules may be initiated by any person, the Colorado Medical Board, the Colorado Board of Nursing, or the Department.

9.3.1 The Department may refer complaints made against medical directors to the Colorado Medical Board or the Colorado Board of Nursing for review.

9.4 The Agency shall refer to the appropriate regulatory body any credible allegation made against a CIHCS Agency provider who is licensed, regulated, or certified concerning the provision of care to the consumer, including an allegation concerning a provider acting outside of his or her scope of practice.

SECTION 10. REPORTING REQUIREMENTS

10.1 Occurrences

10.1.1 Pursuant to Section 25-3.5-1303(1)(f), C.R.S., each CIHCS Agency licensed pursuant to Section 25-3.5-1301 *et seq*., C.R.S., shall report to the Department the occurrences specified at Section 25-1-124 (2), C.R.S.

10.1.2 The Agency shall report the following occurrences to the Department in the format required by the Department by the next business day after the occurrence or when the CIHCS Agency becomes aware of the occurrence:

A) Any occurrence that results in the death of a consumer of the CIHCS Agency and is required to be reported to the coroner pursuant to Section 30-10-606, C.R.S., as arising from an unexplained cause or under suspicious circumstances;

B) Any occurrence that results in any of the following serious injuries to a consumer:

i) Brain or spinal cord injuries;

ii) Life-threatening complications of anesthesia or life-threatening transfusion errors or reactions;

iii) Second or third degree burns involving twenty percent or more of the body surface area of an adult consumer or fifteen percent or more of the body surface area of a child consumer;

C) Any time that a consumer of the CIHCS Agency cannot be located following a reasonable search of the area, and there are circumstances that place the consumer's health, safety, or welfare at risk or, regardless of whether such circumstances exist, the consumer has been missing for eight hours;

D) Any occurrence involving physical, sexual, or verbal abuse of a consumer, as described in Sections 18-3-202, 18-3-203, 18-3-204, 18-3-206, 18-3-402, 18-3-403, 18-3-404, or 18-3-405, C.R.S., by an employee or contractor of the CIHCS Agency;

E) Any occurrence involving neglect of a consumer as described in Section 26-3.1-101(7) (b), C.R.S.

F) Any occurrence involving misappropriation of a consumer's property. For purposes of this paragraph, "misappropriation of a consumer's property" means a pattern of or deliberately misplacing, exploiting, or wrongfully using,

either temporarily or permanently, a consumer's belongings or money without the consumer's consent;

G) Any occurrence in which drugs intended for use by consumers are diverted to use by other persons; and

H) Any occurrence involving the malfunction or intentional or accidental misuse of consumer care equipment that occurs during treatment or diagnosis of a consumer and that significantly adversely affects or if not averted would have significantly adversely affected a consumer of the CIHCS Agency.

10.1.3 Any Agency reports submitted shall be strictly confidential in accordance with and pursuant to Sections 25- 1-124 (4), (5), and (6), C.R.S.

10.1.4 The Department may request further oral or written reports of the occurrence if it determines such report is necessary.

10.1.5 No CIHCS Agency owner, administrator, or employee thereof shall discharge or in any manner discriminate or retaliate against any consumer of a CIHCS Agency, relative or sponsor thereof, employee of the CIHCS Agency, or any other person because such person, relative, legal representative, sponsor, or employee has made in good faith or is about to make in good faith, a report pursuant to this Section 10.1 or has provided in good faith or is about to provide in good faith evidence in any proceeding or investigation relating to any occurrence required to be reported by a CIHCS Agency.

10.1.6 Nothing in this Section 10 shall be construed to limit or modify any statutory or common law right, privilege, confidentiality or immunity.

10.1.7 Nothing in this Section 10 shall affect a person's access to his or her medical record as provided in Section 25-1-801, C.R.S.**,** nor shall it affect the right of a family member or any other person to obtain medical record information upon the consent of the consumer or his/her authorized representative.

10.2 Other Required Reporting

10.2.1 The Agency shall ensure that:

A) All staff have knowledge of Article 3.1, Part 1 of Title 26, C.R.S., regarding protective services for at-risk adults;

B) All staff have knowledge of Article 3, Part 3 of Title 19, C.R.S., if the Agency provides services to pediatric consumers; and

C) All incidents involving neglect, abuse or financial exploitation are reported immediately, through established procedure, to the Agency owner and administrator.

10.2.2 In addition to the Agency's reporting requirements described in Sections 10.1 and 10.2.1 of these rules, the Agency shall report all incidents described in Sections 10.1.1(D) of these rules to the appropriate officials as specified in statute. The Agency shall make copies of all such reports available to the Department upon request.

Section 11. STANDARDS GOVERNING CIHCS AGENCY PROVISION OF CARES PROGRAM SERVICES

11.1 In addition to the services a CIHCS Agency may perform as authorized by these rules, a CIHCS Agency may perform any of the community assistance referral and education services that may be provided through a CARES Program as provided in Section 25-3.5-1203(3), C.R.S.

11.2 In addition to the reporting requirements required by Section 25-3.5-1303, C.R.S. and these rules, any CIHCS Agency providing authorized community assistance referral and education services shall comply with all service, notification, and reporting requirements set forth in Section 25-3.5-1201, *et seq*., C.R.S.