Part 4. WAIVER OF REGULATIONS FOR HEALTH CARE ENTITIES

4.101 Statutory Authority, Applicability and Scope

(1) This Part 4 is promulgated by the State Board of Health pursuant to Section 25-1-108(l)(c), C.R.S., in accordance with the general licensing authority of the Department as set forth in Section 25-1.5-103, C.R.S.
(2) This Part 4 applies to health facilities licensed by the Department and establishes procedures with respect to waiver of regulations relating to state licensing and federal certification of health facilities.
(3) Nothing contained in these provisions abrogates the Applicant’s obligation to meet minimum requirements under local safety, fire, electrical, building, zoning, and similar codes.
(4) Nothing herein shall be deemed to authorize a waiver of any statutory requirement under state or federal law, except to the extent permitted therein.
(5) It is the policy of the State Board of Health and the Department that every licensed health care entity complies in all respects with applicable regulations. Upon application to the Department, a waiver may be granted in accordance with this Part 4, generally for a limited term. Absent the existence of a current waiver issued pursuant to this part, health care entities are expected to comply at all times with all applicable regulations.

4.102 Definitions For This Part 4

(1) “Applicant” means a current health care entity licensee, or an applicant for federal certification or for an initial license to operate a health care entity in the state of Colorado.
(2) “Board” means the State Board of Health.
(3) “Department” means the Colorado Department of Public Health and Environment.
(4) “Health Care Entity” means a health facility or agency licensed pursuant to Sections 25-1.5-103 and 25-3-102, C.R.S., and/or certified pursuant to federal regulations to participate in a federally funded health care program.
(5) “Regulation(s)” means:
   (a) Any state regulation promulgated by the Board relating to standards for operation or licensure of a health care entity, or
   (b) Any federal regulation pertaining to certification of a care entity, but only when final authority for waiver of such federal regulation is vested in the Department. “Regulation(s)” includes the terms “standard(s)” and “rule(s).”

4.103 Application Procedure

(1) General Waiver applications shall be submitted to the Department on the form and in the manner required by the Department.
   (a) Only one Regulation per waiver application will be considered.
   (b) The Applicant shall provide the Department such information and documentation as the Department may require to validate the conditions under which the waiver is being sought.
   (c) The application must include the Applicant’s name and specify the Regulation that is the subject of the application, identified by its citation.
   (d) The application must be signed by an authorized representative of the Applicant, who shall be the primary
contact person for the Department and the individual responsible for ensuring that accurate and complete information is provided to the Department.

(2) At a minimum, each waiver application shall include the following:
(a) A copy of the notice required to be posted pursuant to Section 4.103(4);
(b) If the waiver application pertains to building requirements, schematic drawings of the areas affected and a description of the effect of the requested waiver on the total health care entity;
(c) A description of the programs or services offered by the health care entity that are anticipated to be affected by the waiver;
(d) A description of the number of residents or patients in the health care entity and the level of care they require;
(e) A description of the nature and extent of the Applicant’s efforts to comply with the Regulation;
(f) An explanation of the Applicant’s proposed alternative(s) to meet the intent of the Regulation that is the subject of the waiver application;
(g) An explanation of why granting the waiver would not adversely affect the health, safety or welfare of the health care entity's residents or patients;
(h) If the waiver is being sought for state Regulation, a description of how any applicable federal Regulation similar to the state Regulation for which the waiver is sought (if any) is being met.

(3) A waiver application shall address the following matters, to the extent applicable or relevant:
(a) Staffing considerations, such as staff/resident or patient ratios, staffing patterns, scope of staff training, and cost of extra or alternate staffing;
(b) The location and number of ambulatory and non-ambulatory residents or patients;
(c) The decision-making capacity of the residents or patients;
(d) Recommendations of attending physicians and other care-givers;
(e) The extent and duration of the disruption of normal use of resident or patient areas to bring the health care entity into compliance with the Regulation;
(f) Life safety code factors, including but not limited to:
   (i) The availability and adequacy of areas safe from fire and smoke to hold residents or patients during a fire emergency;
   (ii) Smoking regulations;
   (iii) Fire emergency plan;
   (iv) The availability, extent and types of automatic fire detection and fire extinguishment systems provided in the health care entity;
   (v) The ability to promptly notify, and availability of, the fire department;
(g) Financial factors, including but not limited to:
   (i) The estimated cost of complying with the Regulation, including capital expenditures and any other associated costs, such as moving residents or patients;
   (ii) How application of the Regulation would create a demonstrated financial hardship on the health care entity that would jeopardize its ability to deliver necessary health care services to residents or patients;
   (iii) The availability of financing to implement the Regulation, including financing costs, repayment requirements, if any, and any financing or operating restrictions that may impede delivery of health care to residents or patients; and
   (iv) The potential increase in the cost of care to residents or patients as a result of implementation of the Regulation.
(h) Why waiver of the Regulation is necessary for specific health care entity programs to meet specific patient or resident needs, and why other patient or resident needs are not thereby jeopardized.

(4) Notice and Opportunity to Comment on Application
(a) No later than the date of submitting the waiver application to the Department, the applicant shall post written notice of the application for thirty (30) days at all public entrances to the health care entity, as well as in at least one area commonly used by patients or residents, such as a waiting room, lounge, or dining room.
Applicants that do not provide services on their own licensed premises, such as home care agencies and hospices, shall instead provide such written notice directly to patients. The notice shall be dated and include that an application for a waiver has been made, a meaningful description of the substance of the waiver, and that a copy of the waiver shall be provided by the health care entity upon request.

(b) The notice must also indicate that any person interested in commenting on the waiver application may forward written comments directly to the Department at the following address:

CDPHE - HFD, A2 - Waiver Program
4300 Cherry Creek Drive South
Denver, CO 80246.

(c) The notice must specify that written comments from interested persons must be submitted to the Department within thirty (30) calendar days of the date the notice is posted by the Applicant, and that persons wishing to be notified of the Department's action on the waiver application may submit to the Department at the above address a written request for notification and a self-addressed stamped envelope.

4.104 Department Action Regarding Waiver Application

(1) General. Upon an Applicant’s submission of a completed waiver application to the Department, a waiver of a particular Regulation with respect to a health care entity may be granted in accordance with this Part 4.

(2) Decision on Waiver Application
a) In acting on a waiver application, the Department shall consider:
   (i) The information submitted by the Applicant;
   (ii) The information timely submitted by interested persons, pursuant to Section 4.103 (4); and
   (iii) Whether granting the waiver would adversely affect the health safety or welfare of the health care entity's residents or patients.

b) In making its determination, the Department may also consider any other information it deems relevant, including but not limited to occurrence and complaint investigation reports, and licensure or certification survey reports and findings related to the health care entity and/or the operator or owner thereof.

c) The Department shall act on a waiver application within ninety (90) calendar days of receipt of the completed application. An application shall not be deemed complete until such time as the Applicant has provided all information and documentation requested by the Department.

(3) Terms and conditions of the waiver. The Department may specify terms and conditions under which any waiver is granted, which terms and conditions must be met in order for the waiver to remain effective.

4.105 Termination, Expiration and Revocation of Waiver

(1) General. The term for which each waiver granted will remain effective shall be specified at the time of issuance.

a) The term of any waiver shall not exceed any time limit set forth in applicable state or federal law.

b) At any time, upon reasonable cause, the Department may review any existing waiver to ensure that the terms and conditions of the waiver are being observed, and/or that the continued existence of the waiver is otherwise appropriate.

c) Within thirty (30) calendar days of the termination, expiration or revocation of a waiver, the Applicant shall submit to the Department an attestation, in the form required by the Department, of compliance with the Regulation to which the waiver pertained.

(2) Termination
a) Change of Ownership. A waiver shall automatically terminate upon a change of ownership of the health care entity, as defined in Section 2.7 of Part 2, Chapter II of these Regulations. However, to prevent such automatic termination, the prospective new owner may submit a waiver application to the Department prior to the effective date of the change of ownership. Provided the Department receives the new application by
this date, the waiver will be deemed to remain effective until such time as the Department acts on the application.

(3) **Expiration**
(a) Except as otherwise provided in this Part 4, no waiver shall be granted for a term that exceeds one year from the date of issuance.
(b) A waiver with a term in excess of one year may be granted for Regulations pertaining to state building or fire safety Regulations, or in other specific cases where it is determined a longer term is appropriate.
(c) If an Applicant wishes to maintain a waiver beyond the stated term, it must submit a new waiver application to the Department not less than ninety (90) calendar days prior to the expiration of the current term of the waiver.

(4) **Revocation**
(a) Notwithstanding anything in this Part 4 to the contrary, the Department may revoke a waiver if it determines that:
   (i) The waiver’s continuation jeopardizes the health, safety, or welfare of residents or patients;
   (ii) The Applicant has provided false or misleading information in the waiver application;
   (iii) The Applicant has failed to comply with the terms and conditions of the waiver;
   (iv) The conditions under which a waiver was granted no longer exist or have changed materially; or
   (v) A change in a federal or state law or Regulation prohibits, or is inconsistent with, the continuation of the waiver.
(b) Notice of the revocation of a waiver shall be provided to the Applicant in accordance with the Colorado Administrative Procedures Act, Section 24-4-101 et seq., C.R.S.

4.106 Waiver of Building and Fire Safety Regulations for Skilled and Intermediate Health Facilities

(1) Notwithstanding anything in this Part 4 to the contrary, an application for waiver of building or fire safety Regulations promulgated by the Board that is submitted with respect to a health care entity that is a skilled or intermediate health care facility shall be reviewed and acted upon in accordance with this Section 4.106. To the extent they do not conflict with the express provisions of this Section 4.106, the remaining provisions of this Part 4 shall also apply to this type of waiver application.

(2) A waiver application described in Section 4.106(1) shall be submitted to the Department and notice thereof shall be posted in accordance with Section 4.103. The application must address those matters set forth in Section 4.103(2) and Sections 4.103(3) (f) and (g). Other matters described in Section 4.103(3) may also be addressed, as appropriate.

(3) The Department shall review the application in accordance with Section 4.104(2), and shall make a recommendation to the Board within ninety (90) calendar days of receipt of the complete application as to whether or not the requested waiver should be granted.
(a) The Department may recommend granting a waiver only upon finding that:
   (i) Rigid application of the Regulation would result in demonstrated financial hardship to the health care entity, and
   (ii) Granting the requested waiver would not adversely affect the health and safety of the health care entity’s residents or patients.
(b) The Department’s recommendation shall include the term of the waiver and any terms and conditions for issuance thereof.

(4) The Department’s recommendation to the Board on any waiver application subject to this Section 4.106 shall be in writing and shall include the following:
(a) A statement of the Department’s recommendation, including the required findings described in Section 4.106(3)(a) and a general statement of the basis for the recommendation; and
(b) A list of the documents and other information reviewed by the Department in preparing its recommendation, which documents shall be made available to the Board for review upon request.

(5) The Board shall review and act upon the Department's recommendation at its next regularly scheduled meeting, or as soon as reasonably possible thereafter. The Department shall provide the Applicant notice of the Board's action, and if the waiver is approved, shall issue the waiver in accordance with the direction of the Board.

(6) The Department shall be responsible for monitoring any waiver approved by the Board pursuant to this Section 4.106 and, at the Board's request, shall provide periodic reports to the Board concerning the status thereof. Such waivers shall be subject to the provisions of Section 4.105 concerning termination, expiration and revocation; provided, however, that the Department's action to revoke a waiver pursuant to Section 4.105(4)(a) shall be subject to the Board's prior approval.

4.107 Appeal Rights

(1) An Applicant may appeal the decision of the Department or the Board regarding a waiver application or revocation as provided in the Colorado Administrative Procedures Act, Section 24-4-101 et seq., C.R.S