

EMERGENCY REGULATION

Regulation of the
Department of Public Health

Concerning
**Licensure of Home Health Agencies Waiver
Requests**

Emergency regulations adopted after July 1, 2013, become effective upon electronic submission to the Secretary of the State, or at a later date less than twenty days thereafter, if specified within the regulation.

Website posted on
January 31, 2014

Effective Date
January 29, 2014

Approved by the Attorney General on
EMERGENCY REGULATION. Attorney General
approval not required.

Approved by the Legislative Regulation Review
Committee on
January 17, 2014

Received and filed in the Office of the
Secretary of the State on
January 29, 2014

Electronic copy with agency head certification statement
submitted to the Office of the
Secretary of the State on
January 29, 2014

Emergency Regulations are not Published in the
Connecticut Law Journal

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH



Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of the Commissioner

Electronic Copy Certification Statement

I, Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner of the Department of Public Health, in accordance with the provisions of Section 4-172 of the *General Statutes of the State of Connecticut*, do hereby certify:

That the electronic copy of a regulation concerning **Licensure of Home Health Care Agencies Waiver Requests**, which was approved by the Legislative Regulation Review Committee on **January 17, 2014**, and which shall be submitted electronically for filing to the Secretary of the State by **Jill Kentfield** of this agency on **January 29, 2014**, is a true and accurate copy of the original regulation approved in accordance with Sections 4-169 and 4-170 of the *General Statutes of the State of Connecticut*.

In testimony whereof, I have hereunto set my hand on **January 29, 2014**.

A handwritten signature in cursive script, appearing to read "Jewel Mullen", written over a horizontal line.

(Signature of agency head)



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IMPORTANT: Use this form (REGS-1-E) to submit emergency regulations to the Legislative Regulation Review Committee. For permanent regulations, use form REGS-1 instead. For non-substantive technical amendments and repeals proposed without prior notice or hearing as permitted by subsection (g) of CGS 4-168, as amended by PA 13-247 and PA 13-274, use form REGS-1-T instead.

Please read the additional instructions on the back of the last page (Certification Page) before completing this form. Failure to comply with the instructions may cause disapproval of proposed emergency regulations.

State of Connecticut
EMERGENCY REGULATION
of the

NAME OF AGENCY:

Connecticut Department of Public Health

Concerning

SUBJECT MATTER OF REGULATION:

Licensure of Home Health Care Agencies waiver requests

Section 1. Section 19-13-D66 of the Regulation of Connecticut State Agencies is amended to read as follows:

Definitions. As used in [Sections] sections 19-13-D66 to 19-13-D79 inclusive:

(a) "Agency" means home health care agency as defined in [Section] section [19a-490(a)] 19a-490(d) of the Connecticut General Statutes;

(b) "Central [Office] office" means the agency office responsible and accountable for all agency operations in this state;

(c) "Clinical experience" means employment in providing patient services in a health care setting;

(d) "Clinical quality measure" means a tool that assist in measuring and tracking the quality of health care provided by the agency;

[(d)] (e) "Commissioner" means the [commissioner of health services, or his/her representative] Commissioner of Public Health or the commissioner's designee;

(f) "Continuous skilled nursing" means a total of two or more hours of home health nursing services provided in a twenty-four hour period by an agency licensed in accordance with chapter 368v of the Connecticut General Statutes;

[(e)] (g) "Contracted services" or "services under arrangement" means services provided by the agency which are subject to a written agreement with an individual, another agency or another facility;

(f) (h) "Contractor" means any organization, individual or home health care agency that provides services to patients of a primary agency as defined in [paragraph (cc) of Section 19-13-D66 of these regulations] subsection (e) of this section;

(g) (i) "Chiropractor" means a person possessing a license to practice chiropractic in this state;

(h) (j) "Curriculum" means the plan of classroom and clinical instructions for training and skills assessment as a homemaker-home health aide;

(i) (k) "Dentist" means a person licensed to practice dentistry in this state;

(j) (l) "Department" means the [Connecticut Department of Health Services] Department of Public Health;

- [(k)] [(m)] “Direct service staff” means individuals employed by the agency or under contract whose primary responsibility is delivery of care to patients;
- [(l)] [(n)] “Evening or nighttime service” means service provided between the hours of 5 p.m. and 8 a.m.;
- [(m)] [(o)] “Full-time” means employed and on duty a minimum of thirty-five (35) hours per workweek on a regular basis;
- [(n)] [(p)] “Full-time equivalent” means the total weekly hours of work of all persons in each category of direct service staff divided by the number of hours in the agency’s standard workweek. Full-time equivalents are computed for each category of direct service staff;
- [(o)] [(q)] “Holiday service” means service provided on the days specified in the agency’s official personnel policies as holidays;
- [(p)] [(r)] “Homemaker-home health aide” means an unlicensed person who has successfully completed a training and competency evaluation program for the preparation of homemaker-home health aides approved by the department;
- [(q)] [(s)] “Licensed practical nurse” means a person with a license to practice practical nursing in this state;
- [(r)] [(t)] “Non-visiting program” means services of the agency provided in sites other than a patient’s home;
- [(s)] [(u)] “Occupational therapist” means a person with a license to practice occupational therapy in this state;
- [(t)] [(v)] “Occupational therapy assistant” means a person who has successfully completed a training program approved by the American Occupational Therapy Association and is currently certified by [the] said association;
- [(u)] [(w)] “Patient care services” mean agency activities carried out by agency staff for or on behalf of a patient. Such services include, but are not limited to, receipt of referral for service, admission to service, assignment of personnel, direct patient care, communication/coordination with the source of medical care and development/maintenance of a patient’s clinical record;
- [(v)] [(x)] “Patient service office” means one or more separate and distinct offices which provide patient care services and are included under the agency’s license. This office shall comply with the [regulations of Connecticut State Agencies, Section] section 19-13-D77 of the Regulations of Connecticut State Agencies;
- [(w)] [(y)] “Peer consultation” means a process by which professionals of the same discipline, who meet supervisory qualifications, meet regularly to review patient management, share expertise and take responsibility for their own and each other’s professional development and maintenance of standards of service;
- [(x)] [(z)] “Permanent part-time” means employed and on duty a minimum of twenty (20) hours per workweek on a regular basis;
- [(y)] [(aa)] “Pharmacist” means a person licensed to practice pharmacy in this state;
- [(z)] [(bb)] “Physical therapy assistant” means a person who has successfully completed an education program accredited by the American Physical Therapy Association;
- [(aa)] [(cc)] “Physician” means a doctor of medicine or osteopathy licensed either in Connecticut or in a state which borders Connecticut;
- [(bb)] [(dd)] “Podiatrist” means a person licensed to practice podiatry in this state;
- [(cc)] [(ee)] “Primary agency” means a home health care agency which hires or pays for the services of other organizations, agencies or individuals who provide care or services to its patients;
- [(dd)] [(ff)] “Primary care nurse” means a registered nurse licensed to practice nursing in this state who is the agency employee assigned primary responsibility for planning and implementing the patient’s care;
- [(ee)] [(gg)] “Public health nurse” means a graduate of a baccalaureate degree program in nursing approved by the National League for Nursing for preparation in public health nursing;

[(ff)] (hh) "Quality care" means that the patients receive clinically competent care which meets professional standards, are supported and directed in a planned pattern toward mutually defined outcomes, achieve maximum recovery consistent with individual potential and life style, obtain coordinated service through each level of care and are taught self-management and preventive health measures;

[(gg)] (ii) "Registered nurse" means a person with a license to practice as a registered nurse in this state;

[(hh)] (jj) "Registered physical therapist" means a person with a license to practice physical therapy in this state;

[(ii)] (kk) "Related community health program" means an organized program which provides health services to persons in a community setting;

[(jj)] (ll) "Representative" means a designated member of the patient's family, or person legally designated to act for the patient in the exercise of the patient's rights as contained in [Sections] sections 19-13-D66 to 19-13-D79, inclusive, of the [regulations] Regulations of Connecticut State Agencies.

[(kk)] (mm) "Social work assistant" means a person who holds a baccalaureate degree in social work with at least one (1) year of social work experience; or a baccalaureate degree in a field related to social work with at least two (2) years of social work experience;

[(ll)] (nn) "Social worker" means a graduate of a master's degree program in social work accredited by the Council on Social Work Education;

[(mm)] (oo) "Speech Pathologist" means a person with a license to practice speech pathology in this state;

[(nn)] (pp) "Subdivision", as it relates to an agency, means a unit of a multifunction health care organization which is assigned the primary authority and responsibility for the agency operations. A subdivision shall independently meet the regulations and standards for licensure and shall be independently licensed as a home health care agency;

[(oo)] (qq) "Therapy services" means physical therapy, occupational therapy, or speech pathology services; and

[(pp)] (rr) "Weekend service" means services provided on Saturday or Sunday.

Section 2. Subsection (e) of section 19-13-D68 of the Regulation of Connecticut State Agencies is amended to read as follows:

(e) Supervisor of Clinical Services[;]:

(1) An agency shall employ one full-time supervisor of clinical services for each fifteen (15), or less, full-time or full-time equivalent professional direct service staff.

(2) The supervisor of clinical services shall have primary authority and responsibility for maintaining the quality of clinical services.

(3) The supervisor's responsibilities include, but are not limited to:

(A) Coordination and management of all services rendered to patients and families by direct service staff under his/her supervision;

(B) Supervision of assigned nursing personnel in the delivery of nursing services to patients and families;

(C) Direct evaluation of the clinical competence of assigned nursing personnel and participation with appropriate supervisory staff in the evaluation of other direct service staff;

(D) Participation in or development of all agency objectives, standards of care, policies and procedures affecting clinical services;

(E) Participation in direct services staff recruitment, selection, orientation and inservice education; and

(F) Participation in program planning, budgeting and evaluation activities related to the clinical services of the agency.

(4) The supervisor of clinical services may also serve as the administrator in agencies with six (6) or less full-time or full-time equivalent professional direct service staff.

(5) Any absence of the supervisor of clinical services for longer than one month [must] shall be reported to the commissioner. A registered nurse who has at least two (2) years' experience in a home health care agency, shall be designated, in writing, to act during any absence of the supervisor of clinical services whenever patient care personnel are serving patients.

(6) Special requirement. Agencies that provide continuous skilled nursing care. Waiver.

(A) Waiver.

(i) The commissioner may waive provisions of subdivision (1) of this subsection if the commissioner determines that such waiver would not endanger the life, safety or health of any patient. The commissioner may impose conditions which assure the health, safety and welfare of patients upon the grant of such waiver, or to revoke such waiver upon a finding that the health, safety, or welfare of any patient has been jeopardized.

(ii) Any agency requesting a waiver shall apply in writing to the department.

Such application shall include:

(I) Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the agency upon enforcement of the regulations;

(II) The specific relief requested;

(III) Alternative staffing plan as well as policies or procedures proposed; and

(IV) Any documentation which supports the application for a waiver.

(iii) In consideration of any application for a waiver, the commissioner may consider the following:

(I) The level of care provided; and

(II) The impact of a waiver on the care provided.

(iv) The agency shall provide any additional information requested by the commissioner as part of the determination of the application for a waiver.

(v) Should the commissioner approve such waiver, the agency shall monitor, collect, and report to the department quarterly clinical quality measures as required in the approval to ensure that quality care is provided to patients that require continuous skilled nursing care. Clinical quality measures shall include the following measures in addition to those set forth in the approval:

(I) Abuse and neglect;

(II) Patient satisfaction survey measures;

(III) Incidence of pressure ulcers; and

(IV) Patient re-hospitalization.

(vi) The agency shall provide the department with unrestricted access to the clinical quality measure data collection as provided in clause (v) of this subparagraph. Documentation of clinical quality measures shall be kept on file for a period of five years.

(vii) Clinical quality measure data monitored and collected as provided in clause (v) of this subparagraph shall be analyzed and incorporated into the agency's quality assurance and performance activities.

Statement of Purpose

Statement of Purpose: (A) The purpose of the regulations is to establish a definition of continuous skilled nursing and clinical quality measures and establishes authority for the commissioner to waive the provisions of 19-13-D68 (e)(1) in home health agency if the commissioner determines that such waiver would not endanger the life, safety or health of any patient. (B) The regulations require these agencies to apply for such waiver in writing to the agency and include reasons for such hardship along with monitoring and data collection of clinical quality measures to ensure that quality care is provided to patients that require continuous skilled nursing care. Proposed language is consistent with current waiver language used by other facility types. (C) The proposed regulations revises section 19-13-D66 to include definitions of continuous skilled nursing and clinical quality measures and adds language into section 19-13-D68 to allow the Department to waive the supervisor of clinical services to staff ratio for home health care agencies providing continuous skilled nursing care.

CERTIFICATION

This certification statement must be completed in full and signed by the agency head.

I hereby certify that the above Emergency Regulation(s)

1) is/are adopted by this agency (check one, and complete as applicable)

without prior notice or hearing

upon the following described abbreviated notice and hearing _____.

2) pursuant to the following authority(ies): (complete all that apply)

a. Connecticut General Statutes section(s) 19a-495,

b. Public Act Number(s) _____.

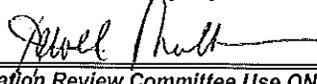
Provide public act number(s) if the authorizing act has not yet been codified in the Connecticut General Statutes.

I further certify that copies of (a) this agency's finding of emergency and (b) the governor's approval of said finding, are appended to said regulation(s),

3) and that said regulation(s) is/are **EFFECTIVE** (check one, and complete as applicable)

When electronically submitted to the Secretary of the State

OR on _____ (insert a date less than 20 days after submission)

4) SIGNED (Head of Board, Agency or Commission)	OFFICIAL TITLE, DULY AUTHORIZED	DATE
	Commissioner	1/7/2014

(For Regulation Review Committee Use ONLY)

APPROVED in WHOLE or WITH technical corrections deletions substitute pages

DEEMED APPROVED, pursuant CGS 4-168(f)(2), as amended.

Rejected without prejudice

Disapproved, pursuant to CGS 4-168(f)(2), as amended.

By the Legislative Regulation Review Committee in accordance with CGS Section 4-170, as amended	SIGNED (Administrator, Legislative Regulation Review Committee)	DATE
		January 17, 2014

(For Secretary of the State Use ONLY)

In accordance with CGS Section 4-172, as amended by PA 13-247 and PA 13-274, one certified paper copy and one electronic copy with agency head certification statement submitted on the date(s) specified below.

DATE	SIGNED (Secretary of the State)	BY

Date Posted to SOTS Regulations Website:

Effective date:

SOTS file stamp:



Dannel P. Malloy
GOVERNOR
STATE OF CONNECTICUT

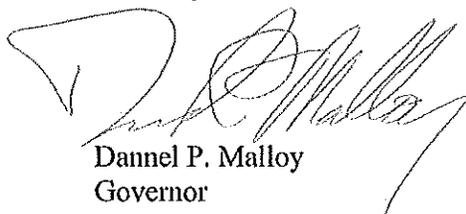
January 6, 2014

Commissioner Jewel Mullen
410 Capitol Avenue
Hartford, CT 06134

Dear Commissioner Mullen,

Thank you for your memorandum dated January 2, 2014 describing the need to adopt emergency regulations to address the shortage of continuous skilled nursing care available to the most vulnerable citizens of our state. The proposed changes to current regulations are necessary to address the capacity shortage and ensure these critical services are available to those who need them most. Pursuant to Connecticut General Statute § 4-168(f), I hereby approve your findings and authorize you to proceed with the adoption of these emergency regulations in accordance with Chapter 54 of the Connecticut General Statutes.

Sincerely,



Dannel P. Malloy
Governor

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH



Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of the Commissioner

January 2, 2014

Governor Dannel P. Malloy
Office of the Governor
State Capitol
210 Capitol Avenue
Hartford, CT 06106

RE: Finding of Imminent Peril to the Public Health Necessitating the Adoption of Emergency Regulations Permitting the Commissioner to Waive § 19-13-D68(e)(1) of the Regulations of Connecticut State Agencies.

Dear Governor Malloy:

In accordance with Connecticut General Statutes § 4-168(f) and as further described below, I have made a finding that an imminent peril to the public health of the residents of Connecticut exists requiring adoption of an emergency regulation that would permit the Commissioner or her designee the authority to waive § 19-13-D68(e)(1) of the Regulations of Connecticut State Agencies, which requires a home health care agency to employ one full-time supervisor of clinical services for each fifteen or less, full-time or full-time equivalent (FTE) professional direct service staff.

I. LEGAL REQUIREMENTS FOR HOME HEALTH CARE AGENCIES

Connecticut General Statutes § 19a-490(d) defines a home health care agency, in part, as "a public or private organization, or a subdivision thereof, engaged in providing professional nursing services and the following services, available twenty-four hours per day, in the patient's home or a substantially equivalent environment: homemaker-home health aide services, physical therapy, speech therapy, occupational therapy or medical social services. The agency is required to provide professional nursing services and at least one additional service directly and all others directly or through contract. An agency shall be available to enroll new patients seven days a week, twenty-four hours per day." A home health care agency may provide intermittent skilled nursing care or continuous skilled nursing care. "Intermittent" care is defined by the Centers for Medicare and Medicaid Services as "skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours each day for periods of 21 days or less, with extensions in exceptional circumstances when the need for additional care is finite and predictable". "Continuous skilled nursing care" is defined as a total of 2 or more hours of skilled nursing care provided in a 24 hour period by a home health care agency licensed under Connecticut General Statutes § 19a-493. Continuous skilled nursing care is typically of a protracted duration.

Section 19-13-D68(e)(1) of the Regulations of Connecticut State Agencies requires a home health care agency to employ one full-time supervisor of clinical services for each fifteen or less, full-time or full-time equivalent (FTE) professional direct service staff. This requirement applies to both intermittent and continuous skilled nursing care



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services provided by a home health agency. The requirement presents a greater challenge to those offering continuous skilled nursing services. The largest group of patients receiving continuous skilled nursing care are children who are medically fragile. Many of these children require 23 hours a day of skilled nursing care, necessitating the agency providing continuous care in these cases to employ up to 5 FTEs for each such case. In such circumstances, a full-time supervisor of clinical services could only supervise 3 cases. By contrast, in an agency that is providing only intermittent care, the supervisor can supervise more than 50 cases.

The required FTE ratio of supervisor of clinical services to professional direct service staff oversight set forth in Connecticut Public Health Code is atypical. The Department has reviewed home health care agency regulations for 12 states, including three New England states, and has found that all twelve have an organizational structure that includes an Administrator and Director of Nurses or Nursing Supervisor who is responsible for the overall management of operations. However, none of the twelve mandate prescribed staffing ratios for supervision.

II. BACKGROUND

On August 28, 2013, Maxim Healthcare Services (hereinafter Maxim), a home health care agency that was providing continuous skilled nursing care to approximately 44 medically complex patients notified the Department of Public Health of its intent to close. At the time, Maxim and the Department anticipated that the care provided to these patients would be assumed by other licensed home health care agencies without challenges.

Maxim's 44 cases receive a median of 16-23 hours of continuous skilled nursing care on a daily basis with parents assuming the nursing care duties for the remaining hour(s) of the day. The patients are dependent for activities of daily living. They need mechanical respiratory ventilation and enteral nutrition. The fragility and chronicity of their medical needs requires consistent care planning and care givers. Achieving consistency is assured when one agency is providing the staff needed for continuous skilled nursing cases. While the majority of these patients are children, these patients age in the system and in most cases continue to require this high level of care throughout their lives.

Great effort has been made to transfer the care of Maxim's medically complex continuous skilled nursing cases. However, the number of agencies that are equipped either by qualified staff or competent supervisors is limited in Connecticut. Less than 10% of the licensed home health care agencies in Connecticut offer or provide this service line of care for medically involved children. Very few agencies have elected to provide continuous skilled nursing as it is cost prohibitive due to the requirement that such agencies provide one full-time supervisor for each FTE professional direct staff. As previously stated, in cases where 23 hours of continuous skilled nursing care is provided daily, compliance with the this requirement could mean that a supervisor of clinical services is providing oversight to as many as 5 professional direct service staff per case limiting that supervisor to only 3 cases. This level of supervision is not efficient and while the professional direct service staff are not only direct care providers, they are also actively engaged in case management of the patients. In an era when we are expected to do more with less and work smarter, this requirement is onerous and not resourceful. This encumbrance has not persuaded home health care agencies to provide this level of care but rather has discouraged it.

III. FINDING OF IMMINENT PERIL TO THE PUBLIC HEALTH

In support of this finding of imminent threat to the public health necessitating the adoption of an emergency regulation, I hereby state the following:

1. Section 19-13-D68(e)(1) of the Regulations of Connecticut State Agencies requires a home health care agency to employ one full-time supervisor of clinical services for each fifteen or less, full-time or full-time equivalent professional direct service staff. This regulation, which effectively requires an agency providing continuous skilled nursing care to employ one full-time supervisor of clinical services for as few as three cases, as

described above, is burdensome and cost prohibitive for home health care agencies. Consequently, Section 19-13-D68(e)(1) has negatively impacted Connecticut's capacity to provide continuous skilled nursing care.

2. Maxim, a home health care agency that was providing continuous skilled nursing care to approximately 44 medically complex patients, has provided the Department of Health with its intent to close. Maxim's closing has created the need to place its 44 patients in other licensed home care agencies. The capacity of the remaining agencies that are equipped to provide continuous skilled nursing care has been reached.

3. Delay in establishing the commissioner's authority to waive § 19-13-D68(e)(1) will lead to the following adverse effects on the public health of Connecticut's citizens:

- Without access to continuous skilled nursing care, it will be necessary to transfer patients to an acute or chronic disease hospital or the patient might remain in the home unsafely without proper care. Transfer to a hospital setting will not be consistent with state and federal initiatives that promote home and community based supportive living for persons with medically complex needs. Additionally, the damaging effects of institutional care versus family based care include an increased risk of infection. It is often the infectious process that is life threatening to children with medically complex needs. In addition, the psychological harm with transfer trauma must always be a consideration, especially in view of altering the integrity of the family when considering the transfer of a child with medically complex needs to an institutional setting.
- Currently, there is no capacity remaining in Connecticut to provide continuous skilled nursing care to any new patients that may require such care, heightening the already existing access to care burden. The need for such care is likely to increase as advances in bio-medical engineering and technology are preserving life where, previously, certain disease states often meant loss of life, necessitating a realignment of our health care regulatory system to create additional capacity.

Therefore, in light of the findings articulated herein, in order to prevent harm to the public health of the citizens of Connecticut by maintaining access to continuous skilled nursing care for medically complex patients, and in accordance with the requirements of Section 4-168(f) of the Connecticut General Statutes, I do hereby find an imminent threat to the public health of the citizens of Connecticut, justifying the emergency adoption of this regulation.

IV. CONCLUSION

For all the reasons stated above, the Department requests approval of its finding of imminent peril to the public health of the citizens of Connecticut, and requests approval of the enclosed emergency regulation. If you have any questions, please contact Barbara Cass at (860) 509-7407, or Elizabeth Keyes at (860) 509-7246.

Sincerely,



Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner