The Connecticut General Assembly

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Memorandum

To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: December 17, 2024

Regulation No:	2024-28
Agency:	Department of Public Health
Subject Matter:	Blood Collection Facilities
Statutory Authority: (copy attached)	19a-565(b), 19a-495(c)

	Yes or No
Mandatory	Y
Federal Requirement	N
Permissive	N

For the Committee's Information:

Sections 19a-36-A47 to 19a-36-A55, inclusive, of the Regulations of Connecticut State Agencies are repealed in proposed regulation 2024-29 concerning Source Plasma Donation Centers, which is scheduled to be before the committee at the December 17, 2024 meeting. The repeal of said sections is also necessary to avoid conflict with new sections 19a-36-F1 to 19a-36-F6, inclusive, in these proposed regulations.

Substantive Concerns:

1. On page 2, in section 19a-36-F1(26), the term “trained person” is defined as “an individual, including a physician substitute, who is adequately instructed and qualified to perform specified functions pertaining to apheresis under the direction of the responsible physician”. Section 19a-36-F5(c)(4)(B) provides that oversight of the clinical training of trained persons is the responsibility of the responsible physician *or* physician substitute. These provisions appear to conflict. It is not clear in what circumstances a physician substitute or responsible physician is responsible for instructing and overseeing the training of trained persons.

   Additionally, the definition of “trained person” in section 19a-36-F1(26) includes a physician substitute, as defined in subdivision (19) of the same section. However, on page 10, section 19a-36-F5(c)(5)(A) states: “Trained persons include phlebotomists, plasmapheresis technicians, or other persons duly qualified under this section.” Phlebotomists, plasmapheresis technicians and "other persons" are not included in the definition of "physician substitute". It is not clear whether the specified health care professionals included in the definition of "physician substitute" are considered "other persons" that are referenced in the definition of "trained persons". These provisions are inconsistent and should be clarified.

2. On page 2, in section 19a-36-F2(a), a person or entity is required to present to the department “satisfactory evidence” of having retained the services of qualified personnel. It is unclear what evidence would qualify as satisfactory and who makes the determination. This provision should be clarified by describing what evidence would be considered satisfactory or if the determination of what evidence is satisfactory is made in the discretion of the commissioner.

3. On page 4, section 19a-36-F2(l) requires the licensee of a blood collection facility to notify the Department of Public Health within twenty-four hours of the absence of a director for a period greater than thirty days. It is not clear whether the licensee is required to notify the department within twenty-four hours of the date the licensee receives notice of a director’s intent to be absent for such period or from some other date, such as the end of the thirty-day period. Additionally, while section 19a-36-F2(l) does not specify the manner in which such notification shall be made, on page 9, section 19a-36-F5(c)(1) requires that notification of a director's absence of thirty days or more be made in writing, but does not provide a deadline for the provision of such notification, as in section 19a-36-F2(l). These provisions should be revised, for clarity and consistency.

4. On page 5, section 19a-36-F3(d) requires that policies and procedures be “provided to the department for review upon initial application and on request”. However, on page 3, section 19a-36-F2(g)(2)(I) requires an application for “initial licensure or licensure renewal” to include those policies and procedures. These provisions should be revised for consistency and to indicate whether such policies and procedures shall be included only upon initial application or both upon initial and renewal application.

5. On page 9, in section 19a-36-F5(c)(3)(E), a "director", as defined in section 19a-36-

F1(15), may delegate responsibilities to a "responsible physician", as defined in subdivision (22) of the same section. However, the differences between the responsibilities of a director and a responsible physician are unclear. In section 19a-36-F1(22), “responsible physician” is defined as having the same meaning as provided in 21 CFR 630.3. Subsection (i) of said section of the federal regulation defines a "responsible physician" as an individual who is licensed to practice medicine in the jurisdiction where the collection establishment is located and qualified and trained to direct and control personnel relating to collection of blood components by apheresis and designated to perform certain other related activities. These responsibilities are similar to the responsibilities of a "blood collection facility director", as specified in section 19a-36-F5(c)(3). The distinction between these roles and their respective responsibilities should be clarified.

Technical Corrections:

1. Throughout the proposed regulations, "on site" and "onsite" should be "on-site", for proper form.

2. On page 1, in the introductory language to section 19a-36-F1, “and sections 19a-36-F2 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies” should be inserted after "section", for accuracy.

3. On page 1, in section 19a-36-F1(1), in the second line, “as such facilities are defined in these regulations,” should be deleted as unnecessary.

4. On page 1, subdivisions (3), (8) and (17) should be deleted as unnecessary, and the remaining subdivisions should be redesignated accordingly.

5. On page 1, in section 19a-36-F1(9), in the first line, in the second instance, "CPR" should be "cardiopulmonary resuscitation", for consistency, in the second line, "using" should be "that uses", for proper form, and, in the fifth line, the semicolon should be a period, for consistency.

6. On page 1, in section 19a-36-F1(11), in the first line, ““Clinical Laboratory Improvement Amendments” or” should be deleted, for consistency.

7. On page 1, in section 19a-36-F1(13), in the first line, "the Department of" should be deleted, for accuracy.

8. On page 1, in section 19a-36-F1(14), "Connecticut" should be deleted, for consistency.

9. On page 1, in section 19a-36-F1(15), "the person", "the licensee" and "the blood" should be "a person", "a licensee" and "a blood", respectively, for clarity and consistency.

10. On page 2, in section 19a-36-F1(18) "blood collection facility licensed pursuant to this section” should be “holder of a blood collection facility license issued pursuant to

section 19a-36-F2 of the Regulations of Connecticut State Agencies", for clarity and accuracy.

11. On page 2, in section 19a-36-F1(19), in three instances, "Chapter" should be "chapter", for consistency, and, in the second line, "of the Connecticut General Statutes" should be inserted after "chapter 370", for consistency and proper form.

12. On page 2, in section 19a-36-F1(21), in the second line, "facility" should be "blood collection facility", for consistency, and "this section" should be "section 19a-36-F2 of the Regulations of Connecticut State Agencies", for accuracy.

13. On page 2, in section 19a-36-F2(a), in the second line, the second instance of "facility" should be "person or business entity", for consistency, in the third and fourth lines, "including CLIA certificate of waiver" should be "or a CLIA certification of waiver", for accuracy, in the fourth line, "center" should be "facility", for consistency, and, in the sixth line, "these regulations" should be "section 19a-36-F5 of the Regulations of Connecticut State Agencies", for accuracy.

14. On page 2, in section 19a-36-F2(b), in the first and second lines, "as defined in section 19a-490(u) of the Connecticut General Statutes 1 and licensed pursuant to the Regulations of Connecticut State Agencies" should be deleted, for clarity and consistency with the defined term.

15. On page 2, in section 19a-36-F2(c), in the first line, "chapter 386v" should be "chapter 368v", for accuracy.

16. On page 2, in sections 19a-36-F2(d) and 19a-36-F2(e), "under section 19a-565(b) of the Connecticut General Statutes as amended by section 9 of Public Act 23-31" should be deleted for clarity and consistency with the defined terms.

17. On page 3, in section 19a-36-F2(f), in the third line, "these regulations" should be "this section", for accuracy.

18. On page 3, in section 19a-36-F2(g)(1), in the fourth and fifth lines, "as defined in section 19a-36-A47 of the Regulations of Connecticut State Agencies" should be deleted, for accuracy and consistency with the defined term, and, in the sixth line, "upon the expiration of licensure or if the" should be "after the expiration of a license or if a", for clarity.

19. On page 3, in section 19a-36-F2(g)(2), "Application for the grant of initial licensure or licensure renewal" should be "Each application for initial or renewal licensure", for clarity and consistency.

20. On page 3, in section 19a-36-F2(g)(2)(B), in the first line, a comma should be inserted after "operation" and "applicant or" should be inserted after "the", for consistency.

21. On page 3, in section 19a-36-F2(g)(2)(D), "the" should be inserted before "State", for accuracy.

22. On page 3, in section 19a-36-F2(g)(2)(F), “or a CLIA certificate of waiver” should be inserted before the semicolon, for consistency.

23. On page 3, in section 19a-36-F2(g)(2)(J), in the first line, “under section 19a-36-F2(a)” should be “as described in subsection (a) of this section”, for proper form.

24. On page 3, in section 19a-36-F2(g)(2)(K), in the first line, "licensing or renewal fee" should be "initial licensure or renewal fee", for consistency.

25. On page 4, in section 19a-36-F2(g)(4), "and" should be "or", for consistency.

26. On page 4, in section 19a-36-F2(g)(4)(A), in the first line, "renewal of" should be "renew" and, in the third line, "complies" should be "is in compliance with", for clarity.

27. On page 4, in section 19a-36-F2(g)(4)(B), in the second and third lines, "owner of the blood collection facility, business entity or parent organization appearing on the application" should be "applicant", for clarity.

28. On page 4, in section 19a-36-F2(g)(4)(E), in the second and third lines, "by the end of the twentieth month" should be "not later than four months prior to the expiration", for clarity.

29. On page 4, in section 19a-36-F2(h), ", suspension or revocation" should be deleted, for accuracy and consistency, and "licensure" should be "a license", for consistency, subdivision (1) designator should be deleted and subparagraphs (A) to (D) should be redesignated as subdivisions (1) to (4), for proper form.

30. On page 4, in section 19a-36-F2(h)(1)(A), "applicant or" should be inserted before "licensee", for consistency, and "and" should be "or", for accuracy.

31. On page 4, in section 19a-36-F2(h)(1)(C), in the first line, "and" should be "or", for accuracy.

32. On page 4, section 19a-36-F2(i) should be deleted as unnecessary and the remaining subdivisions redesignated accordingly because it is a restatement of the provisions in section 19a-565(g) of the Connecticut General Statutes.

33. On page 4, in section 19a-36-F2(j), in the first line, "an entity" should be "a blood collection facility", for consistency.

34. On page 4, in section 19a-36-F2(k), in the first line, "entity" should be "blood collection facility", for consistency, and, in the third line, "changes" should be deleted, for consistency.

35. On page 4, in section 19a-36-F2(l), in the first line, "entity" should be "blood collection facility", and, in the third line, "greater than" should be "a period of more than", for clarity.

36. On page 5, in section 19a-36-F2(m)(1), in the first line, “these regulations” should be “sections 19a-36-F2 to 19a-36-F6, inclusive, of the Regulations of Connecticut State Agencies”, for clarity, and, in the second to sixth lines, "if the commissioner determines that such waiver would not endanger the health, safety or welfare of any donor. The commissioner may impose conditions upon granting the waiver that assure the health, safety and welfare of donors, and may revoke the waiver upon a finding that the health, safety, or welfare of any donor has been jeopardized", should be deleted as unnecessary because it is duplicative of statutory provisions.

37. On page 5, in section 19a-36-F2(m)(3), "consideration of any request for" should be "determining whether to grant or deny a", for clarity.

38. On page 5, in section 19a-36-F2(m)(4), in the first line, "reserves the right to" should be "may", for clarity and consistency, "processing" should be "determining whether to grant or deny", and "a" should be inserted before "waiver", for clarity and consistency.

39. On page 5, in sections 19a-36-F3(a), 19a-36-F3(b) and 19a-36-F3(c), “this section” should be “section 19a-36-F2 of the Regulations of Connecticut State Agencies”, for accuracy.

40. On page 5, in section 19a-36-F3(b), in the third line, “section” should be deleted, for consistency and proper form.

41. On page 5, in section 19a-36-F3(c), in the second line, “federal CLIA certificate” should be “CLIA certificate”, for consistency.

42. On page 5, in section 19a-36-F3(d), in the fourth line, “these regulations” should be “section 19a-36-F2 of the Regulations of Connecticut State Agencies”, for accuracy.

43. On page 6, in sections 19a-36-F3(d)(1)(G) and 19a-36-F3(d)(1)(H), in the second lines, "under this section" should be "pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies", for accuracy and consistency.

44. On page 6, in section 19a-36-F3(d)(3), a comma should be inserted after "Staffing", "requirements" and the second instance of "including", for proper form.

45. On page 6, in section 19a-36-F3(d)(3)(A), in the first line, "qualifications and" should be inserted after "the", for consistency, and, in the second and third lines, “19a-36-E5 of these regulations” should be “19a-36-F5(c)(5) of the Regulations of Connecticut State Agencies”, for accuracy.

46. On page 6, in section 19a-36-F3(d)(3)(C), in two instances, “staff” should be “personnel”, for consistency.

47. On page 6, in section 19a-36-F3(d)(3)(D), “Each facility licensed pursuant to this section shall establish and maintain” should be “Establishment and maintenance of”, for consistency.

48. On page 6, section 19a-36-F3(d)(3)(E) should be rewritten as follows: "Staffing plans to ensure that personnel cross-trained in blood collection specific to the equipment and facility are available to maintain safe staffing levels in the event of a personnel or donor emergency and to maintain minimum staffing levels established pursuant to subparagraph (D) of this subdivision", for clarity and consistency.

49. On page 6, in section 19a-36-F3(d)(4), in the second line, "medical director" should be "director", for consistency.

50. On page 6, in section 19a-36-F3(d)(6), in the first line, "19a-36-F7" should be "19a-36-F6", for accuracy.

51. On page 7, in section 19a-36-F3(d)(7)(D), "which shall conform with the most recent FDA standards" should be deleted as unnecessary because it is duplicative of the introductory language.

52. On page 7, in section 19a-36-F3(d)(7)(E), the third and fourth lines, ", in accord with CDC standards for infection prevention and control that apply in healthcare settings and" should be deleted as unnecessary because it is duplicative of the introductory language, in the fourth line, a comma should be inserted after "include" and, in the fifth line, a comma should be inserted after "to", for proper form.

53. On page 7, in section 19a-36-F3(d)(7)(F), in the third line, "to such events" should be inserted after "response", for clarity, in the fourth line, "capture" should be "identification", for clarity, and, in the eighth line, "or failure" should be inserted after "deviation", for consistency.

54. On page 7, in section 19a-36-F3(d)(8)(A), "facilities," should be deleted, for clarity.

55. On page 7, in section 19a-36-F3(d)(8)(B), in the first line, "physical" should be inserted before "environment", for clarity, in the first and second lines, "provided to maintain" should be "maintained to provide", for clarity, in the third and fourth lines, "shall consist of at least" should be "shall maintain at a minimum", for clarity, and, in the tenth line, "the collections" should be "such blood and components", for consistency.

56. On page 8, in sections 19a-36-F3(d)(8)(D), in the first line, and 19a-36-F3(d)(8)(E), in the eighth and ninth lines, and in section 19a-36-F3(e), in the first line, "this section" should be "section 19a-36-F2 of the Regulations of Connecticut State Agencies", for accuracy.

57. On page 8, section 19a-36-F3(d)(8)(F) should be deleted as unnecessary.

58. On page 8, in section 19a-36-F3(e), in the second line, "staff" should be deleted, for clarity and consistency.

59. On page 8, in section 19a-36-F4(c), "eligibility" should be inserted after "donor", for clarity and consistency.

60. On page 8, in section 19a-36-F5(a), in the first line, "this section" should be “section 19a-36-F2 of the Regulations of Connecticut State Agencies”, for accuracy, in the first and second lines, "two personnel" should be "two members of the personnel", for proper form, in the second line, "is onsite" should be "are on-site", for proper form, and ", with a minimum" should be "and a minimum", for clarity, in the third line, "one personnel" should be "one member of the personnel", for proper form, and "for less" should be "if fewer", for clarity, and "are present" should be inserted after "donors", for clarity, and, in the fifth line, "donor emergency response protocols" should be "emergency response protocols for donor adverse events", for consistency.

61. On page 8, in section 19a-36-F5(c), "blood collection facility director" should be "director", for consistency.

62. On page 8, in section 19a-36-F5(c)(1), in the first and fourth lines, "be responsible for ensuring" should be "ensure", for clarity, and, in the third line, "such responsibility is" should be inserted after "unless", for clarity.

63. On page 9, in section 19a-36-F5(c)(2), "a" should be inserted before "laboratory director", for consistency.

64. On page 9, in section 19a-36-F5(c)(3), "blood collection facility director" should be "a director", for consistency.

65. On page 9, in section 19a-36-F5(c)(3)(A), in the first line, "of the blood collection facility" should be deleted, for consistency, and "shall" should be "may", for consistency with section 19a-565(b) of the Connecticut General Statutes, as amended by section 1 of Public Act 24-7, and, in the first and second lines, “as defined in Section 19a-36-F1 of the Regulations of Connecticut State Agencies” should be deleted as unnecessary, and the last sentence of the subparagraph should be deleted as unnecessary and for clarity.

66. On page 9, in section 19a-36-F5(c)(3)(C), in the third line, "blood collection" should be inserted before "facility", for clarity, and "Connecticut" should be "the state", for consistency.

67. On page 9, in section 19a-36-F5(c)(3)(E), in the second line, "properly qualified and trained" should be deleted, for consistency with the defined term, in the third and fourth lines, “who shall be a physician licensed in the state of Connecticut under Chapter 370 of the Connecticut General Statutes,” should be deleted as unnecessary, in the fourth and fifth lines, "who shall meet the qualifications of subdivision (4) of this section" should be deleted as unnecessary, in the eighth line "or activities" should be inserted after "responsibilities", for consistency, and, in the ninth line, "duties" should be "responsibilities or activities", for consistency.

68. On page 9, in section 19a-36-F5(c)(3)(F), the second to fourth lines should be rewritten as follows, for consistency and clarity: "delegated his or her responsibilities pursuant to

this section and when a responsible physician or a physician substitute is permitted under 21 CFR 630.5, as amended from time to time, to be on-site without a director."

69. On page 9, in section 19a-36-F5(c)(4), "Qualification and responsibilities of a physician substitute" should be "Responsibilities of a physician substitute and responsible physician", for consistency.

70. On pages 9 and 10, in section 19a-36-F5(c)(4), subparagraph (A) should be deleted as unnecessary, subparagraph (B) designator should be deleted and clauses (i) to (iv) should be redesignated as subparagraphs (A) to (D) and, in redesignated subparagraph (D), "duties" should be "responsibilities", for consistency.

71. On page 10, in section 19a-36-F5(c)(5), "and responsibilities of trained persons" should be ", responsibilities and training of a trained person", for consistency.

72. On page 10, in section 19a-36-F5(c)(5)(A), ", or" should be "and", for proper form.

73. On page 10, in section 19a-36-F5, the last paragraph designated "(2)" should be redesignated as subsection “(d)”, for proper form, in the first line, “under this section” should be “pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies”, for accuracy and consistency, in the first and third lines, "staff" should be "personnel", for consistency, and, in the third and fourth lines, “section 19a-36-F3(e)(3)(E)” should be “section 19a-36-F3(d)(3)(E)”, for accuracy.

74. On page 10, in section 19a-36-F6(a), in the first and second lines, "and in accordance with the federal requirements in" should be ", including", for clarity.

75. On pages 10 and 11, in section 19a-36-F6, the second paragraph designated "(a)" should be redesignated "(b)" and the remaining subsections redesignated accordingly, for proper form, and, in redesignated subsections (b), (d) and (e), “under this section” should be “pursuant to section 19a-36-F2 of the Regulations of Connecticut State Agencies”, for consistency and accuracy.

76. On page 10, in section 19a-36-F6, in redesignated subsection (c), in the first line, "Adverse reactions." should be "Adverse events.", for consistency, and, in the second line, "this section" should be "section 19a-36-F2 of the Regulations of Connecticut State Agencies", for accuracy.

77. On page 10, in section 19a-36-F6, in redesignated subsection (d), in the second line, “adverse reactions” should be “adverse events”, for consistency.

78. On page 11, in section 19a-36-F6, in redesignated subsection (f), in the second line, "such blood or blood" should be inserted before "components", for consistency.

Recommendation:

	Approval in whole
	with technical corrections
	with deletions
	with substitute pages
	Disapproval in whole or in part
X	**Rejection without prejudice**

Reviewed by: Naurin Hashmi / Heather Bannister

Date: 12/13/2024

Sec. 19a-565. (a) As used in this section, "business entity" means a corporation, association, trust, estate, partnership, limited partnership, limited liability partnership, limited liability company, sole proprietorship, joint stock company, nonstock corporation, John Dempsey Hospital and The University of Connecticut Health Center.

(b) The Department of Public Health shall adopt regulations, in accordance with the provisions of chapter 54, governing clinical laboratories, blood collection facilities and source plasma donation centers. Such regulations shall establish reasonable standards for entities exempt from licensure as a clinical laboratory, operations and facilities, personnel qualifications and certification, levels of acceptable proficiency in testing programs approved by the department, the collection, acceptance and suitability of specimens for analysis and such other pertinent laboratory functions, including the establishment of advisory committees, as may be necessary to ensure public health and safety. Such regulations shall provide that a responsible physician, as defined in 21 CFR 630.3, as amended from time to time, may serve as the director of a blood collection facility or source plasma donation center. On or before October 1, 2023, the Commissioner of Public Health shall implement policies and procedures necessary to administer the provisions of this section while in the process of adopting such policies and procedures as regulations, provided the department posts such policies and procedures on the eRegulations System prior to adopting them. On or before October 1, 2024, the commissioner shall update the department’s policies and procedures to include policies and procedures consistent with the provisions of this subsection. Policies and procedures implemented pursuant to this section shall be valid until final regulations are adopted in accordance with the provisions of chapter 54.

(c) No person or business entity shall establish, conduct, operate or maintain a clinical laboratory, blood collection facility or source plasma donation center unless such laboratory, facility or center is licensed or approved by said department in accordance with its regulations. Each blood collection facility or plasmapheresis center, as defined in section 19a-36-A47 of the regulations of Connecticut state agencies, that is registered with the department on or before October 1, 2023, shall apply to the department for an initial license pursuant to the provisions of this section not later than thirty days after the date that procedures for such licensure are implemented by the department pursuant to subsection (b) of this section. On and after the date on which procedures for licensure are implemented by the department pursuant to the provisions of said subsection, the department shall not renew any blood collection facility or plasmapheresis center registration. Each clinical laboratory, blood collection facility or source plasma donation center shall comply with all standards for such facilities established by the department and shall be subject to inspection by said department, including inspection of all records necessary to carry out the purposes of this section.

(d) Each initial or renewal application for licensure of a clinical laboratory, blood collection facility or source plasma donation center shall be made in a form and manner prescribed by the commissioner and shall be executed by the owner or owners or by a responsible officer of the firm or corporation owning such laboratory, facility or donation center and be accompanied by the fee required pursuant to the provisions of subsection (f) of this section. A mobile or temporary blood collection facility shall not be required to obtain a license if such person or business entity operating such facility is licensed as a

blood collection facility. A licensed source plasma donation center shall not be required to obtain a clinical laboratory license to perform any pre-donation screening test required by Title 21, Chapter I of the Code of Federal Regulations. A hospital licensed under this chapter shall not be required to obtain a license as a blood collection facility for blood component collection activities that take place on the hospital campus, as defined in section 19a-508c.

(e) After the department receives an initial or renewal application for licensure pursuant to subsection (d) of this section, it shall conduct any inspections or investigations that are deemed necessary by the commissioner to determine the applicant's eligibility for licensure. As a condition of licensure, the commissioner may require the applicant to sign a consent order providing reasonable assurances of compliance with federal and state laws and regulations. The commissioner may deny licensure of an applicant if the commissioner determines that the applicant has previously failed to comply with federal and state laws and regulations or that licensure would pose a threat to the health, safety and well-being of the public. Licensure pursuant to the provisions of this section shall not be effective until the applicant receives notice of such licensure, including the effective date and term of such licensure, from the department.

(f) A nonrefundable fee of two hundred dollars shall accompany each application for a license or for renewal thereof, except in the case of a clinical laboratory owned and operated by a municipality, the state, the United States or any agency of said municipality, state or United States. Each license shall be issued for a period of not less than twenty-four months. Renewal applications shall be made biennially within the twentieth month of the current license. Any change in ownership of an entity licensed pursuant to the provisions of this section shall be made in compliance with section 19a-493. If any such entity changes its director, it shall notify the commissioner in a form and manner prescribed by the commissioner. If any such entity intends to expand or alter its facility, it shall notify the commissioner in a form and manner prescribed by the commissioner prior to such expansion or alteration. The licensed clinical laboratory shall report to the Department of Public Health, in a form and manner prescribed by the commissioner, the name and address of each specimen collection facility owned and operated by the clinical laboratory, prior to the issuance of a new license, prior to the issuance of a renewal license or whenever a specimen collection facility opens or closes.

(g) A license issued under this section may be revoked or suspended in accordance with chapter 54 or subject to any other disciplinary action specified in section 19a-17 if the licensed clinical laboratory, blood collection facility or source plasma donation center has engaged in fraudulent practices, fee-splitting inducements or bribes, including, but not limited to, in the case of a clinical laboratory, violations of subsection (h) of this section, or violated any other provision of this section or regulations adopted under this section after notice and a hearing is provided in accordance with the provisions of said chapter.

(h) No representative or agent of a clinical laboratory shall solicit referral of specimens to his or any other clinical laboratory in a manner which offers or implies an offer of fee-splitting inducements to persons submitting or referring specimens, including inducements through rebates, fee schedules, billing methods, personal solicitation or payment to the practitioner for consultation or assistance or for scientific, clerical or janitorial services.

(i) No clinical laboratory, blood collection facility or source plasma donation center shall terminate the employment of an employee because such employee reported a violation of this section to the Department of Public Health.

(j) Any person or business entity operating a clinical laboratory, blood collection facility or source plasma donation center in violation of this section shall be fined not less than one hundred dollars or more than three hundred dollars for each offense. For purposes of calculating civil penalties under this section, each day a licensee operates in violation of this section or a regulation adopted under this section shall constitute a separate violation.

(k) The Commissioner of Public Health shall adopt regulations in accordance with the provisions of chapter 54 to establish levels of acceptable proficiency to be demonstrated in testing programs approved by the department for those laboratory tests which are not performed in a licensed clinical laboratory. Such levels of acceptable proficiency shall be determined on the basis of the volume or the complexity of the examinations performed.

Sec. 19a-495. (a) The Department of Public Health shall, after consultation with the appropriate public and voluntary hospital planning agencies, establish classifications of institutions. The department shall, in the Public Health Code, adopt, amend, promulgate and enforce such regulations based upon reasonable standards of health, safety and comfort of patients and demonstrable need for such institutions, with respect to each classification of institutions to be licensed under sections 19a-490 to 19a-503, inclusive, including their special facilities, as will further the accomplishment of the purposes of said sections in promoting safe, humane and adequate care and treatment of individuals in institutions. The department shall adopt such regulations, in accordance with chapter 54, concerning home health care agencies and home health aide agencies.

(b) The Department of Public Health, with the advice of the Department of Mental Health and Addiction Services, shall include in the regulations adopted pursuant to subsection (a) of this section, additional standards for community residences, as defined in section 19a-507a, which shall include, but not be limited to, standards for: (1) Safety, maintenance and administration; (2) protection of human rights; (3) staffing requirements; (4) administration of medication; (5) program goals and objectives; (6) services to be offered; and (7) population to be served.

(c) The commissioner may waive any provisions of the regulations affecting an institution or a clinical laboratory, licensed pursuant to section 19a-30, if the commissioner determines that such waiver would not endanger the health, safety or welfare of any patient or resident. The commissioner may impose conditions, upon granting the waiver, that assure the health, safety and welfare of patients or residents, and may revoke the waiver upon a finding that the health, safety or welfare of any patient or resident has been jeopardized. The commissioner shall not grant a waiver that would result in a violation of the Fire Safety Code or State Building Code. The commissioner may adopt regulations, in accordance with chapter 54, establishing procedures for an application for a waiver pursuant to this subsection.

(d) The Commissioner of Public Health, in consultation with the Commissioner of Mental Health and Addiction Services, may implement policies and procedures, in compliance with federal law, permitting licensed health care providers with prescriptive authority to prescribe medications to treat persons dependent on opiates in freestanding substance abuse treatment facilities, licensed under section 19a-490, while in the process of adopting such policies and procedures in regulation form, provided the commissioner prints notice of the intent to adopt regulations in the Connecticut Law Journal not later than thirty days after the date of implementation of such policies and procedures. Policies and procedures implemented pursuant to this subsection shall be valid until the time final regulations are adopted.