



**Substitute Senate Bill No. 428**

**Public Act No. 10-117**

**Sections 82 through 96**

**AN ACT CONCERNING REVISIONS TO PUBLIC HEALTH RELATED STATUTES AND THE ESTABLISHMENT OF THE HEALTH INFORMATION TECHNOLOGY EXCHANGE OF CONNECTICUT.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Sec. 82. (NEW) (*Effective from passage*) (a) There is hereby created as a body politic and corporate, constituting a public instrumentality and political subdivision of the state created for the performance of an essential public and governmental function, the Health Information Technology Exchange of Connecticut, which is empowered to carry out the purposes of the authority, as defined in subsection (b) of this section, which are hereby determined to be public purposes for which public funds may be expended. The Health Information Technology Exchange of Connecticut shall not be construed to be a department, institution or agency of the state.

(b) For purposes of this section, sections 83 to 85, inclusive, of this act and section 19a-25g of the general statutes, as amended by this act, "authority" means the Health Information Technology Exchange of Connecticut and "purposes of the authority" means the purposes of the authority expressed in and pursuant to this section, including the promoting, planning and designing, developing, assisting, acquiring, constructing, maintaining and equipping, reconstructing and improving of health care information technology. The powers enumerated in this section shall be interpreted broadly to effectuate the purposes of the authority and shall not be construed as a limitation of powers. The authority shall have the power to:

- (1) Establish an office in the state;
- (2) Employ such assistants, agents and other employees as may be necessary or desirable, which employees shall be exempt from the classified service and shall not be employees, as defined in subsection (b) of section 5-270 of the general statutes;
- (3) Establish all necessary or appropriate personnel practices and policies, including those relating to hiring, promotion, compensation, retirement and collective bargaining, which need not be in accordance with chapter 68 of the general statutes, and the authority shall not be an employer, as defined in subsection (a) of section 5-270 of the general statutes;
- (4) Engage consultants, attorneys and other experts as may be necessary or desirable to carry out the purposes of the authority;
- (5) Acquire, lease, purchase, own, manage, hold and dispose of personal property, and lease, convey or deal in or enter into agreements with respect to such property on any terms necessary or incidental to the carrying out of these purposes;
- (6) Procure insurance against loss in connection with its property and other assets in such amounts and from such insurers as it deems desirable;
- (7) Make and enter into any contract or agreement necessary or incidental to the performance of its duties and execution of its powers. The contracts entered into by the authority shall not be subject to the approval of any other state department, office or agency. However, copies of all contracts of the authority shall be maintained by the authority as public records, subject to the proprietary rights of any party to the contract;
- (8) To the extent permitted under its contract with other persons, consent to any termination, modification, forgiveness or other change of any term of any contractual right, payment, royalty, contract or agreement of any kind to which the authority is a party;
- (9) Receive and accept, from any source, aid or contributions, including money, property, labor and other things of value;
- (10) Invest any funds not needed for immediate use or disbursement in obligations issued or guaranteed by the United States of America or the state and in obligations that are legal investments for savings banks in this state;

(11) Account for and audit funds of the authority and funds of any recipients of funds from the authority;

(12) Sue and be sued, plead and be impleaded, adopt a seal and alter the same at pleasure;

(13) Adopt regular procedures for exercising the power of the authority not in conflict with other provisions of the general statutes; and

(14) Do all acts and things necessary and convenient to carry out the purposes of the authority.

(c) (1) The Health Information Technology Exchange of Connecticut shall be managed by a board of directors. The board shall consist of the following members: The Lieutenant Governor, or his or her designee; the Commissioners of Public Health, Social Services and Consumer Protection, or their designees; the Chief Information Officer of the Department of Information Technology, or his or her designee; three appointed by the Governor, one of whom shall be a representative of a medical research organization, one of whom shall be an insurer or representative of a health plan and one of whom shall be an attorney with background and experience in the field of privacy, health data security or patient rights; three appointed by the president pro tempore of the Senate, one of whom shall have background and experience with a private sector health information exchange or health information technology entity, one of whom shall have expertise in public health and one of whom shall be a physician licensed under chapter 370 of the general statutes who works in a practice of not more than ten physicians and who is not employed by a hospital, health network, health plan, health system, academic institution or university; three appointed by the speaker of the House of Representatives, one of whom shall be a representative of hospitals, an integrated delivery network or a hospital association, one of whom shall have expertise with federally qualified health centers and one of whom shall be a consumer or consumer advocate; one appointed by the majority leader of the Senate, who shall be a primary care physician whose practice utilizes electronic health records; one appointed by the majority leader of the House of Representatives, who shall be a consumer or consumer advocate; one appointed by the minority leader of the Senate, who shall be a pharmacist or a health care provider utilizing electronic health information exchange; and one appointed by the minority leader of the House of Representatives, who shall be a large employer or a representative of a business group. The Secretary of the Office of Policy and Management and the Healthcare Advocate, or their designees, shall be ex-officio, nonvoting members of the board. The Commissioner of Public Health, or his or her designee, shall serve as the chairperson of the board.

(2) All initial appointments to the board shall be made on or before October 1, 2010. The initial term for the board members appointed by the Governor shall be for four years. The initial term for board members appointed by the speaker of the House of Representatives and the majority leader of the House of Representatives shall be for three years. The initial term for board members appointed by the minority leader of the House of Representatives and the minority leader of the Senate shall be for two years. The initial term for the board members appointed by the president pro tempore of the Senate and the majority leader of the Senate shall be for one year. Terms shall expire on September thirtieth of each year in accordance with the provisions of this subsection. Any vacancy shall be filled by the appointing authority for the balance of the unexpired term. Other than an initial term, a board member shall serve for a term of four years. No board member, including initial board members, may serve for more than two terms. Any member of the board may be removed by the appropriate appointing authority for misfeasance, malfeasance or wilful neglect of duty.

(3) The chairperson shall schedule the first meeting of the board, which shall be held not later than November 1, 2010.

(4) Any member appointed to the board who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from the board.

(5) Notwithstanding any provision of the general statutes, it shall not constitute a conflict of interest for a trustee, director, partner, officer, stockholder, proprietor, counsel or employee of any person, firm or corporation to serve as a board member, provided such trustee, director, partner, officer, stockholder, proprietor, counsel or employee shall abstain from deliberation, action or vote by the board in specific respect to such person, firm or corporation. All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10 of the general statutes.

(6) Board members shall receive no compensation for their services, but shall receive actual and necessary expenses incurred in the performance of their official duties.

(d) The board shall select and appoint a chief executive officer who shall be responsible for administering the authority's programs and activities in accordance with policies and objectives established by the board. The chief executive officer shall serve at the pleasure of the board and shall receive such compensation as shall be determined by the board. The chief executive officer (1) may employ such other employees as shall be designated by the board of

directors; and (2) shall attend all meetings of the board, keep a record of all proceedings and maintain and be custodian of all books, documents and papers filed with the authority and of the minute book of the authority.

(e) The board shall direct the authority regarding: (1) Implementation and periodic revisions of the health information technology plan submitted in accordance with the provisions of section 74 of public act 09-232, including the implementation of an integrated state-wide electronic health information infrastructure for the sharing of electronic health information among health care facilities, health care professionals, public and private payors, state and federal agencies and patients; (2) appropriate protocols for health information exchange; and (3) electronic data standards to facilitate the development of a state-wide integrated electronic health information system, as defined in subsection (a) of section 19a-25d of the general statutes, for use by health care providers and institutions that receive state funding. Such electronic data standards shall: (A) Include provisions relating to security, privacy, data content, structures and format, vocabulary and transmission protocols; (B) limit the use and dissemination of an individual's Social Security number and require the encryption of any Social Security number provided by an individual; (C) require privacy standards no less stringent than the "Standards for Privacy of Individually Identifiable Health Information" established under the Health Insurance Portability and Accountability Act of 1996, P. L. 104-191, as amended from time to time, and contained in 45 CFR 160, 164; (D) require that individually identifiable health information be secure and that access to such information be traceable by an electronic audit trail; (E) be compatible with any national data standards in order to allow for interstate interoperability, as defined in subsection (a) of section 19a-25d of the general statutes; (F) permit the collection of health information in a standard electronic format, as defined in subsection (a) of section 19a-25d of the general statutes; and (G) be compatible with the requirements for an electronic health information system, as defined in subsection (a) of section 19a-25d of the general statutes.

(f) Applications for grants from the authority shall be made on a form prescribed by the board. The board shall review applications and decide whether to award a grant. The board may consider, as a condition for awarding a grant, the potential grantee's financial participation and any other factors it deems relevant.

(g) The board may consult with such parties, public or private, as it deems desirable in exercising its duties under this section.

(h) Not later than February 1, 2011, and annually thereafter until February 1, 2016, the chief executive officer of the authority shall report, in accordance with section 11-4a of the general statutes, to the Governor and the General Assembly

on (1) any private or federal funds received during the preceding year and, if applicable, how such funds were expended, (2) the amount and recipients of grants awarded, and (3) the current status of health information exchange and health information technology in the state.

Sec. 83. (NEW) (*Effective from passage*) (a) The Health Information Technology Exchange of Connecticut may establish or designate one or more subsidiaries for the purpose of creating, developing, coordinating and operating a state-wide health information exchange, or for such other purposes as prescribed by resolution of the authority's board of directors, which purposes shall be consistent with the purposes of the authority. Each subsidiary shall be deemed a quasi-public agency for purposes of chapter 12 of the general statutes. The authority may transfer to any such subsidiary any moneys and real or personal property. Each such subsidiary shall have all the privileges, immunities, tax exemptions and other exemptions of the authority. A resolution of the authority shall prescribe the purposes for which each subsidiary is formed.

(b) Each such subsidiary may sue and shall be subject to suit, provided the liability of each such subsidiary shall be limited solely to the assets, revenues and resources of such subsidiary and without recourse to the general funds, revenues, resources or any other assets of the authority or any other subsidiary. Each such subsidiary shall have the power to do all acts and things necessary or convenient to carry out the purposes for which such subsidiary is established, including, but not limited to: (1) Solicit, receive and accept aid, grants or contributions from any source of money, property or labor or other things of value, subject to the conditions upon which such grants and contributions may be made, including, but not limited to, gifts, grants or loans from any department, agency or quasi-public agency of the United States or the state, or from any organization recognized as a nonprofit organization under Section 501(c)(3) of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to time; (2) enter into agreements with persons upon such terms and conditions as are consistent with the purposes of such subsidiary; and (3) acquire, take title, lease, purchase, own, manage, hold and dispose of real and personal property and lease, convey or deal in or enter into agreements with respect to such property.

(c) Each such subsidiary shall act through its board of directors, not less than fifty per cent of whom shall be members of the board of directors of the authority or their designees.

(d) The provisions of section 1-125 of the general statutes, as amended by this act, and this section shall apply to any officer, director, designee or employee appointed as a member, director or officer of any such subsidiary. Neither any

such persons so appointed nor the directors, officers or employees of the authority shall be personally liable for the debts, obligations or liabilities of any such subsidiary as provided in said section 1-125. Each subsidiary shall, and the authority may, provide for the indemnification to protect, save harmless and indemnify such officer, director, designee or employee as provided by said section 1-125.

(e) The authority or any such subsidiary may take such actions as are necessary to comply with the provisions of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to time, to qualify and maintain any such subsidiary as a corporation exempt from taxation under said Internal Revenue Code.

(f) The authority may make loans or grants to, and may guarantee specified obligations of, any such subsidiary, following standard authority procedures, from the authority's assets and the proceeds of its bonds, notes and other obligations, provided the source and security, if any, for the repayment of any such loans or guarantees is derived from the assets, revenues and resources of such subsidiary.

Sec. 84. (NEW) (*Effective from passage*) The state of Connecticut does hereby pledge to and agree with any person with whom the Health Information Technology Exchange of Connecticut may enter into contracts pursuant to the provisions of sections 82 to 85, inclusive, of this act that the state will not limit or alter the rights hereby vested in the authority until such contracts and the obligations thereunder are fully met and performed on the part of the authority, provided nothing contained in this section shall preclude such limitation or alteration if adequate provision shall be made by law for the protection of such persons entering into contracts with the authority.

Sec. 85. (NEW) (*Effective from passage*) The Health Information Technology Exchange of Connecticut shall be and is hereby declared exempt from all franchise, corporate business, property and income taxes levied by the state or any municipality, provided nothing in this section shall be construed to exempt from any such taxes, or from any taxes levied in connection with the manufacture or sale of any products which are the subject of any agreement made by the authority, any person entering into any agreement with the authority.

Sec. 86. Section 19a-25g of the 2010 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) **[On and after July 1, 2009, the]** The Department of Public Health shall be the lead health information exchange organization for the state from July 1, 2009, to December 31, 2010, inclusive. The department shall seek private and federal funds, including funds made available pursuant to the federal American Recovery and Reinvestment Act of 2009, for the initial development of a state-wide health information exchange. **[Any private or federal funds received by the department may be used for the purpose of establishing health information technology pilot programs and the grant programs described in section 19a-25h.**  
]

(b) On and after January 1, 2011, the Health Information Technology Exchange of Connecticut, created pursuant to section 82 of this act, shall be the lead health information organization for the state. The authority shall continue to seek private and federal funds for the development and operation of a state-wide health information exchange. The Department of Public Health may contract with the authority to transfer unexpended federal funds received by the department pursuant to the federal American Recovery and Reinvestment Act of 2009, P.L. 111-05, if any, for the initial development of a state-wide health information exchange. The authority shall, within available resources, provide grants for the advancement of health information technology and exchange in this state, pursuant to subsection (f) of section 82 of this act.

**[(b)] (c)** The department shall **[: (1) Facilitate]** facilitate the implementation and periodic revisions of the health information technology plan after the plan is initially submitted in accordance with the provisions of section 74 of public act 09-232, including the implementation of an integrated state-wide electronic health information infrastructure for the sharing of electronic health information among health care facilities, health care professionals, public and private payors, state and federal agencies and patients **[, and (2) develop standards and protocols for privacy in the sharing of electronic health information. Such standards and protocols shall be no less stringent than the "Standards for Privacy of Individually Identifiable Health Information" established under the Health Insurance Portability and Accountability Act of 1996, P. L. 104-191, as amended from time to time, and contained in 45 CFR 160, 164. Such standards and protocols shall require that individually identifiable health information be secure and that access to such information be traceable by an electronic audit trail]** until December 31, 2010. On and after January 1, 2011, the Health Information Technology Exchange of Connecticut shall be responsible for the implementation and periodic revisions of the health information technology plan.

Sec. 87. Subsection (l) of section 1-79 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(l) "Quasi-public agency" means the Connecticut Development Authority, Connecticut Innovations, Incorporated, Connecticut Health and Education Facilities Authority, Connecticut Higher Education Supplemental Loan Authority, Connecticut Housing Finance Authority, Connecticut Housing Authority, Connecticut Resources Recovery Authority, Lower Fairfield County Convention Center Authority, Capital City Economic Development Authority, **[and]** Connecticut Lottery Corporation [and Health Information Technology Exchange of Connecticut](#).

Sec. 88. Subdivision (1) of section 1-120 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(1) "Quasi-public agency" means the Connecticut Development Authority, Connecticut Innovations, Incorporated, Connecticut Health and Educational Facilities Authority, Connecticut Higher Education Supplemental Loan Authority, Connecticut Housing Finance Authority, Connecticut Housing Authority, Connecticut Resources Recovery Authority, Capital City Economic Development Authority, **[and]** Connecticut Lottery Corporation [and Health Information Technology Exchange of Connecticut](#).

Sec. 89. Section 1-124 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) The Connecticut Development Authority, the Connecticut Health and Educational Facilities Authority, the Connecticut Higher Education Supplemental Loan Authority, the Connecticut Housing Finance Authority, the Connecticut Housing Authority, the Connecticut Resources Recovery Authority, [the Health Information Technology Exchange of Connecticut](#) and the Capital City Economic Development Authority shall not borrow any money or issue any bonds or notes which are guaranteed by the state of Connecticut or for which there is a capital reserve fund of any kind which is in any way contributed to or guaranteed by the state of Connecticut until and unless such borrowing or issuance is approved by the State Treasurer or the Deputy State Treasurer appointed pursuant to section 3-12. The approval of the State Treasurer or said deputy shall be based on documentation provided by the authority that it has sufficient revenues to (1) pay the principal of and interest on the bonds and notes issued, (2) establish, increase and maintain any reserves deemed by the authority to be advisable to secure the payment of the principal of and interest on such bonds and notes, (3) pay the cost of maintaining, servicing and properly insuring the purpose for which the proceeds of the bonds and notes have been issued, if applicable, and (4) pay such other costs as may be required.

(b) To the extent the Connecticut Development Authority, Connecticut Innovations, Incorporated, Connecticut Higher Education Supplemental Loan Authority, Connecticut Housing Finance Authority, Connecticut Housing Authority, Connecticut Resources Recovery Authority, Connecticut Health and Educational Facilities Authority, [the Health Information Technology Exchange of Connecticut](#) or the Capital City Economic Development Authority is permitted by statute and determines to exercise any power to moderate interest rate fluctuations or enter into any investment or program of investment or contract respecting interest rates, currency, cash flow or other similar agreement, including, but not limited to, interest rate or currency swap agreements, the effect of which is to subject a capital reserve fund which is in any way contributed to or guaranteed by the state of Connecticut, to potential liability, such determination shall not be effective until and unless the State Treasurer or his or her deputy appointed pursuant to section 3-12 has approved such agreement or agreements. The approval of the State Treasurer or his or her deputy shall be based on documentation provided by the authority that it has sufficient revenues to meet the financial obligations associated with the agreement or agreements.

Sec. 90. Section 1-125 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

The directors, officers and employees of the Connecticut Development Authority, Connecticut Innovations, Incorporated, Connecticut Higher Education Supplemental Loan Authority, Connecticut Housing Finance Authority, Connecticut Housing Authority, Connecticut Resources Recovery Authority, including ad hoc members of the Connecticut Resources Recovery Authority, Connecticut Health and Educational Facilities Authority, Capital City Economic Development Authority, [the Health Information Technology Exchange of Connecticut](#) and Connecticut Lottery Corporation and any person executing the bonds or notes of the agency shall not be liable personally on such bonds or notes or be subject to any personal liability or accountability by reason of the issuance thereof, nor shall any director or employee of the agency, including ad hoc members of the Connecticut Resources Recovery Authority, be personally liable for damage or injury, not wanton, reckless, wilful or malicious, caused in the performance of his or her duties and within the scope of his or her employment or appointment as such director, officer or employee, including ad hoc members of the Connecticut Resources Recovery Authority. The agency shall protect, save harmless and indemnify its directors, officers or employees, including ad hoc members of the Connecticut Resources Recovery Authority, from financial loss and expense, including legal fees and costs, if any, arising out of any claim, demand, suit or judgment by reason of alleged negligence or alleged deprivation of any person's civil rights or any other act or omission

resulting in damage or injury, if the director, officer or employee, including ad hoc members of the Connecticut Resources Recovery Authority, is found to have been acting in the discharge of his or her duties or within the scope of his or her employment and such act or omission is found not to have been wanton, reckless, wilful or malicious.

Sec. 91. Section 20-631 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2010*):

(a) [(1) One] Except as provided in section 2 of this act, one or more pharmacists licensed under this chapter who are determined [eligible] competent in accordance with [subsection (c) of this section, and employed by a hospital] regulations adopted pursuant to subsection (d) of this section may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients. [receiving inpatient services in a hospital licensed under chapter 368v, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the hospital. ] In order to enter into a written protocol-based collaborative drug therapy management agreement, such physician shall have established a physician-patient relationship with the patient who will receive collaborative drug therapy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. For purposes of this subsection, a "physician-patient relationship" is a relationship based on (1) the patient making a medical complaint, (2) the patient providing a medical history, (3) the patient receiving a physical examination, and (4) a logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient.

[(2) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a nursing home facility, as defined in section 19a-521, may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving services in a nursing home facility, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the nursing home facility. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. Each such protocol shall be reviewed and approved by the active organized medical staff of the nursing home in accordance with the requirements of section 19-13-D8t(i) of the Public Health Code.

(3) One or more pharmacists licensed under this chapter who are determined eligible in accordance with subsection (c) of this section and employed by or under contract with a hospital licensed under chapter 368v may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients receiving outpatient hospital care or services for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation, including patients who qualify as targeted beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with subsections (b) to (d), inclusive, of this section and subject to the approval of the hospital. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. ]

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of such discontinuance no later than twenty-four hours from the time of such discontinuance. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) A pharmacist shall be responsible for demonstrating, in accordance with [this subsection] [regulations adopted pursuant to subsection \(d\) of this section](#), the competence necessary for participation in each drug therapy management agreement into which such pharmacist enters. [The pharmacist's competency shall be determined by the hospital or nursing home facility for which the pharmacist is employed. A copy of the criteria upon which the hospital or nursing home facility determines competency shall be filed with the Commission of Pharmacy. ]

(d) The Commissioner of [**Public Health**] Consumer Protection, in consultation with the Commissioner of [**Consumer Protection, may**] Public Health, shall adopt regulations, in accordance with chapter 54, concerning competency requirements for participation in a written protocol-based collaborative drug therapy management agreement described in subsection (a) of this section, the minimum content of the collaborative drug therapy management agreement and the written protocol and [**as otherwise**] such other matters said commissioners deem necessary to carry out the purpose of this section.

Sec. 92. (NEW) (*Effective October 1, 2010*) The provisions of section 20-631 of the general statutes, as amended by this act, in effect on September 30, 2010, shall apply to any written protocol-based collaborative drug therapy management agreement entered into prior to October 1, 2010.

Sec. 93. (NEW) (*Effective October 1, 2010*) As used in sections 93 and 94 of this act:

(1) "Biologic" means a "biological product", as defined in 42 USC 262(i), as amended from time to time, that is regulated as a drug under the federal Food, Drug and Cosmetic Act, 21 USC 301 et seq. ;

(2) "Department" means the Department of Consumer Protection;

(3) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is: (A) Recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (B) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (C) intended to affect the structure or function of the body of a person or animal, and that does not achieve its primary intended purposes through chemical action within or on such body and that is not dependent upon being metabolized for the achievement of its primary intended purposes; and

(4) "Pharmaceutical or medical device manufacturing company" means any entity that: (A) Is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics or medical devices, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (B) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics or medical devices. "Pharmaceutical or medical device manufacturing company" does not include a health care provider, physician

practice, home health agency, hospital licensed in this state, wholesale drug distributor licensed in this state or a retail pharmacy licensed in this state.

Sec. 94. (NEW) (*Effective October 1, 2010*) (a) On or before January 1, 2011, each pharmaceutical or medical device manufacturing company shall adopt and implement a code that is consistent with, and minimally contains all of the requirements prescribed in, the Pharmaceutical Research and Manufacturers of America's "Code on Interaction with Healthcare Professionals" or AdvaMed's "Code of Ethics on Interactions with Health Care Professionals" as such codes were in effect on January 1, 2010.

(b) Each pharmaceutical or medical device manufacturing company shall adopt a comprehensive compliance program in accordance with the guidelines provided in the "Compliance Program Guidance for Pharmaceutical Manufacturers" dated April, 2003 and issued by the United States Department of Health and Human Services Office of Inspector General.

(c) Upon complaint, the department may investigate an alleged (1) violation of subsection (a) of this section, or (2) failure to conduct any training program or regular audit for compliance with the code adopted pursuant to subsection (a) of this section by a pharmaceutical or medical device manufacturing company. The Commissioner of Consumer Protection may impose a civil penalty of not more than five thousand dollars for any violation of the provisions of this section.

Sec. 95. Section 19a-185 of the general statutes is repealed. (*Effective October 1, 2010*)

Sec. 96. Section 19a-25h of the general statutes is repealed. (*Effective January 1, 2011*)