To: Subst. House Bill No. 7267 File No. 353 Cal. No. 231

"AN ACT CONCERNING PUBLIC OPTIONS FOR HEALTH CARE IN CONNECTICUT."

1 Strike everything after the enacting clause and substitute the following in lieu thereof:

"Section 1. Section 19a-754a of the general statutes is repealed and the following is substituted in lieu thereof (Effective July 1, 2019):

(a) There is established an Office of Health Strategy, which shall be within the Department of Public Health for administrative purposes only. The department head of said office shall be the executive director of the Office of Health Strategy, who shall be appointed by the Governor in accordance with the provisions of sections 4-5 to 4-8, inclusive, with the powers and duties therein prescribed.

(b) The Office of Health Strategy shall be responsible for the following:

(1) Developing and implementing a comprehensive and cohesive
health care vision for the state, including, but not limited to, a coordinated state health care cost containment strategy;

(2) Promoting effective health planning and the provision of quality health care in the state in a manner that ensures access for all state residents to cost-effective health care services, avoids the duplication of such services and improves the availability and financial stability of such services throughout the state;

(3) (A) Directing and overseeing innovative health care delivery and payment models in the state that reduce health care cost growth and improve the quality of patient care, including, but not limited to, the State Innovation Model Initiative and related successor initiatives, (B) setting a health care cost growth benchmark, as defined in section 2 of this act, for the state across all payers and populations, (C) enhancing the transparency of health care entities in the state, (D) monitoring the development of accountable care organizations and patient-centered medical homes in the state, and (E) monitoring the adoption of alternative payment methodologies in the state;

(4) (A) Coordinating the state's health information technology initiatives, (B) seeking funding for and overseeing the planning, implementation and development of policies and procedures for the administration of the all-payer claims database program established under section 19a-775a, (C) establishing and maintaining a consumer health information Internet web site under 19a-755b, and (D) designating an unclassified individual from the office to perform the duties of a health information technology officer as set forth in sections 17b-59f and 17b-59g;

(5) Directing and overseeing the Health Systems Planning Unit established under section 19a-612 and all of its duties and responsibilities as set forth in chapter 368z; and

(6) Convening forums and meetings with state government and external stakeholders, including, but not limited to, the Connecticut Health Insurance Exchange, to discuss health care issues designed to
develop effective health care cost and quality strategies.

(c) The Office of Health Strategy shall constitute a successor, in accordance with the provisions of sections 4-38d, 4-38e and 4-39, to the functions, powers and duties of the following:

(1) The Connecticut Health Insurance Exchange, established pursuant to section 38a-1081, relating to the administration of the all-payer claims database pursuant to section 19a-755a; and

(2) The Office of the Lieutenant Governor, relating to the (A) development of a chronic disease plan pursuant to section 19a-6q, (B) housing, chairing and staffing of the Health Care Cabinet pursuant to section 19a-725, and (C) (i) appointment of the health information technology officer, and (ii) oversight of the duties of such health information technology officer as set forth in sections 17b-59f and 17b-59g.

(d) Any order or regulation of the entities listed in subdivisions (1) and (2) of subsection (c) of this section that is in force on July 1, 2018, shall continue in force and effect as an order or regulation until amended, repealed or superseded pursuant to law.

Sec. 2. (NEW) (Effective July 1, 2019) For the purposes of this section and sections 3 to 9, inclusive, of this act:

(1) "Device manufacturer" means a manufacturer that manufactures a device for which annual sales attributable to residents of this state exceed ten million dollars;

(2) "Drug manufacturer" means the manufacturer of a drug that is: (A) Reported by a health carrier pursuant to section 38a-479qqq of the general statutes; (B) studied or listed pursuant to subsection (c) or (d) of section 19a-754b of the general statutes; or (C) in a therapeutic class of drugs that the office determines, through public or private reports, has had a substantial impact on prescription drug expenditures, net of rebates, as a percentage of total health care expenditures;
(3) "Executive director" means the executive director of the office;

(4) "Health care cost growth benchmark" means the annual benchmark established pursuant to section 3 of this act;

(5) "Health care entity" means an accountable care organization, ambulatory surgical center, clinic, hospital or physician organization in this state, other than a physician contracting unit that, for a given calendar year: (A) Has a patient panel of not more than ten thousand patients; or (B) represents providers who collectively receive less than twenty million dollars in net patient service revenue from health carriers;

(6) "Health status adjusted total medical expenses" means: (A) The total cost of care for the patient population of a group of health care providers with at least thirty-six thousand member months for a given calendar year, which cost (i) is calculated for such year on the basis of the allowed claims for all categories of medical expenses and all nonclaims payments for such year, including, but not limited to, cost-sharing payments, adjusted by health status and expressed on a per member, per month basis for all members in this state who are required to select a primary care physician for such year, (ii) is reported separately for Medicaid, Medicare and nongovernment health plans for such year, and (iii) discloses the health adjustment risk score and the version of the risk adjustment tool used to calculate such score for such group for such year; and (B) the total aggregate medical expenses for all physicians and physician groups with fewer than thirty-six thousand member months for a given calendar year;

(7) "Office" means the Office of Health Strategy established under section 19a-754a of the general statutes, as amended by this act;

(8) "Other entity" means a device manufacturer, drug manufacturer or pharmacy benefits manager;

(9) "Payer" means a payer that, during a given calendar year, pays providers for health care services on behalf of, or pharmacies for
prescription drugs dispensed to, more than ten thousand individuals in this state;

(10) "Pharmacy benefits manager" has the same meaning as provided in section 38a-479000 of the general statutes;

(11) "Total health care expenditures" means the per capita sum of all health care expenditures in this state from public and private sources for a given calendar year, including: (A) All categories of medical expenses and all nonclaims-related payments to health care providers, as included in the health status adjusted total medical expenses reported by the office pursuant to subsection (c) of section 5 of this act; (B) all patient cost-sharing amounts, including, but not limited to, deductibles and copayments; (C) the net cost of nongovernment health insurance; (D) prescription drug expenditures net of rebates and discounts; (E) device manufacturer expenditures net of rebates and discounts; and (F) any other expenditures specified by the executive director;

(12) "Total medical expenses" means the sum, for a given calendar year, of medical claims and total nonclaims payments for: (A) Each physician and physician group with at least thirty-six thousand member months, and serving members in this state required to select a primary care physician, for such year; and (B) medical claims and total nonclaims payments for all physicians or physician groups with fewer than thirty-six thousand member months for such year; and

(13) "Total nonclaims payments" means the sum of all nonclaims payments for a given calendar year, aggregated for the following categories: (A) Incentive programs; (B) risk settlements; (C) care management expenses; and (D) other.

Sec. 3. (NEW) (Effective July 1, 2019) (a) Not later than October 1, 2020, and annually thereafter, the office shall establish a health care cost growth benchmark for the calendar year next succeeding. Such benchmark shall address the average growth in health care expenditures across all payers and populations in this state for such
year.

(b) In establishing each health care cost growth benchmark pursuant to subsection (a) of this section, the office shall, at a minimum:

(1) Consider any change in the consumer price index for all urban consumers in the northeast region from the preceding calendar year, and the most recent publicly available information concerning the growth rate of the gross state product; and

(2) (A) Hold an informational public hearing concerning such benchmark:

(i) At a time and place designated by the executive director in a notice prominently posted on the office's Internet web site;

(ii) In a form and manner prescribed by the executive director; and

(iii) On the basis of the most recent report prepared by the office pursuant to subsection (c) of section 5 of this act and any other information that the executive director, in the executive director's discretion, deems relevant for the purposes of such hearing.

(B) Notwithstanding subparagraph (A) of this subdivision, the office shall not be required to hold an informational public hearing concerning a health care cost growth benchmark for any calendar year beginning on or after January 1, 2022, if such benchmark is the same as the benchmark for the preceding calendar year.

(c) If the executive director determines, after any public hearing held pursuant to subdivision (2) of subsection (b) of this section, that a modification to the health care cost growth benchmark is, in such executive director's discretion, reasonably warranted, the office may modify such benchmark.

(d) The executive director shall cause each health care cost growth benchmark to be posted on the office's Internet web site.
(e) The office may enter into such contractual agreements as may be
necessary to carry out the purposes of this section, including, but not
limited to, contractual agreements with actuarial, economic and other
experts and consultants to assist the office in establishing health care
cost growth benchmarks.

Sec. 4. (NEW) (Effective July 1, 2019) (a) (1) Not later than May 1,
2022, and annually thereafter, the office shall hold a public hearing to
compare the growth in total health care expenditures during the
preceding calendar year to the health care cost growth benchmark
established pursuant to section 3 of this act for such year. Each hearing
shall involve an examination of:

(A) The report most recently prepared by the office pursuant to
subsection (c) of section 5 of this act;

(B) The expenditures of health care entities, including, but not
limited to, health care cost trends and the factors contributing to such
costs;

(C) Whether one category of expenditures may be offset by savings
in another category; and

(D) Any other matters that the executive director, in the executive
director's discretion, deems relevant for the purposes of this section.

(2) The executive director may require that any health care entity
that is found to be a significant contributor to health care cost growth
in this state during the preceding calendar year participate in the
public hearing. Each such health care entity that is required to
participate in such public hearing shall provide testimony on issues
identified by the executive director, and provide additional
information on actions taken to reduce such health care entity's
contribution to future state-wide health care costs.

(b) Not later than October 1, 2022, and annually thereafter, the office
shall prepare and submit a report, in accordance with section 11-4a of
the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to insurance and public health. Such report shall:

(1) Be based on the office's analysis of the information submitted during the most recent public hearing conducted pursuant to subsection (a) of this section and any other information that the executive director, in the executive director's discretion, deems relevant for the purposes of this section;

(2) Describe health care spending trends in this state and the factors underlying such trends; and

(3) Disclose the office's recommendations, if any, concerning strategies to increase the efficiency of this state's health care system, including, but not limited to, any recommended legislation concerning this state's health care system.

Sec. 5. (NEW) (Effective July 1, 2019) (a) Not later than March 1, 2021, and annually thereafter, each institutional provider, on behalf of such institutional provider and its parent organization and affiliated entities, noninstitutional provider and provider organization in this state shall submit to the office, for the preceding calendar year:

(1) Data concerning:

(A) The utilization of health care services provided by such provider or organization;

(B) The charges, prices imposed and payments received by such provider or organization for such services;

(C) The costs incurred, and revenues earned, by such provider or organization in providing such services; and

(D) Any other matter that the executive director deems relevant for the purposes of this section; and
(2) If such provider is a hospital, the data described in subdivision (1) of this subsection and such additional data, information and documents designated by the executive director, including, but not limited to, charge masters, cost data, audited financial statements and merged billing and discharge data, provided such provider shall not be required to submit any data contained in a report that is filed pursuant to chapters 368aa to 368ll, inclusive, of the general statutes and available to the executive director.

(b) The executive director shall establish standards to ensure that the data, information and documents submitted to the office pursuant to subsection (a) of this section are submitted to the office in a uniform manner. Such standards shall enable the executive director to identify, on a patient-centered and provider-specific basis, state-wide and regional trends in the availability, cost, price and utilization of medical, surgical, diagnostic and ancillary services provided by acute care hospitals, chronic disease hospitals, rehabilitation hospitals and other specialty hospitals, clinics, including, but not limited to, psychiatric clinics, and facilities providing ambulatory care. Such standards may require hospitals to submit such data, information and documents to the office in an electronic form, provided such standards shall provide for a waiver of such requirement if such waiver is reasonable in the judgment of the executive director.

(c) (1) Not later than December 1, 2021, and annually thereafter, the office shall prepare, and the executive director shall cause to be posted on the office's Internet web site, a report concerning health status adjusted total medical expenses for the preceding calendar year, including, but not limited to, a breakdown of such health status adjusted total medical expenses by:

   (A) Major service category;

   (B) Payment methodology;

   (C) Relative price;
(D) Direct hospital inpatient cost;

(E) Indirect hospital inpatient cost;

(F) Direct hospital outpatient cost; and

(G) Indirect hospital outpatient cost.

(2) Notwithstanding subdivision (1) of this subsection, the office shall not disclose any provider specific data or information unless the executive director provides at least ten days' advance written notice of such disclosure to each provider that would be affected by such disclosure.

(d) The executive director shall, at least annually, submit a request to the federal Centers for Medicare and Medicaid Services for the health status adjusted total medical expenses of provider groups that served Medicare patients during the calendar year next preceding.

(e) The office may enter into such contractual agreements as may be necessary to carry out the purposes of this section, including, but not limited to, contractual agreements with actuarial, economic and other experts and consultants.

Sec. 6. (NEW) (Effective July 1, 2019) (a) (1) For each calendar year beginning on or after January 1, 2022, if the executive director determines that the average annual percentage change in total health care expenditures for the preceding calendar year exceeded the health care cost growth benchmark for such year, the executive director shall identify, not later than April first of such calendar year, each health care entity or payer that exceeded such benchmark for such year.

(2) The executive director may require that any health care entity that is found to be a significant contributor to health care cost growth in this state during the preceding calendar year participate in the public hearing held pursuant to subsection (a) of section 4 of this act. Each such health care entity that is required to participate in such public hearing shall provide testimony on issues identified by the
executive director, and provide additional information on actions taken to reduce such health care entity's contribution to future statewide health care costs.

(b) Not later than thirty days after the executive director identifies each health care entity or payer pursuant to subsection (a) of this section, the executive director shall send a notice to each such entity or payer. Such notice shall be in a form and manner prescribed by the executive director, and disclose to each such entity or payer, at a minimum:

(1) That the executive director has identified such entity or payer pursuant to subsection (a) of this section;

(2) The factual basis for the executive director's identification of such entity or payer pursuant to subsection (a) of this section; and

(3) That such entity or payer shall file a proposed performance improvement plan pursuant to subdivision (1) of subsection (e) of this section, provided such entity or payer may:

(A) File a request for an extension of time, or a waiver, pursuant to subdivision (1) of subsection (c) of this section; and

(B) Request a hearing pursuant to subsection (d) of this section.

(c) (1) (A) Each health care entity or payer identified by the executive director pursuant to subsection (a) of this section may, not later than thirty days after the executive director sends a notice to such entity or payer pursuant to subsection (b) of this section, file with the office, in a form and manner prescribed by the executive director, a request seeking:

(i) An extension of time to file a proposed performance improvement plan pursuant to subdivision (1) of subsection (e) of this section; or

(ii) A waiver from the requirement that such entity or payer file a
proposed performance improvement plan pursuant to subdivision (1) of subsection (e) of this section.

(B) Each health care entity or payer that files a request pursuant to subparagraph (A) of this subdivision shall set forth the reasons for such request in such request.

(2) Not later than thirty days after a health care entity, payer or other entity files a request pursuant to subdivision (1) of this subsection, the executive director shall:

(A) Examine the reasons set forth in the request and decide, on the basis of such reasons, whether to approve or deny such request; and

(B) Send a notice, in a form and manner prescribed by the executive director, to the entity or payer that filed such request disclosing, at a minimum:

(i) The executive director's decision concerning such request and the reasons therefor;

(ii) If the executive director denies such entity's or payer's request, that such entity or payer may file a request for a hearing pursuant to subsection (d) of this section; and

(iii) If such entity's or payer's request is a request for an extension of time to file a proposed performance improvement plan pursuant to subdivision (1) of subsection (e) of this section and the executive director approves such request, the date by which such entity or payer shall file such proposed plan.

(d) Each health care entity or payer identified by the executive director pursuant to subsection (a) of this section may, not later than thirty days after the executive director sends a notice to such entity or payer pursuant to subsection (b) of this section or subparagraph (B) of subsection (2) of subsection (c) of this section, as applicable, file with the office a request for a hearing. Each hearing conducted pursuant to this subsection shall be conducted in accordance with the procedures.
for hearings on contested cases established in chapter 54 of the general statutes.

(e) (1) Each health care entity or payer identified by the executive director pursuant to subsection (a) of this section, or required by the executive director pursuant to subparagraph (C)(ii)(III) of subdivision (4) of subsection (f) of this section, shall, subject to the provisions of subsections (b) to (d), inclusive, of this section, file with the office a proposed performance improvement plan. Such entity or payer shall file such proposed plan, which shall include an implementation timetable, with the office, in a form and manner prescribed by the executive director, not later than whichever of the following dates first occurs:

(A) The date that is thirty days after the date on which the executive director sent a notice to such entity or payer pursuant to subsection (b) of this section;

(B) The date that the executive director disclosed to such entity or payer pursuant to subparagraph (B)(iii) of subdivision (2) of subsection (c) of this section; or

(C) The date that is thirty days after the date on which the notice of a final decision is issued following a public hearing conducted pursuant to subsection (d) of this section.

(2) (A) The executive director shall review each health care entity's and payer's proposed performance improvement plan filed pursuant to subdivision (1) of this subsection to determine whether, in the executive director's judgment, it is reasonably likely that:

(i) Such proposed plan will address the cause of such entity's or payer's excessive cost growth; and

(ii) Such entity or payer will successfully implement such proposed plan.

(B) After the executive director reviews a proposed performance
improvement plan pursuant to subparagraph (A) of this subdivision, the executive director shall:

(i) Approve such proposed plan if the executive director determines, in the executive director's judgment, that such proposed plan satisfies the criteria established in subparagraph (A) of this subdivision; or

(ii) Deny such proposed plan if the executive director determines, in the executive director's judgment, that such proposed plan does not satisfy the criteria established in subparagraph (A) of this subdivision.

(C) (i) Not later than thirty days after the executive director approves or denies a proposed performance improvement plan pursuant to subparagraph (B) of this subdivision, the executive director shall send a notice to the health care entity, payer or other entity that filed such proposed plan disclosing, at a minimum, that:

(I) The executive director approved such proposed plan; or

(II) The executive director denied such proposed plan, the reasons for such denial and that such entity or payer shall file with the office such amendments as are necessary for such proposed plan to satisfy the criteria established in subparagraph (A) of this subdivision.

(ii) The executive director shall cause a notice to be posted on the office's Internet web site disclosing:

(I) The name of each health care entity or payer that files, and receives approval for, a proposed performance improvement plan; and

(II) That such health care entity, payer or other entity is implementing such plan.

(D) Each health care entity or payer that receives a notice from the executive director pursuant to subparagraph (C)(i) of this subdivision notifying such entity or payer that the executive director has denied such entity's or payer's proposed performance improvement plan shall file with the office, in a form and manner prescribed by the executive
director and not later than thirty days after the date that the executive
director sends such notice to such entity or payer, such amendments as
are necessary for such proposed plan to satisfy the criteria established
in subparagraph (A) of this subdivision.

(f) (1) Each health care entity or payer that receives a notice from the
executive director pursuant to subparagraph (C)(i) of subdivision (2) of
subsection (e) of this section notifying such entity or payer that the
executive director has approved such entity's or payer's proposed
performance improvement plan:

(A) Shall immediately make good faith efforts to implement such
plan; and

(B) May amend such plan at any time during the implementation
timetable included in such plan, provided the executive director
approves such amendment.

(2) The office shall provide such assistance to each health care entity
or payer that the executive director, in the executive director's
discretion, deems necessary and appropriate to ensure that such entity
or payer successfully implements such entity's or payer's performance
improvement plan.

(3) Each health care entity or payer shall be subject to such
additional reporting requirements that the executive director, in the
executive director's discretion, deems necessary to ensure that such entity
or payer successfully implements such entity's or payer's performance
improvement plan.

(4) (A) Each health care entity or payer that files, and receives
approval for, a performance improvement plan pursuant to this
section shall, not later than thirty days after the last date specified in
the implementation timetable included in such plan, submit to the
office, in a form and manner prescribed by the executive director, a
report regarding the outcome of such entity's or payer's
implementation of such plan.
(B) If the executive director determines, on the basis of the report submitted by a health care entity or payer pursuant to subparagraph (A) of this subdivision, that such entity or payer successfully implemented such entity's or payer's performance improvement plan, the executive director shall:

(i) Send a notice to such entity or payer, in a form and manner prescribed by the executive director, disclosing such determination; and

(ii) Cause the notice posted on the office's Internet web site pursuant to subparagraph (C)(ii) of subdivision (2) of subsection (e) of this section concerning such entity or payer to be removed from such Internet web site.

(C) If the executive director determines, on the basis of the report submitted by a health care entity or payer pursuant to subparagraph (A) of this subdivision, that such entity or payer failed to successfully implement such entity's or payer's performance improvement plan, the executive director shall:

(i) Send a notice to such entity or payer, in a form and manner prescribed by the executive director, disclosing such determination and any action taken by the executive director pursuant to clause (ii) of this subparagraph; and

(ii) In the executive director's discretion:

(I) Extend the implementation timetable included in such plan;

(II) Require such entity or payer to file with the office, in a form and manner prescribed by the executive director, such amendments to such plan as are, in the executive director's judgment, necessary to ensure that such entity or payer successfully implements such plan;

(III) Require such entity or payer to file a new proposed performance improvement plan pursuant to subdivision (1) of subsection (e) of this section; or
(IV) Waive or delay the requirement that such entity or payer file any future proposed performance improvement plan until the executive director determines, in the executive director's discretion, that such entity or payer has successfully implemented such plan.

(g) The office shall keep confidential all nonpublic clinical, financial, operational or strategic documents and information filed with, or submitted to, the office pursuant to this section. The office shall not disclose any such document or information to any person without the consent of the health care entity or payer that filed such document or information with, or submitted such document or information to, the office pursuant to this section, except in summary form as part of an evaluative report if the executive director determines that such disclosure should be made in the public interest after taking into account any privacy, trade secret or anti-competitive considerations. Notwithstanding any provision of the general statutes, no document or information filed with, or submitted to, the office pursuant to this section shall be deemed to be a public record or subject to disclosure under the Freedom of Information Act, as defined in section 1-200 of the general statutes.

Sec. 7. (NEW) (Effective July 1, 2019) (a) (1) For each calendar year beginning on or after January 1, 2022, if the executive director determines that the average annual percentage change in total health care expenditures for the preceding calendar year exceeded the health care cost growth benchmark for such year, the executive director shall identify each other entity that significantly contributed to exceeding such benchmark. Each identification shall be based on:

(A) The report prepared pursuant to subsection (c) of section 5 of this act;

(B) The reports filed and submitted pursuant to sections 38a-479ooo and 38a-479ppp of the general statutes;

(C) The information and data reported to the office pursuant to section 19a-754b of the general statutes;
(D) Information obtained from the all-payer claims database established under section 19a-755a of the general statutes; and

(E) Any other information that the executive director, in the executive director's discretion, deems relevant for the purposes of this section.

(2) The executive director shall account for costs, net of rebates and discounts, when identifying other entities pursuant to this section.

(b) The executive director may require that any other entity that is found to be a significant contributor to health care cost growth in this state during the preceding calendar year participate in the public hearing held pursuant to subsection (a) of section 4 of this act. Each such other entity that is required to participate in such public hearing shall provide testimony on issues identified by the executive director, and provide additional information on actions taken to reduce such health care entity's contribution to future state-wide health care costs. If such other entity is a drug manufacturer, and the executive director requires that such drug manufacturer participate in such public hearing with respect to a specific drug or class of drugs, such public hearing may, to the extent possible, include representatives from at least one brand name manufacturer, one generic manufacturer and one innovator company that is less than ten years old.

Sec. 8. (NEW) (Effective July 1, 2019) (a) The executive director shall appoint a quality council, and shall ensure that the membership of such council includes individuals with experience providing health care services, and coverage for such services, in this state.

(b) The quality council shall have the following duties:

(1) (A) To develop, in consultation with national and other state organizations and residents of this state who are stakeholders in all aspects of the health care system that monitor and develop health care quality and safety measures, a proposed standard quality measure set, which, if adopted by the office, would:
(i) Enable health care providers, facilities, medical groups and health care provider groups in this state to report to the office a standard set of information concerning health care quality and safety measures; and

(ii) Include measures concerning health outcomes.

(B) Not later than November 1, 2020, submit the proposed standard quality measure set developed pursuant to subparagraph (A) of this subdivision to the office, and make recommendations to the executive director regarding adoption of such proposed standard quality measure set.

(2) (A) To develop, on an ongoing basis, proposed updates to any standard quality measure set adopted by the office. Such updates may include, but need not be limited to:

(i) Nationally recognized quality measures that are recommended by medical groups and health care provider groups concerning appropriate quality measures for such groups' specialties; and

(ii) Newly developed measures concerning health outcomes, which measures shall meet standards of patient-centeredness and ensure consideration of important differences in preferences and clinical characteristics within patient subpopulations.

(B) The quality council shall provide an opportunity for stakeholder engagement and transparency surrounding any measure development and research, whether provided by a state agency or third party, relied upon for decision-making that addresses access to health care treatments and services.

(C) Not later than November 1, 2021, and annually thereafter, make recommendations to the executive director regarding adoption of proposed updates to any standard quality measure set adopted by the office.

(3) Advise the office on such other matters that the executive
director, in the executive director's discretion, may deem appropriate
to assist the office in performing its duties.

Sec. 9. (NEW) (Effective July 1, 2019) The office may adopt
regulations, in accordance with chapter 54 of the general statutes, to
implement the provisions of sections 2 to 8, inclusive, of this act.

Sec. 10. (NEW) (Effective July 1, 2019) (a) For the purposes of this
section:

   (1) "Affordable Care Act" means the Patient Protection and
   Affordable Care Act, P.L. 111-148, as amended by the Health Care and
   Education Reconciliation Act, P.L. 111-152, as both may be amended
   from time to time, and regulations adopted thereunder;

   (2) "Exchange" means the Connecticut Health Insurance Exchange
   established under section 38a-1081 of the general statutes;

   (3) "Exempt insurer" means an insurer that administers self-insured
   health benefit plans and is exempt from third-party administrator
   licensure under subparagraph (C) of subdivision (11) of section 38a-
   720 of the general statutes and section 38a-720a of the general statutes;
   and

   (4) "Office" means the Office of Health Strategy established under
   section 19a-754a of the general statutes.

   (b) The office shall seek a state innovation waiver from the United
   States Department of the Treasury or the United States Department of
   Health and Human Services, as applicable, pursuant to Section 1332 of
   the Affordable Care Act to establish a reinsurance program pursuant
to subsection (e) of this section.

   (c) Subject to the approval of a waiver described in subsection (b) of
   this section, the office, not later than September 1, 2020, for plan year
   2021 and annually thereafter for the subsequent plan year, shall:

   (1) Determine the amount needed, not to exceed thirty million
dollars, annually, to fund the reinsurance program described in subsection (e) of this section; and

(2) Inform the Office of Policy and Management of the amount determined pursuant to subdivision (1) of this subsection, which office shall then inform the Insurance Commissioner of such amount.

(d) (1) Each insurer and health care center doing health insurance business in this state, and each exempt insurer, shall annually pay to the Insurance Commissioner, for deposit in the Insurance Fund established under section 38a-52a of the general statutes, a reinsurance fee assessed by the commissioner pursuant to this section.

(2) Not later than September first, annually, each insurer, health care center and exempt insurer described in subdivision (1) of this subsection shall report to the commissioner, on a form designated by said commissioner, the number of insured or enrolled lives in this state as of the May first immediately preceding for which such insurer, health care center or exempt insurer is providing health insurance coverage, or administering a self-insured health benefit plan providing coverage, of the types specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes. Such number shall not include lives enrolled in Medicare, any medical assistance program administered by the Department of Social Services, workers' compensation insurance or Medicare Part C plans.

(3) Not later than November first, annually, the commissioner shall determine the fee to be assessed for the next plan year against each insurer, health care center and exempt insurer described in subdivision (1) of this subsection. Such fee shall be calculated by multiplying the number of lives reported to the commissioner pursuant to subdivision (2) of this subsection by a factor, determined annually by the commissioner, to fully fund the amount determined under subsection (c) of this section, adjusted for a reinsurance fee by subtracting, if the amount appropriated was more than the amount expended, or by adding, if the amount expended was more than the amount
appropriated, the amount determined under subsection (c) of this section, less the amount of federal pass-through savings available pursuant to the waiver described in subsection (b) of this section. The commissioner shall determine the factor by dividing the adjusted amount by the total number of lives reported to the commissioner pursuant to subdivision (2) of this subsection.

(4) (A) Not later than December first, annually, the commissioner shall submit a statement to each insurer, health care center and exempt insurer described in subdivision (1) of this subsection that includes the proposed fee, identified on such statement as the "reinsurance fee", for such insurer, health care center or exempt insurer calculated in accordance with this subsection. Each such insurer, health care center and exempt insurer shall pay such fee to the commissioner not later than February first, annually.

(B) Any insurer, health care center or exempt insurer described in subdivision (1) of this subsection that is aggrieved by an assessment levied under this subsection may appeal therefrom in the same manner as provided for appeals under section 38a-52 of the general statutes.

(5) Any insurer, health care center or exempt insurer that fails to file the report required under subdivision (2) of this subsection shall pay a late filing fee of one hundred dollars per day for each day from the date such report was due. The commissioner may require an insurer, health care center or exempt insurer subject to this subsection to produce any records in its possession, and may require any other person to produce any records in such other person's possession, that were used to prepare such report for examination by the commissioner or the commissioner's designee. If the commissioner determines there exists anything other than a good faith discrepancy between the actual number of insured or enrolled lives that should have been reported pursuant to subdivision (2) of this subsection and the number actually reported, such insurer, health care center or exempt insurer shall pay a civil penalty of not more than fifteen thousand dollars for each report filed for which the commissioner determines there is such a
discrepancy.

653 (6) (A) The commissioner shall apply an overpayment of the
654 reinsurance fee by an insurer, health care center or exempt insurer for
655 any fiscal year as a credit against the reinsurance fee due from such
656 insurer, health care center or exempt insurer for the succeeding fiscal
657 year, subject to an adjustment under subdivision (3) of this subsection,
658 if:

659 (i) The amount of the overpayment exceeds five thousand dollars;
660 and

661 (ii) On or before June first of the calendar year of the overpayment,
662 the insurer, health care center, or exempt insurer:

663 (I) Notifies the commissioner of the amount of the overpayment;
664 and

665 (II) Provides the commissioner with evidence sufficient to prove the
666 amount of the overpayment.

667 (B) Not later than ninety days following receipt of notice and
668 supporting evidence under subparagraph (A) of this subdivision, the
669 commissioner shall:

670 (i) Determine whether the insurer, health care center or exempt
671 insurer made an overpayment; and

672 (ii) Notify the insurer, health care center or exempt insurer of the
673 commissioner's determination under clause (i) of this subparagraph.

674 (C) Failure of an insurer, health care center or exempt insurer to
675 notify the commissioner of the amount of an overpayment within the
676 time prescribed in subparagraph (A) of this subdivision constitutes a
677 waiver of any demand of the insurer, health care center or exempt
678 insurer against this state on account of such overpayment.

679 (D) Nothing in this subdivision shall be construed to prohibit or
limit the right of an insurer, health care center or exempt insurer to
appeal pursuant to subparagraph (B) of subdivision (4) of this
subsection.

(e) The assessment imposed under this section shall be utilized to
establish a reinsurance program for the individual health insurance
market designed to lower premiums by between five and ten per cent
annually on health benefit plans sold in such market, on and off the
exchange, provided the United States Department of the Treasury or
the United States Department of Health and Human Services, as
applicable, approves a state innovation waiver under Section 1332 of
the Affordable Care Act for such reinsurance program. Any such
reinsurance program shall be administered by the Health Reinsurance
Association created under section 38a-556 of the general statutes.

(f) If another state, territory or district of the United States, or a
foreign country, imposes on a Connecticut domiciled insurer, fraternal
benefit society, hospital service corporation, medical service
corporation, health care center or other domestic entity a retaliatory
charge for the fee imposed under this section, such domestic entity
may, not later than sixty days after receipt of notice of the imposition
of the retaliatory charge for such fee, appeal to the Insurance
Commissioner for a verification that the fee imposed under this section
is subject to retaliation by another state, territory or district of the
United States, or a foreign country. If the Insurance Commissioner
verifies, upon appeal to and certification by the commissioner, that the
fee imposed under this section is the subject of a retaliatory tax, fee,
assessment or other obligation by another state, territory or district of
the United States, or a foreign country, such fee shall not be assessed
against nondomestic insurers and nondomestic exempt insurers
pursuant to this section. Any such domestic insurer, fraternal benefit
society, hospital service corporation, medical service corporation,
health care center or other entity aggrieved by the commissioner's
decision issued under this subsection may appeal therefrom in the
same manner as provided under section 38a-52 of the general statutes.
(g) If the waiver described in subsection (b) of this section terminates and is not replaced, the fee imposed under this section shall immediately terminate.

(h) The Insurance Commissioner may adopt regulations, in accordance with chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 11. (NEW) (Effective July 1, 2019) For the purposes of this section and sections 12 to 18, inclusive, of this act, unless the context otherwise requires:

(1) "Canadian supplier" means a manufacturer or wholesale drug distributor that is licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs;

(2) "Drug" means an article that is (A) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement thereto, (B) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) not food and intended to affect the structure or any function of the human body, and (D) not a device and intended for use as a component of any article specified in subparagraphs (A) to (C), inclusive, of this subdivision;

(3) "Drug Quality and Security Act" means the federal Drug Quality and Security Act, 21 USC 351, et seq., as amended from time to time;

(4) "Food, Drug and Cosmetic Act" means the federal Food, Drug and Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and Security Act, as both may be amended from time to time;

(5) "Laboratory" means an environmental laboratory as defined in section 19a-29a of the general statutes and accredited by ISO 17025;

(6) "Laboratory testing" means a quantitative and qualitative analysis of a drug consistent with the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement thereto.
Pharmacopoeia;

(7) "Participating Canadian supplier" means a Canadian supplier that is exporting prescription drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the program;

(8) "Participating wholesaler" means a wholesaler that is (A) designated by the Department of Consumer Protection to distribute prescription drugs, in the manufacturer's original container, obtained from a participating Canadian supplier, and (B) participating in the program;

(9) "Program" means the Canadian prescription drug importation program established by the Commissioner of Consumer Protection, in conjunction with the Commissioner of Public Health, pursuant to section 12 of this act;

(10) "Track-and-trace" means the product tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act; and

(11) "Wholesaler" means a wholesaler, as defined in section 21a-70 of the general statutes, that has received a certificate of registration from the Commissioner of Consumer Protection pursuant to said section.

Sec. 12. (NEW) (Effective July 1, 2019) (a) The Commissioner of Consumer Protection, in conjunction with the Commissioner of Public Health, shall establish a program to be known as the "Canadian prescription drug importation program". Under such program, the Commissioner of Consumer Protection and the Commissioner of Public Health shall, notwithstanding any contrary provision of the general statutes, provide for the importation of safe and effective prescription drugs from Canada that have the highest potential for cost savings in this state.
(b) (1) Not later than January 1, 2021, the Commissioner of Consumer Protection shall, after consulting with the Commissioner of Public Health, submit a request to the federal Secretary of Health and Human Services seeking approval for the program under 21 USC 384(l), as amended from time to time. Such request shall, at a minimum:

(A) Describe the Commissioner of Consumer Protection's and Commissioner of Public Health's plans for operating the program;

(B) Demonstrate that the prescription drugs that will be imported and distributed in this state under the program will:

(i) Meet all applicable federal and state standards for safety and effectiveness; and

(ii) Comply with all federal tracing procedures; and

(C) Disclose the costs of implementing the program.

(2) (A) If the federal Secretary of Health and Human Services approves the Commissioner of Consumer Protection's request, the Commissioner of Consumer Protection shall:

(i) Submit to the Commissioner of Public Health a notice disclosing that the federal Secretary of Health and Human Services approved such request;

(ii) Submit to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services and public health a notice disclosing that the federal Secretary of Health and Human Services approved such request; and

(iii) Begin operating the program in conjunction with the Commissioner of Public Health not later than one hundred eighty days after the date of such approval.

(B) Except as otherwise provided in sections 11 to 18, inclusive, of
this act, the Commissioner of Consumer Protection and the
Commissioner of Public Health shall not operate the program unless
the federal Secretary of Health and Human Services approves the
Commissioner of Consumer Protection's request.

Sec. 13. (NEW) (Effective July 1, 2019) Each participating wholesaler
may import and distribute a prescription drug in this state from a
participating Canadian supplier under the program if:

(1) Such drug meets the United States Food and Drug
Administration's standards concerning drug safety, effectiveness,
misbranding and adulteration;

(2) Importing such drug would not violate federal patent laws; and

(3) Such drug is not:

(A) A controlled substance, as defined in 21 USC 802, as amended
from time to time;

(B) A biological product, as defined in 42 USC 262, as amended
from time to time;

(C) An infused drug;

(D) An intravenously injected drug;

(E) A drug that is inhaled during surgery; or

(F) A drug that is a parenteral drug, the importation of which is
determined by the federal Secretary of Health and Human Services to
pose a threat to the public health.

Sec. 14. (NEW) (Effective July 1, 2019) Participating wholesalers may,
subject to the provisions of sections 11 to 18, inclusive, of this act,
import and distribute drugs in this state from a participating Canadian
supplier under the program to:

(1) A pharmacy or institutional pharmacy, as defined in section 20-
571 of the general statutes; and

(2) A laboratory registered with the Department of Public Health under section 19a-29a of the general statutes to perform analytical testing.

Sec. 15. (NEW) (Effective July 1, 2019) Each participating Canadian supplier and participating wholesaler shall comply with all applicable track-and-trace requirements, and shall not distribute, dispense or sell outside of this state any prescription drugs that are imported into this state under the program. Each participating wholesaler shall make available to the Commissioner of Consumer Protection all track-and-trace records not later than forty-eight hours after the Commissioner of Consumer Protection requests such records.

Sec. 16. (NEW) (Effective July 1, 2019) (a) The participating wholesaler shall ensure the safety and quality of all drugs that are imported and distributed in this state under the program. The participating wholesaler shall:

(1) For each initial shipment of a drug that is imported into this state by a participating wholesaler, ensure that a laboratory engaged by the participating wholesaler tests a statistically valid sample size for each batch of each drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(2) For each shipment of a drug that is imported into this state by a participating wholesaler and has been sampled and tested pursuant to subdivision (1) of this subsection, ensure that a laboratory engaged by the participating wholesaler tests a statistically valid sample of such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act;

(3) Certify that each drug imported into this state under the program:

(A) Is approved for marketing in the United States and not
adulterated or misbranded; and

(B) Meets all of the labeling requirements under 21 USC 352, as amended from time to time;

(4) Maintain laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each drug imported into this state under the program is in compliance with the requirements of this section; and

(5) Maintain documentation demonstrating that the testing required by this section was conducted at a laboratory in accordance with the Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations concerning laboratory qualifications.

(b) The participating wholesaler shall maintain all information and documentation that is submitted pursuant to this section for a period of not less than three years.

(c) Each participating wholesaler shall maintain all of the following information for each drug that such participating wholesaler imports and distributes in this state under the program, and submit such information to the Commissioner of Consumer Protection upon request by the Commissioner of Consumer Protection:

(1) The name and quantity of the active ingredient of such drug;

(2) A description of the dosage form of such drug;

(3) The date on which such participating wholesaler received such drug;

(4) The quantity of such drug that such participating wholesaler received;

(5) The point of origin and destination of such drug;

(6) The price paid by such participating wholesaler for such drug;
(7) A report for any drug that fails laboratory testing; and

(8) Such additional information and documentation that the Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, deems necessary to ensure the protection of the public health.

(d) Each participating Canadian supplier shall maintain the following information and documentation and, upon request by the Commissioner of Consumer Protection, submit such information and documentation to the Commissioner of Consumer Protection for each drug that such participating Canadian supplier exports into this state under the program:

(1) The original source of such drug, including, but not limited to:

(A) The name of the manufacturer of such drug;

(B) The date on which such drug was manufactured; and

(C) The location where such drug was manufactured;

(2) The date on which such drug was shipped;

(3) The quantity of such drug that was shipped;

(4) The quantity of each lot of such drug originally received and the source of such lot;

(5) The lot or control number and the batch number assigned to such drug by the manufacturer; and

(6) Such additional information and documentation that the Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, deems necessary to ensure the protection of the public health.

Sec. 17. (NEW) (Effective July 1, 2019) (a) The Commissioner of Consumer Protection shall issue a written order:
(1) Suspending importation and distribution of a drug under the program if the Commissioner of Consumer Protection discovers that such distribution or importation violates any provision of sections 11 to 18, inclusive, of this act or any other applicable state or federal law or regulation;

(2) Suspending all importation and distribution of drugs by a participating wholesaler under the program if the Commissioner of Consumer Protection discovers that the participating wholesaler has violated any provision of sections 11 to 18, inclusive, of this act or any other applicable state or federal law or regulation;

(3) Suspending all importation and distribution of drugs by a participating Canadian supplier under the program if the Commissioner of Consumer Protection discovers that the participating Canadian supplier has violated any provision of sections 11 to 18, inclusive, of this act or any other applicable state or federal law or regulation; or

(4) Requiring the recall or seizure of any drug that was imported and distributed under the program and has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded.

(b) The Commissioner of Consumer Protection shall send a notice to each participating Canadian supplier and participating wholesaler affected by an order issued pursuant to subsection (a) of this section notifying such participating Canadian supplier or participating wholesaler that:

(1) The Commissioner of Consumer Protection has issued such order, and provide the legal and factual basis for such order; and

(2) Such participating Canadian supplier or participating wholesaler may request, in writing, a hearing before the Commissioner of Consumer Protection, provided such request is received by the Commissioner of Consumer Protection not later than thirty days after
the date of such notice.

(c) If a hearing is timely requested pursuant to subsection (b) of this section, the Commissioner of Consumer Protection shall, not later than thirty days after the receipt of the request, convene the hearing as a contested case in accordance with the provisions of chapter 54 of the general statutes. Not later than sixty days after the receipt of such request, the Commissioner of Consumer Protection shall issue a final decision vacating, modifying or affirming the Commissioner of Consumer Protection's order. The participating Canadian supplier or participating wholesaler aggrieved by such final decision may appeal such decision in accordance with the provisions of section 4-183 of the general statutes.

Sec. 18. (NEW) (Effective July 1, 2019) The Commissioner of Consumer Protection may, in consultation with the Commissioner of Public Health, adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 11 to 17, inclusive, of this act.

Sec. 19. (NEW) (Effective July 1, 2019) Not later than July 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy established under section 19a-754a of the general statutes shall submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services and public health. Such report shall describe the operations of the program established pursuant to section 12 of this act during the fiscal year next preceding, and include all information prescribed in regulations adopted pursuant to section 18 of this act.

Sec. 20. Subsection (a) of section 38a-510 of the general statutes is repealed and the following is substituted in lieu thereof (Effective July 1, 2019):

(a) No insurance company, hospital service corporation, medical service corporation, health care center or other entity delivering,
issuing for delivery, renewing, amending or continuing an individual health insurance policy or contract that provides coverage for prescription drugs may:

   (1) Require any person covered under such policy or contract to obtain prescription drugs, except for prescription drugs indicated as maintenance drugs in such policy or contract, from a mail order pharmacy as a condition of obtaining benefits for such drugs; or

   (2) Require, if such insurance company, hospital service corporation, medical service corporation, health care center or other entity uses step therapy for such drugs, the use of step therapy for (A) any prescribed drug for longer than sixty days, or (B) a prescribed drug for cancer treatment for an insured who has been diagnosed with stage IV metastatic cancer provided such prescribed drug is in compliance with approved federal Food and Drug Administration indications.

   (3) At the expiration of the time period specified in subparagraph (A) of subdivision (2) of this subsection or for a prescribed drug described in subparagraph (B) of subdivision (2) of this subsection, an insured's treating health care provider may deem such step therapy drug regimen clinically ineffective for the insured, at which time the insurance company, hospital service corporation, medical service corporation, health care center or other entity shall authorize dispensation of and coverage for the drug prescribed by the insured's treating health care provider, provided such drug is a covered drug under such policy or contract. If such provider does not deem such step therapy drug regimen clinically ineffective or has not requested an override pursuant to subdivision (1) of subsection (b) of this section, such drug regimen may be continued. For purposes of this section, "step therapy" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition are to be prescribed.

Sec. 21. Subsection (a) of section 38a-544 of the general statutes is repealed and the following is substituted in lieu thereof (Effective July
(a) No insurance company, hospital service corporation, medical service corporation, health care center or other entity delivering, issuing for delivery, renewing, amending or continuing a group health insurance policy or contract that provides coverage for prescription drugs may:

1. Require any person covered under such policy or contract to obtain prescription drugs, except for prescription drugs indicated as maintenance drugs in such policy or contract, from a mail order pharmacy as a condition of obtaining benefits for such drugs; or

2. Require, if such insurance company, hospital service corporation, medical service corporation, health care center or other entity uses step therapy for such drugs, the use of step therapy for (A) any prescribed drug for longer than sixty days, or (B) a prescribed drug for cancer treatment for an insured who has been diagnosed with stage IV metastatic cancer provided such prescribed drug is in compliance with approved federal Food and Drug Administration indications.

3. At the expiration of the time period specified in subparagraph (A) of subdivision (2) of this subsection or for a prescribed drug described in subparagraph (B) of subdivision (2) of this subsection, an insured's treating health care provider may deem such step therapy drug regimen clinically ineffective for the insured, at which time the insurance company, hospital service corporation, medical service corporation, health care center or other entity shall authorize dispensation of and coverage for the drug prescribed by the insured's treating health care provider, provided such drug is a covered drug under such policy or contract. If such provider does not deem such step therapy drug regimen clinically ineffective or has not requested an override pursuant to subdivision (1) of subsection (b) of this section, such drug regimen may be continued. For purposes of this section, "step therapy" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical
This act shall take effect as follows and shall amend the following sections:

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