

Senate

General Assembly

File No. 420

January Session, 2025

Substitute Senate Bill No. 11

Senate, April 2, 2025

The Committee on Human Services reported through SEN. LESSER of the 9th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING PRESCRIPTION DRUG ACCESS AND AFFORDABILITY.

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

- 1 Section 1. (NEW) (*Effective July 1, 2025*) For the purposes of this 2 section and sections 2 and 3 of this act:
- 3 (1) "Biological product" has the same meaning as provided in section
 4 20-619 of the general statutes;
- 5 (2) "Brand-name drug" means a drug that is produced or distributed 6 in accordance with an original new drug application approved under 21 7 USC 355, as amended from time to time, but does not include an 8 authorized generic drug as defined in 42 CFR 447.502, as amended from 9 time to time;
- 10 (3) "Commissioner" means the Commissioner of Revenue Services;

(4) "Consumer price index" means the consumer price index, annualaverage, for all urban consumers: United States city average, all items,

published by the United States Department of Labor, Bureau of Labor
Statistics, or its successor, or, if the index is discontinued, an equivalent
index published by a federal authority, or, if no such index is published,
a comparable index published by the United States Department of
Labor, Bureau of Labor Statistics;

(5) "Generic drug" means (A) a prescription drug product that is
marketed or distributed in accordance with an abbreviated new drug
application approved under 21 USC 355, as amended from time to time,
(B) an authorized generic drug as defined in 42 CFR 447.502, as
amended from time to time, or (C) a drug that entered the market before
calendar year 1962 that was not originally marketed under a new
prescription drug product application;

(6) "Identified prescription drug" means (A) a brand-name drug or
biological product for which the patent has expired for at least twentyfour months, or (B) a generic drug or interchangeable biological
product;

(7) "Interchangeable biological product" has the same meaning asprovided in section 20-619 of the general statutes;

(8) "Person" has the same meaning as provided in section 12-1 of thegeneral statutes;

(9) "Pharmaceutical manufacturer" means a person that
manufactures a prescription drug and sells, directly or through another
person, the prescription drug for distribution in this state;

(10) "Prescription drug" means a legend drug, as defined in section
20-571 of the general statutes, approved by the federal Food and Drug
Administration, or any successor agency, and prescribed by a health
care provider to an individual in this state;

(11) "Reference price" means the wholesale acquisition cost, as
defined in 42 USC 1395w-3a, as amended from time to time, of (A) a
brand-name drug or biological product (i) on January 1, 2025, if the
patent for the brand-name drug or biological product expired on or

before said date, or (ii) if the patent for the brand-name drug or 44 45 biological product expires after January 1, 2025, on the date the patent 46 for such brand-name drug or biological product expires, or (B) a generic 47 drug or interchangeable biological product (i) on January 1, 2025, or (ii) 48 if the generic drug or interchangeable biological product is first 49 commercially marketed in the United States after January 1, 2025, on the 50 date such generic drug or interchangeable biological product is first 51 commercially marketed in the United States; and

(12) "Wholesale distributor" means a person, including, but not
limited to, a repacker, own-label distributor, private-label distributor or
independent wholesale drug trader, engaged in the wholesale
distribution of prescription drugs.

56 Sec. 2. (NEW) (*Effective July 1, 2025*) (a) (1) Notwithstanding any 57 provision of the general statutes and except as provided in subdivision 58 (2) of this subsection, no pharmaceutical manufacturer or wholesale 59 distributor shall, on or after January 1, 2026, sell an identified 60 prescription drug in this state at a price that exceeds the reference price 61 for the identified prescription drug, adjusted for any increase in the 62 consumer price index.

(2) A pharmaceutical manufacturer or wholesale distributor may, on
or after January 1, 2026, sell an identified prescription drug in this state
at a price that exceeds the reference price for the identified prescription
drug, adjusted for any increase in the consumer price index, if the
federal Secretary of Health and Human Services determines, pursuant
to 21 USC 356e, as amended from time to time, that such identified
prescription drug is in shortage in the United States.

(b) (1) Except as provided in subdivision (2) of this subsection, any pharmaceutical manufacturer or wholesale distributor that violates the provisions of subsection (a) of this section shall be liable to this state for a civil penalty. Such civil penalty shall be imposed, calculated and collected on a calendar year basis by the Commissioner of Revenue Services, and the amount of such civil penalty for a calendar year shall be equal to eighty per cent of the difference between: (A) The revenue that the pharmaceutical manufacturer or wholesale
distributor earned from all sales of the identified prescription drug in
this state during the calendar year; and

(B) The revenue that the pharmaceutical manufacturer or wholesale distributor would have earned from all sales of the identified prescription drug in this state during the calendar year if the pharmaceutical manufacturer or wholesale distributor had sold such identified prescription drug at a price that did not exceed the reference price for such identified prescription drug, as such reference price is adjusted for any increase in the consumer price index.

(2) No pharmaceutical manufacturer or wholesale distributor of an
identified prescription drug shall be liable to this state for the civil
penalty imposed under subdivision (1) of this subsection unless the
pharmaceutical manufacturer or wholesale distributor made at least
two hundred fifty thousand dollars in total annual sales in this state for
the calendar year for which such civil penalty would otherwise be
imposed.

94 (c) (1) (A) For calendar years commencing on or after January 1, 2026,
95 each pharmaceutical manufacturer or wholesale distributor that
96 violated the provisions of subsection (a) of this section during any
97 calendar year shall, not later than the first day of March immediately
98 following the end of such calendar year:

99 (i) Pay to the commissioner the civil penalty imposed under100 subsection (b) of this section for such calendar year; and

(ii) File with the commissioner a statement for such calendar year ina form and manner, and containing all information, prescribed by thecommissioner.

(B) A pharmaceutical manufacturer or wholesale distributor that is
required to file the statement and pay the civil penalty pursuant to
subparagraph (A) of this subdivision shall electronically file such
statement and make such payment by electronic funds transfer in the

108 manner provided by chapter 228g of the general statutes, irrespective of 109 whether the pharmaceutical manufacturer or wholesale distributor 110 would have otherwise been required to electronically file such 111 statement or make such payment by electronic funds transfer under 112 chapter 228g of the general statutes.

(2) If no statement is filed pursuant to subdivision (1) of this
subsection, the commissioner may make such statement at any time
thereafter, according to the best obtainable information and the
prescribed form.

117 The commissioner may examine the records of any (d) 118 pharmaceutical manufacturer or wholesale distributor that is subject to 119 the civil penalty imposed under subsection (b) of this section as the 120 commissioner deems necessary. If the commissioner determines from 121 such examination that the pharmaceutical manufacturer or wholesale 122 distributor failed to pay the full amount of such civil penalty, the 123 commissioner shall bill such pharmaceutical manufacturer or wholesale 124 distributor for the full amount of such civil penalty.

(e) (1) The commissioner may require each pharmaceutical
manufacturer or wholesale distributor that is subject to the civil penalty
imposed under subsection (b) of this section to keep such records as the
commissioner may prescribe, and produce books, papers, documents
and other data to provide or secure information pertinent to the
enforcement and collection of such civil penalty.

131 (2)The commissioner, or the commissioner's authorized 132 representative, may examine the books, papers, records and equipment 133 of any person who is subject to the provisions of this section and may 134 investigate the character of the business of such person to verify the 135 accuracy of any statement made or, if no statement is made by such 136 person, to ascertain and determine the amount of the civil penalty due 137 under subsection (b) of this section.

(f) Any pharmaceutical manufacturer or wholesale distributor that issubject to the civil penalty imposed under subsection (b) of this section

140 and aggrieved by any action of the commissioner under subdivision (2) 141 of subsection (c) of this section or subsection (d) of this section may 142 apply to the commissioner, in writing and not later than sixty days after 143 the notice of such action is delivered or mailed to such pharmaceutical 144 manufacturer or wholesale distributor, for a hearing, setting forth the 145 reasons why such hearing should be granted and if such pharmaceutical 146 manufacturer or wholesale distributor believes that such 147 pharmaceutical manufacturer or wholesale distributor is not liable for 148 such civil penalty or the full amount of such civil penalty, the grounds 149 for such belief and the amount by which such pharmaceutical 150 manufacturer or wholesale distributor believes such civil penalty 151 should be reduced. The commissioner shall promptly consider each 152 such application and may grant or deny the hearing requested. If the 153 hearing request is denied, the commissioner shall immediately notify 154 the pharmaceutical manufacturer or wholesale distributor. If the 155 hearing request is granted, the commissioner shall notify the 156 pharmaceutical manufacturer or wholesale distributor of the date, time 157 and place for such hearing. After such hearing, the commissioner may 158 make such order as appears just and lawful to the commissioner and 159 shall furnish a copy of such order to the pharmaceutical manufacturer or wholesale distributor. The commissioner may, by notice in writing, 160 161 order a hearing on the commissioner's own initiative and require a 162 pharmaceutical manufacturer or wholesale distributor, or any other 163 person who the commissioner believes to be in possession of relevant 164 information concerning such pharmaceutical manufacturer or 165 wholesale distributor, to appear before the commissioner or the 166 commissioner's authorized agent with any specified books of account, 167 papers or other documents for examination under oath.

(g) Any pharmaceutical manufacturer or wholesale distributor that is aggrieved by any order, decision, determination or disallowance of the commissioner made under subsection (f) of this section may, not later than thirty days after service of notice of such order, decision, determination or disallowance, take an appeal therefrom to the superior court for the judicial district of New Britain, which appeal shall be accompanied by a citation to the commissioner to appear before said

File No. 420

175 court. Such citation shall be signed by the same authority and such 176 appeal shall be returnable at the same time and served and returned in 177 the same manner as is required in case of a summons in a civil action. 178 The authority issuing the citation shall take from the appellant a bond 179 or recognizance to this state, with surety, to prosecute the appeal to 180 effect and to comply with the orders and decrees of the court. Such 181 appeals shall be preferred cases, to be heard, unless cause appears to the 182 contrary, at the first session, by the court or by a committee appointed 183 by the court. Said court may grant such relief as may be equitable and, 184 if the civil penalty was paid prior to the granting of such relief, may 185 order the Treasurer to pay the amount of such relief. If the appeal was 186 taken without probable cause, the court may tax double or triple costs, 187 as the case demands and, upon all such appeals that are denied, costs 188 may be taxed against such pharmaceutical manufacturer or wholesale 189 distributor at the discretion of the court but no costs shall be taxed 190 against this state.

191 (h) The commissioner, and any agent of the commissioner duly 192 authorized to conduct any inquiry, investigation or hearing pursuant to 193 this section, shall have power to administer oaths and take testimony 194 under oath relative to the matter of inquiry or investigation. At any 195 hearing ordered by the commissioner, the commissioner, or the 196 commissioner's agent authorized to conduct such hearing and having 197 authority by law to issue such process, may subpoena witnesses and 198 require the production of books, papers and documents pertinent to 199 such inquiry or investigation. No witness under any subpoena 200 authorized to be issued under the provisions of this section shall be 201 excused from testifying or from producing books, papers or 202 documentary evidence on the ground that such testimony or the 203 production of such books, papers or documentary evidence would tend 204 to incriminate such witness, but such books, papers or documentary 205 evidence so produced shall not be used in any criminal proceeding 206 against such witness. If any person disobeys such process or, having 207 appeared in obedience thereto, refuses to answer any pertinent question 208 put to such person by the commissioner, or the commissioner's 209 authorized agent, or to produce any books, papers or other

210 documentary evidence pursuant thereto, the commissioner, or such 211 agent, may apply to the superior court of the judicial district wherein 212 the pharmaceutical manufacturer or wholesale distributor resides or 213 wherein the business was conducted, or to any judge of such court if the 214 same is not in session, setting forth such disobedience to process or 215 refusal to answer, and such court or such judge shall cite such person to 216 appear before such court or such judge to answer such question or to 217 produce such books, papers or other documentary evidence and, upon 218 such person's refusal to do so, shall commit such person to a community 219 correctional center until such person testifies, but not for a period longer 220 than sixty days. Notwithstanding the serving of the term of such 221 commitment by any person, the commissioner may proceed in all 222 respects with such inquiry and examination as if the witness had not 223 previously been called upon to testify. Officers who serve subpoenas 224 issued by the commissioner or under the commissioner's authority and 225 witnesses attending hearings conducted by the commissioner pursuant 226 to this section shall receive fees and compensation at the same rates as 227 officers and witnesses in the courts of this state, to be paid on vouchers 228 of the commissioner on order of the Comptroller from the proper 229 appropriation for the administration of this section.

230 (i) The amount of any civil penalty unpaid under the provisions of 231 this section may be collected under the provisions of section 12-35 of the 232 general statutes. The warrant provided under section 12-35 of the 233 general statutes shall be signed by the commissioner or the 234 commissioner's authorized agent. The amount of any such civil penalty 235 shall be a lien on the real property of the pharmaceutical manufacturer 236 or wholesale distributor from the last day of the month next preceding 237 the due date of such civil penalty until such civil penalty is paid. The 238 commissioner may record such lien in the records of any town in which 239 the real property of such pharmaceutical manufacturer or wholesale 240 distributor is situated, but no such lien shall be enforceable against a 241 bona fide purchaser or qualified encumbrancer of such real property. 242 When any civil penalty with respect to which a lien was recorded under 243 the provisions of this subsection is satisfied, the commissioner shall, 244 upon request of any interested party, issue a certificate discharging such 245 lien, which certificate shall be recorded in the same office in which such 246 lien was recorded. Any action for the foreclosure of such lien shall be 247 brought by the Attorney General in the name of this state in the superior 248 court for the judicial district in which the real property subject to such 249 lien is situated, or, if such property is located in two or more judicial 250 districts, in the superior court for any one such judicial district, and the 251 court may limit the time for redemption or order the sale of such real 252 property or make such other or further decree as the court judges 253 equitable. The provisions of section 12-39g of the general statutes shall 254 apply to all civil penalties imposed under this section.

255 (j) (1) Any officer or employee of a pharmaceutical manufacturer or 256 wholesale distributor, who owes a duty to the pharmaceutical 257 manufacturer or wholesale distributor to pay the civil penalty imposed 258 under subsection (b) of this section on behalf of such pharmaceutical 259 manufacturer or wholesale distributor, shall file a statement with the 260 commissioner pursuant to subsection (c) of this section on behalf of such 261 pharmaceutical manufacturer or wholesale distributor and keep records 262 or supply information to the commissioner on behalf of such 263 pharmaceutical manufacturer or wholesale distributor pursuant to this section. Any such officer or employee who wilfully fails, at the time 264 265 required under this section, to pay such civil penalty, file such 266 statement, keep such records or supply such information on behalf of 267 such pharmaceutical manufacturer or wholesale distributor shall, in 268 addition to any other penalty provided by law, be fined not more than 269 one thousand dollars or imprisoned not more than one year, or both. 270 Notwithstanding the provisions of section 54-193 of the general statutes, 271 no such officer or employee shall be prosecuted for a violation of the 272 provisions of this subdivision committed on or after January 1, 2026, 273 except within three years next after such violation is committed.

(2) Any officer or employee of a pharmaceutical manufacturer or
wholesale distributor, who owes a duty to the pharmaceutical
manufacturer or wholesale distributor to deliver or disclose to the
commissioner, or the commissioner's authorized agent, any list,
statement, return, account statement or other document on behalf of

such pharmaceutical manufacturer or wholesale distributor, and who
wilfully delivers or discloses to the commissioner, or the commissioner's
authorized agent, any such list, statement, return, account statement or
other document that such officer or employee knows to be fraudulent
or false in any material matter shall, in addition to any other penalty
provided by law, be guilty of a class D felony.

(3) No officer or employee of a pharmaceutical manufacturer or
wholesale distributor shall be charged with an offense under both
subdivisions (1) and (2) of this subsection in relation to the same civil
penalty, but such officer or employee may be charged and prosecuted
for both such offenses upon the same information.

(k) Each civil penalty imposed under subsection (b) of this section
shall be deemed to constitute a civil fine or penalty within the meaning
of 42 USC 1396b(w), as amended from time to time. No portion of any
civil penalty imposed under subsection (b) of this section shall be
waived under section 12-3a of the general statutes or any other
applicable law. No tax credit shall be allowable against any civil penalty
imposed under subsection.

(l) Not later than July 1, 2027, and annually thereafter, the
commissioner shall prepare a list containing the name of each
pharmaceutical manufacturer or wholesale distributor that violated
subsection (a) of this section during the preceding calendar year. The
commissioner shall make each such list publicly available.

302 (m) The commissioner may adopt regulations, in accordance with the
303 provisions of chapter 54 of the general statutes, to implement the
304 provisions of this section.

Sec. 3. (NEW) (*Effective July 1, 2025*) (a) No pharmaceutical manufacturer or wholesale distributor of an identified prescription drug shall withdraw the identified prescription drug from sale in this state for the purpose of avoiding the civil penalty established in subsection (b) of section 2 of this act. (b) Any pharmaceutical manufacturer or wholesale distributor that
intends to withdraw an identified prescription drug from sale in this
state shall, at least one hundred eighty days before such withdrawal,
send advance written notice to the Office of Health Strategy disclosing
such pharmaceutical manufacturer's or wholesale distributor's
intention.

(c) Any pharmaceutical manufacturer or wholesale distributor that
violates the provisions of subsection (a) or (b) of this section shall be
liable to this state for a civil penalty in the amount of five hundred
thousand dollars.

Sec. 4. (NEW) (Effective July 1, 2025) (a) As used in this section and 320 321 sections 5 and 6 of this act, "drug purchasing agency" means The 322 University of Connecticut Health Center, the Judicial Branch and the 323 Department of Mental Health and Addiction Services, Children and 324 Families, Developmental Services or Public Health. The University of 325 Connecticut Health Center shall negotiate bulk prices for prescription 326 drugs on behalf of drug purchasing agencies with the goal of purchasing 327 such drugs at lower prices than the prices of such drugs purchased by a 328 single drug purchasing agency.

329 (b) Not later than September 1, 2025, the chief executive officer of The 330 University of Connecticut Health Center, or the chief executive officer's 331 designee, shall file a report, in accordance with the provisions of section 332 11-4a of the general statutes, with the joint standing committees of the 333 General Assembly having cognizance of matters relating to general law, 334 human services and public health on any savings realized from bulk 335 purchases of prescription drugs pursuant to subsection (a) of this 336 section.

Sec. 5. (NEW) (*Effective July 1, 2025*) (a) As used in this section, (1) "maximum fair prices" means the prices negotiated by the Centers for Medicare and Medicaid Services for certain prescription drugs under the Inflation Reduction Act, P.L. 117-69, and (2) "drug purchasing agency" has the same meaning as provided in section 4 of this act. A drug purchasing agency shall incorporate by reference maximum fair prices in any negotiation with a pharmaceutical drug manufacturer to
supply prescription drugs for health care programs subsidized by the
state.

346 (b) In purchasing drugs at bulk prices pursuant to section 4 of this act 347 or maximum fair prices pursuant to this section, a drug purchasing 348 agency may enter into a compact with officials in other states to increase 349 the state's purchasing power in negotiations with pharmaceutical 350 companies. A drug purchasing agency shall consider recommendations 351 of the council established pursuant to section 6 of this act in any 352 negotiations for prescription drugs pursuant to this section or section 4 353 of this act.

Sec. 6. (NEW) (*Effective from passage*) (a) There is established a Prescription Drug Affordability Council to advise the chief executive officer of The University of Connecticut Health Center and drug purchasing agencies on prescription drug negotiations pursuant to sections 4 and 5 of this act. The council shall consist of the following members:

(b) (1) Two appointed by the speaker of the House of Representatives,
one of whom represents an organization representing hospitals and one
of whom represents an organization representing physicians;

363 (2) Two appointed by the president pro tempore of the Senate, one of
364 whom represents an academic who has conducted research into the
365 affordability of prescription drugs and one of whom represents an
366 organization representing senior citizens in the state;

367 (3) One appointed by the majority leader of the House of
368 Representatives, who represents physicians who treat patients with rare
369 diseases;

370 (4) One appointed by the majority leader of the Senate;

371 (5) One appointed by the minority leader of the House of372 Representatives;

	sSB11 File No. 420
373	(6) One appointed by the minority leader of the Senate;
374	(7) The Commissioner of Health Strategy, or the commissioner's
375	designee;
376	(8) The Commissioner of Social Services, or the commissioner's
377	designee;
378	(9) The Commissioner of Consumer Protection, or the commissioner's
379	designee;
380	(10) The Insurance Commissioner, or the commissioner's designee;
381	and
382	(11) The Commissioner of Children and Families, or the
383	commissioner's designee.
384	(c) Any member of the council appointed under subdivision (1), (2),
385	(3), (4), (5) or (6) of subsection (b) of this section may be a member of the
386	General Assembly.
387	(d) All initial appointments to the council shall be made not later than
388	thirty days after the effective date of this section. Any vacancy shall be
389	filled by the appointing authority.
390	(e) The speaker of the House of Representatives and the president pro
391	tempore of the Senate shall select the chairpersons of the council from
392	among the members of the council. Such chairpersons shall schedule the
393	first meeting of the council, which shall be held not later than sixty days
394	after the effective date of this section.
395	(f) The administrative staff of the joint standing committee of the
396	General Assembly having cognizance of matters relating to human
397	services shall serve as administrative staff of the council.
398	(g) Not later than January 1, 2026, and annually thereafter, the council
399	shall submit a report on its findings and recommendations to the
400	Commissioner of Health Strategy and the joint standing committees of
401	the General Assembly having cognizance of matters relating to general

402 law, human services and public health, in accordance with the403 provisions of section 11-4a of the general statutes.

Sec. 7. Subsection (a) of section 17b-340d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1*, 2025):

(a) The Commissioner of Social Services shall implement an acuitybased methodology for Medicaid reimbursement of nursing home
services effective July 1, 2022. Notwithstanding section 17b-340, for the
fiscal year ending June 30, 2023, and annually thereafter, the
Commissioner of Social Services shall establish Medicaid rates paid to
nursing home facilities based on cost years ending on September
thirtieth in accordance with the following:

414 (1) Case-mix adjustments to the direct care component, which will be 415 based on Minimum Data Set resident assessment data as well as cost 416 data reported for the cost year ending September 30, 2019, shall be made 417 effective beginning July 1, 2022, and updated every quarter thereafter. 418 After modeling such case-mix adjustments, the Commissioner of Social 419 Services shall evaluate impact on a facility by facility basis and, not later 420 than October 1, 2021, (A) make recommendations to the Secretary of the 421 Office of Policy and Management, and (B) submit a report on the 422 recommendations, in accordance with the provisions of section 11-4a, to 423 the joint standing committees of the General Assembly having 424 cognizance of matters relating to appropriations and the budgets of state 425 agencies and human services on any adjustments needed to facilitate the transition to the new methodology on July 1, 2022. This evaluation may 426 427 include a review of inflationary allowances, case mix and budget 428 adjustment factors and stop loss and stop gain corridors and the ability 429 to make such adjustments within available appropriations.

(2) Beginning July 1, 2022, facilities [will be required to] <u>shall</u> comply
with collection and reporting of quality metrics as specified by the
Department of Social Services, after consultation with the nursing home
industry, consumers, employees and the Department of Public Health.
Rate adjustments based on performance on quality metrics [will] <u>shall</u>

435 be phased in, beginning July 1, 2022, with a period of reporting only. 436 Effective July 1, 2023, the Department of Social Services shall issue 437 individualized reports annually to each nursing home facility showing 438 the impact to the Medicaid rate for such home based on the quality 439 metrics program. A nursing home facility receiving an individualized 440 quality metrics report may use such report to evaluate the impact of the 441 quality metrics program on said facility's Medicaid reimbursement. Not 442 later than June 30, 2025, the department shall submit a report, in 443 accordance with the provisions of section 11-4a, to the joint standing 444 committees of the General Assembly having cognizance of matters 445 relating to appropriations and the budgets of state agencies and human 446 services on the quality metrics program. Such report shall include 447 information regarding individualized reports and the anticipated 448 impact on nursing homes if the state were to implement a rate withhold 449 on nursing homes that fail to meet certain quality metrics.

(3) Geographic peer groupings of facilities shall be established by the
Department of Social Services pursuant to regulations adopted in
accordance with subsection (b) of this section.

(4) Allowable costs shall be divided into the following five cost 453 454 components: (A) Direct costs, which shall include salaries for nursing 455 personnel, related fringe benefits and costs for nursing personnel 456 supplied by a temporary nursing services agency; (B) indirect costs, 457 which shall include professional fees, dietary expenses, housekeeping 458 expenses, laundry expenses, supplies related to patient care, salaries for 459 indirect care personnel and related fringe benefits; (C) fair rent, which 460 shall be defined in regulations adopted in accordance with subsection 461 (b) of this section; (D) capital-related costs, which shall include property 462 taxes, insurance expenses, equipment leases and equipment 463 depreciation; and (E) administrative and general costs, which shall 464 include maintenance and operation of plant expenses, salaries for 465 administrative and maintenance personnel and related fringe benefits. 466 For (i) direct costs, the maximum cost shall be equal to one hundred 467 thirty-five per cent of the median allowable cost of that peer grouping; 468 (ii) indirect costs, the maximum cost shall be equal to one hundred

469 fifteen per cent of the state-wide median allowable cost; (iii) fair rent, 470 the amount shall be calculated utilizing the amount approved pursuant 471 to section 17b-353; (iv) capital-related costs, there shall be no maximum; 472 and (v) administrative and general costs, the maximum shall be equal to 473 the state-wide median allowable cost. For purposes of this subdivision, 474 "temporary nursing services agency" and "nursing personnel" have the 475 same meaning as provided in section 19a-118.

(5) Costs in excess of the maximum amounts established under this
subsection shall not be recognized as allowable costs, except that the
commissioner may establish rates whereby allowable costs may exceed
such maximum amounts for beds which are restricted to use by patients
with acquired immune deficiency syndrome, traumatic brain injury or
other specialized services.

482 (6) On or after June 30, 2022, the commissioner may, in the 483 commissioner's discretion and within available appropriations, provide 484 pro rata fair rent increases to facilities which have documented fair rent 485 additions placed in service in the most recently filed cost report that are 486 not otherwise included in the rates issued. The commissioner may 487 provide, within available appropriations, pro rata fair rent increases, 488 which may, at the discretion of the commissioner, include increases for 489 facilities which have undergone a material change in circumstances 490 related to fair rent additions in the most recently filed cost report. The 491 commissioner may allow minimum fair rent as the basis upon which 492 reimbursement associated with improvements to real property is 493 added.

494 (7) For the purpose of determining allowable fair rent, a facility with 495 allowable fair rent less than the twenty-fifth percentile of the state-wide 496 allowable fair rent shall be reimbursed as having allowable fair rent 497 equal to the twenty-fifth percentile of the state-wide allowable fair rent. Any facility with a rate of return on real property other than land in 498 499 excess of eleven per cent shall have such allowance revised to eleven per 500 cent. Any facility or its related realty affiliate which finances or 501 refinances debt through bonds issued by the Connecticut Health and

sSB11

502 Education Facilities Authority shall report the terms and conditions of 503 such financing or refinancing to the Commissioner of Social Services not later than thirty days after completing such financing or refinancing. 504 505 The commissioner may revise the facility's fair rent component of its rate 506 to reflect any financial benefit the facility or its related realty affiliate 507 received as a result of such financing or refinancing. The commissioner 508 shall determine allowable fair rent for real property other than land 509 based on the rate of return for the cost year in which such bonds were 510 issued. The financial benefit resulting from a facility financing or 511 refinancing debt through such bonds shall be shared between the state 512 and the facility to an extent determined by the commissioner on a case-513 by-case basis and shall be reflected in an adjustment to the facility's 514 allowable fair rent.

(8) A facility shall receive cost efficiency adjustments for indirect costs and for administrative and general costs if such costs are below the state-wide median costs. The cost efficiency adjustments shall equal twenty-five per cent of the difference between allowable reported costs and the applicable median allowable cost established pursuant to subdivision (4) of this subsection.

(9) On and after July 1, 2025, costs shall be rebased no more frequently
than every two years and no less frequently than every four years, as
determined by the commissioner. There shall be no inflation adjustment
during a year in which a facility's rates are rebased. The commissioner
shall determine whether and to what extent a change in ownership of a
facility shall occasion the rebasing of the facility's costs.

(10) The method of establishing rates for new facilities shall bedetermined by the commissioner in accordance with the provisions ofthis subsection.

(11) There shall be no increase to rates based on inflation or any
inflationary factor for the fiscal years ending June 30, 2022, and June 30,
2023, unless otherwise authorized under subdivision (1) of this
subsection. Notwithstanding section 17-311-52 of the regulations of
Connecticut state agencies, for the fiscal years ending June 30, 2024, and

535 June 30, 2025, there shall be no inflationary increases to rates beyond 536 those already factored into the model for the transition to an acuity-537 based reimbursement system. Notwithstanding any other provisions of 538 this chapter, any subsequent increase to allowable operating costs, 539 excluding fair rent, shall be inflated by the gross domestic product 540 deflator when funding is specifically appropriated for such purposes in 541 the enacted budget. The rate of inflation shall be computed by 542 comparing the most recent rate year to the average of the gross domestic 543 product deflator for the previous four fiscal quarters ending March 544 thirty-first. Any increase to rates based on inflation shall be applied 545 prior to the application of any other budget adjustment factors that may 546 impact such rates.

547 (12) For the fiscal year beginning July 1, 2025, and each fiscal year 548 thereafter, the commissioner shall require a nursing home facility to 549 spend not less than eighty per cent of funding received from Medicaid, 550 Medicare and all other payment sources on direct care of residents, 551 provided the commissioner may adjust the percentage spent on direct 552 care for a nursing home facility with a capital improvement project or a 553 fair rent increase approved by the commissioner. For the fiscal year 554 beginning July 1, 2027, and each fiscal year thereafter, the commissioner 555 may decrease rates of Medicaid reimbursement for any nursing home 556 that does not comply with the provisions of this subdivision. For 557 purposes of this subdivision, (A) "direct care" means hands-on care provided to a facility resident by nursing personnel, including, but not 558 559 limited to, assistance with feeding, bathing, toileting, dressing, lifting or 560 moving residents, medication administration and salary, fringe benefits 561 and supplies related to direct care; and (B) "nursing personnel" means 562 an advanced practice registered nurse, licensed pursuant to chapter 378, 563 a registered nurse or practical nurse, licensed pursuant to chapter 378, or a nurse's aide, registered pursuant to chapter 378a. 564

565 [(12)] (13) For purposes of computing minimum allowable patient 566 days, utilization of a facility's certified beds shall be determined at a 567 minimum of ninety per cent of capacity, except for facilities that have 568 undergone a change in ownership, new facilities, and facilities which

569	are certified for additional beds which may be permitted a lower
570	occupancy rate for the first three months of operation after the effective
571	date of licensure.

572 [(13)] (14) Rates determined under this section shall comply with 573 federal laws and regulations.

[(14)] (15) The Commissioner of Social Services may authorize an interim rate for a facility demonstrating circumstances particular to that individual facility impacting facility finances or costs not reflected in the underlying rates.

578 Sec. 8. (NEW) (Effective July 1, 2025) (a) As used in this section, (1) 579 "emergency medical condition" means a medical condition, including 580 emergency labor and delivery, manifesting itself by acute symptoms of 581 sufficient severity, including severe pain, such that the absence of 582 immediate medical attention could reasonably be expected to result in 583 (A) placing the patient's health in serious jeopardy, (B) serious 584 impairment to bodily functions, or (C) serious dysfunction of any bodily 585 organ or part; and (2) "emergency Medicaid coverage" means Medicaid 586 coverage for treatment of an emergency medical condition.

587 (b) The Commissioner of Social Services shall expand emergency 588 Medicaid coverage consistent with federal law for treatment of 589 emergency medical conditions, including, but not limited to, emergency 590 medical conditions related to (1) a high-risk pregnancy, (2) diabetes type 591 1 in persons under the age of twenty-one, (3) diabetic emergencies, 592 including, but not limited to, diabetic ketoacidosis, (4) renal failure 593 requiring ongoing dialysis, (5) fracture of a bone in the skull, arm, neck, 594 leg, spine or pelvis occurring in the two-month period prior to a request 595 for emergency Medicaid coverage, (6) hypertensive emergencies 596 involving persons presenting with signs or symptoms of end organ 597 damage and systolic blood pressure equaling or exceeding one hundred 598 eighty or diastolic blood pressure equaling or exceeding one hundred 599 twenty, (7) unstable seizure disorder characterized by at least five 600 minutes of uncontrollable seizures or at least two discrete seizures 601 between which the person does not regain consciousness, (8) active

treatment for cancer related to a current diagnosis, (9) ventilator
dependency, (10) labor and delivery, and (11) acute inpatient or
outpatient psychiatric treatment.

605 (c) Not later than July 1, 2026, the commissioner shall establish an 606 administrative system for persons to apply in advance for emergency 607 Medicaid coverage for emergency medical conditions that can be 608 treated in outpatient settings rather than in hospital emergency 609 departments. The commissioner shall include a prominent link to the 610 application and a list of covered emergency medical conditions on the 611 Internet web site of the Department of Social Services. The 612 shall also include information about advance commissioner 613 applications for emergency Medicaid coverage and a list of covered 614 emergency medical conditions in department forms and policy 615 manuals.

Sec. 9. (NEW) (*Effective July 1, 2025*) (a) The Commissioner of Social
Services shall increase and then eliminate the asset limit for the HUSKY
C health program, as defined in section 17b-290 of the general statutes,
over a five-year period in accordance with the provisions of this section:

(1) For the fiscal year ending June 30, 2026, the commissioner shall
increase the asset limit for (A) an unmarried person from one thousand
six hundred dollars to ten thousand dollars, and (B) married persons
from two thousand four hundred dollars to fifteen thousand dollars;

(2) For the fiscal year ending June 30, 2027, the commissioner shall
increase the asset limit for (A) an unmarried person to twenty-five
thousand dollars, and (B) married persons to forty thousand dollars;

(3) For the fiscal year ending June 30, 2028, the commissioner shall
increase the asset limit for (A) an unmarried person to seventy-five
thousand dollars, and (B) married persons to one hundred thousand
dollars;

(4) For the fiscal year ending June 30, 2029, the commissioner shallincrease the asset limit for (A) an unmarried person to one hundred

thousand dollars, and (B) married persons to one hundred fiftythousand dollars; and

(5) For the fiscal year ending June 30, 2030, and each fiscal year
thereafter, there shall be no asset limit for unmarried or married
persons.

(b) The Commissioner of Social Services shall allow any person,
whose income exceeds the income limits for the HUSKY C health
program but who otherwise qualifies, to qualify for the program by
spending down such person's excess income over the program income
limits on incurred medical bills in accordance with 42 CFR 435.831.

643 (c) Not later than July 1, 2026, and annually thereafter until July 1, 644 2030, the commissioner shall file a report, in accordance with the 645 provisions of section 11-4a of the general statutes, with the joint 646 standing committees of the General Assembly having cognizance of 647 matters relating to appropriations and the budgets of state agencies and 648 human services on (1) the number of persons eligible for the HUSKY C 649 health program for the prior fiscal year, and (2) any increased costs 650 incurred by the state that are attributable to changes in the asset limits.

- 651 Sec. 10. (NEW) (*Effective January 1, 2026*) (a) As used in this section:
- (1) "General anesthesia" has the same meaning as provided in section20-123a of the general statutes; and

(2) "Medical necessity" has the same meaning as provided in section38a-482a of the general statutes.

656 (b) No individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 657 658 of the general statutes delivered, issued for delivery, renewed, amended 659 or continued in this state on or after January 1, 2026, shall (1) if such 660 policy provides coverage for general anesthesia, (A) impose an arbitrary 661 time limit on reimbursement for general anesthesia provided during 662 any medically necessary procedure, or (B) deny, reduce, terminate or 663 fail to provide such reimbursement, in whole or in part, for general

anesthesia solely because the duration of care exceeded a predetermined 664 665 time limit as determined by the insurer, or (2) impose unilateral 666 arbitrary limitations on reimbursement for medically necessary 667 ancillary services. 668 (c) The medical necessity for administering general anesthesia during 669 any medical procedure shall be determined by the attending board-670 certified anesthesiologist during such medical procedure. 671 Sec. 11. (NEW) (Effective January 1, 2026) (a) As used in this section: 672 (1) "General anesthesia" has the same meaning as provided in section 673 20-123a of the general statutes; and 674 (2) "Medical necessity" has the same meaning as provided in section 675 38a-482a of the general statutes. 676 (b) No group health insurance policy providing coverage of the type 677 specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of 678 the general statutes delivered, issued for delivery, renewed, amended 679 or continued in this state on or after January 1, 2026, shall (1) if such 680 policy provides coverage for general anesthesia, (A) impose an arbitrary 681 time limit on reimbursement for general anesthesia provided during 682 any medically necessary procedure, or (B) deny, reduce, terminate or 683 fail to provide such reimbursement, in whole or in part, for general 684 anesthesia solely because the duration of care exceeded a predetermined 685 time limit as determined by the insurer, or (2) impose unilateral 686 arbitrary limitations on reimbursement for medically necessary 687 ancillary services.

(c) The medical necessity for administering general anesthesia during
any medical procedure shall be determined by the attending boardcertified anesthesiologist during such medical procedure.

691 Sec. 12. (NEW) (*Effective January 1, 2026*) Any stop loss insurance 692 policy used in conjunction with a self-funded employee health benefit 693 plan shall: (1) Provide coverage for (A) essential health benefits as 694 defined in the Patient Protection and Affordable Care Act, P.L. 111-148, and regulations adopted thereunder, and (B) the group state-mandated
coverage requirements under chapter 700c of the general statutes; or (2)
have (A) a minimum individual attachment point of not less than
seventy-five thousand dollars, and (B) an aggregate attachment point of
not less than two hundred fifty thousand dollars.

Sec. 13. (NEW) (*Effective from passage*) (a) Not later than thirty days after the effective date of this section, the Commissioner of Social Services shall petition the Secretary of the Department of Health and Human Services pursuant to 28 USC 1498, as amended from time to time, to authorize generic, lower cost forms of glucagon-like peptide (GLP-1) prescription drugs approved by the federal Food and Drug Administration to treat obesity or diabetes.

(b) Upon approval of such petition, the commissioner shall enter into
a contract with any manufacturer of generic forms of such drugs
approved by the federal Food and Drug Administration to supply such
drugs to the state for use by HUSKY Health program members. The
commissioner may enter into a consortium with officials in other states
in contracting with such manufacturer for such drugs.

(c) The commissioner shall develop a strategic plan to maximize
access to and minimize the cost of such drugs and, not later than
December 31, 2025, submit a report, in accordance with the provisions
of section 11-4a of the general statutes, on the plan to the joint standing
committee of the General Assembly having cognizance of matters
relating to human services and to the advisory committee established
pursuant to section 14 of this act.

Sec. 14. (*Effective from passage*) (a) There is established an advisory committee to (1) study ways to maximize access to cost-effective prescription drugs approved by the federal Food and Drug Administration for the treatment of obesity, and (2) make recommendations concerning implementation of the strategic plan developed pursuant to section 13 of this act to the Commissioner of Social Services.

727	(b) The committee shall consist of the following members:
728	(1) Two patient advocates appointed by the chairperson of the
729	Council on Medical Assistance Program Oversight, established
730	pursuant to section 17b-28 of the general statutes;
731	(2) Two pharmacists enrolled as Medicaid providers, appointed by
732	the Commissioner of Social Services; and
733	(3) Two medical professionals, including at least one doctor certified
734	by the American Board of Obesity Medicine, appointed by the Senate
735	and House chairpersons of the joint standing committee of the General
736	Assembly having cognizance of matters relating to human services.
737	(c) The committee shall be appointed and convene not later than
738	thirty days after the effective date of this section and choose a
739	chairperson. The committee shall meet at least bimonthly.
740	(d) The committee shall review the strategic plan developed by the
741	Commissioner of Social Services pursuant to section 13 of this act and
742	shall make recommendations to the commissioner on implementation
743	of the plan and the results of its study not later than January 31, 2026.
744	The committee shall terminate upon submission of its recommendations
745	to the commissioner or January 31, 2026, whichever is later.
746	Sec. 15. Section 17b-278l of the general statutes is repealed and the
747	following is substituted in lieu thereof (<i>Effective July 1, 2025</i>):
748	(a) (1) As used in this section, "bariatric surgery" means surgical
749	changes to the digestive system to help a patient with obesity to lose
750	weight;
751	(2) "Body mass index", or "BMI", means the number calculated by
752	dividing an individual's weight in kilograms by the individual's height
753	in meters squared;
754	(3) "Medical services" means (A) prescription drugs approved by the

(3) "Medical services" means (A) prescription drugs approved by the
federal Food and Drug Administration for the treatment of obesity on

756 an outpatient basis, and (B) nutritional counseling provided by a 757 registered dietitian-nutritionist certified pursuant to section 20-206n; 758 (4) "Severe obesity" means a body mass index that is: 759 (A) Greater than forty; or 760 (B) Thirty-five or more if an individual has been diagnosed with a 761 comorbid disease or condition, including, but not limited to, a 762 cardiopulmonary condition, diabetes, hypertension or sleep apnea; 763 [and] 764 (5) "Obesity" means a body mass index of thirty or higher; and (6) "Weight loss drugs" means glucagon-like peptide 1 (GLP-1) 765 766 prescription drugs approved by the federal Food and Drug 767 Administration for weight loss or commonly used for weight loss, sleep 768 apnea or to reduce risks of cardiovascular disease. 769 (b) The Commissioner of Social Services shall provide medical 770 assistance for (1) bariatric surgery and related medical services for 771 Medicaid and HUSKY B beneficiaries with severe obesity, and (2) 772 medical services for Medicaid and HUSKY B beneficiaries with a body 773 mass index greater than thirty-five, [provided such beneficiaries 774 otherwise meet conditions set by the Centers for Medicare and Medicaid 775 Services for such surgery and medical services] including weight loss 776 drugs. The commissioner shall continue to provide Medicaid coverage 777 for beneficiaries treated with weight loss drugs if their BMI drops below 778 thirty-five and a licensed physician certifies, in writing, that their BMI 779 would increase above thirty-five if such drugs were discontinued. If 780 necessary, the commissioner may amend the Medicaid state plan and 781 the state plan for the Children's Health Insurance Program to implement 782 the provisions of this section. 783 Sec. 16. Section 38a-479ttt of the general statutes is repealed and the 784 following is substituted in lieu thereof (*Effective October 1, 2025*): 785 Not later than March 1, 2021, and annually thereafter, the

786 commissioner shall prepare a report, for the immediately preceding 787 calendar year, describing the rebate practices of health carriers. The 788 report shall contain (1) an explanation of the manner in which health 789 carriers accounted for rebates in calculating premiums for health care 790 plans delivered, issued for delivery, renewed, amended or continued 791 during such year, (2) a statement disclosing whether, and describing the 792 manner in which, health carriers made rebates available to insureds at 793 the point of purchase during such year, (3) any other manner in which 794 health carriers applied rebates during such year, (4) the percentage of 795 rebate dollars used by health carriers to reduce cost-sharing 796 requirements during such year, (5) an evaluation of rebate practices to 797 reduce cost-sharing for health care plans delivered, issued for delivery, 798 renewed, amended or continued during such year, and [(4)] (6) such 799 other information as the commissioner, in the commissioner's 800 discretion, deems relevant for the purposes of this section. The 801 commissioner shall publish a copy of the report on the department's 802 Internet web site.

803 Sec. 17. (NEW) (*Effective from passage*) As used in this section and 804 section 18 of this act:

(1) "340B drug" means a drug that (A) is a covered outpatient drug
within the meaning of 42 USC 256b; (B) has been subject to any offer for
reduced prices by a manufacturer under 42 USC 256b(a)(1); and (C) is
purchased by a covered entity. "340B drug" includes a drug that would
have been purchased but for the restriction or limitation described in
subsection (a) of section 18 of this act;

811 (2) "Biologic" has the same meaning as provided in section 21a-70d of812 the general statutes;

813 (3) "Covered entity" means The University of Connecticut Health
814 Center, a federally qualified health center, a family planning clinic and
815 a Ryan White clinic;

816 (4) "Manufacturer" has the same meaning as provided in section 21a817 70 of the general statutes, except that such definition shall include

818	manufacturers of biologics;
819 820	(5) "Package" has the same meaning as provided in 21 USC 360eee(11)(A); and
821 822	(6) "Pharmacy" has the same meaning as provided in section 20-571 of the general statutes.
823 824	Sec. 18. (NEW) (<i>Effective from passage</i>) (a) A manufacturer, or an agent or affiliate of such manufacturer, shall not, either directly or indirectly:
825 826 827 828 829	(1) Deny, restrict, prohibit, discriminate against or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity unless such receipt is prohibited under federal law; or
830 831 832 833 834 835 836	(2) Require a covered entity, or a pharmacy that is under contract with a covered entity, to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, or a pharmacy that is under contract with a covered entity, unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.
837 838 839 840 841 842 843 844 845 846 847 848	(b) (1) On and after July 1, 2025, if the Commissioner of Consumer Protection receives information and has a reasonable belief, after evaluating such information, that any manufacturer, or an agent or affiliate of such manufacturer, has acted in violation of any provision of this section or regulation adopted thereunder, such manufacturer, or an agent or affiliate of such manufacturer, shall be subject to a civil penalty of not more than fifty thousand dollars for each violation. The commissioner shall issue a notice of violation and civil penalty and may issue such notice by first-class mail or personal service. Such notice shall include: (A) A reference to the section of the general statutes or regulation of Connecticut state agencies believed or alleged to have been violated; (B) a short and plain-language statement of the matters

asserted or charged; (C) a description of the activity to cease; (D) a
statement of the amount of the civil penalty or penalties that may be
imposed; (E) a statement concerning the right to a hearing; and (F) a
statement that such manufacturer, or an agent or affiliate of such
manufacturer, may, not later than ten business days after receipt of such
notice, make a request for a hearing on the matters asserted.

855 (2) The manufacturer, or an agent or affiliate of such manufacturer, 856 to whom such notice is provided pursuant to subparagraph (A) of 857 subdivision (1) of this subsection may, not later than ten business days 858 after receipt of such notice, make written application to the Department 859 of Consumer Protection to request a hearing to demonstrate that such 860 violation did not occur. The failure to make a timely request for a 861 hearing shall result in the issuance of a cease and desist order or 862 imposition of a civil penalty by the department. All hearings held under 863 this subsection shall be conducted in accordance with the provisions for 864 contested cases under chapter 54 of the general statutes.

865 (3) Following any hearing before the Department of Consumer Protection pursuant to subdivision (2) of this subsection, if the 866 867 department finds, by a preponderance of the evidence, that any 868 manufacturer, or an agent or affiliate of such manufacturer, violated or 869 is violating any provision of this subsection, any regulation adopted 870 thereunder or any order issued by the department, the department shall 871 issue a final cease and desist order in addition to any civil penalty the 872 department imposes.

(c) Nothing in this section shall be construed or applied to be inconflict with or less restrictive than:

875 (1) Applicable federal law and related regulations, including 21 USC876 355-1, as amended from time to time; or

877 (2) Other laws of this state to the extent such laws are compatible with878 applicable federal law.

879 (d) The Commissioner of Consumer Protection shall adopt

regulations in accordance with the provisions of chapter 54 of thegeneral statutes to implement the provisions of this section.

Sec. 19. (NEW) (*Effective July 1, 2025*) (a) As used in this section, "pay to delay" means an agreement between a pharmaceutical manufacturer and a competitor to delay the launch of a generic drug based on an expiring or expired patent for a drug made by the pharmaceutical manufacturer.

(b) A pharmaceutical manufacturer doing business in this state shall
annually report to the Commissioner of Consumer Protection any "pay
to delay" agreements such manufacturer has with any competitor and
the prescription drugs included in such agreement. A pharmaceutical
manufacturer shall make such reports in a form and manner prescribed
by the commissioner.

(c) The commissioner shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section and may establish penalties and an administrative hearing process in accordance with chapter 54 of the general statutes for a pharmaceutical manufacturer that violates the provisions of this section.

Sec. 20. (NEW) (*Effective January 1, 2026*) (a) As used in this section:

900 (1) "Health benefit plan" has the same meaning as provided in section901 38a-472f of the general statutes;

902 (2) "Insulin" means an insulin product, including, but not limited to,
903 an insulin pen or vial, that is licensed under 42 USC 262(a) or 42 USC
904 262(k), as amended from time to time;

905 (3) "Eligible insulin product" means an insulin product for which at
906 least two licenses have been issued and continues to be marketed
907 pursuant to such licensure;

908 (4) "Net cost" means the cost of an insulin product taking into account 909 rebates or discounts for that specific product, excluding (A) rebates or 910 discounts required by state or federal law, including Medicaid,
911 Medicare and Section 340B of the Public Health Service Act, 42 USC
912 256b, as amended from time to time, and (B) rebates or discounts related
913 to portfolio agreements that relate to purchase of multiple insulin
914 products or other drugs;

(5) "State entity" means any state agency, or any person acting on
behalf of the state, that purchases a prescription drug for an individual
with health insurance paid for by the state, including health insurance
offered by local, state or federal agencies, or through organizations
licensed in the state;

920 (6) "Wholesale acquisition cost" means the price of a medication set
921 by a pharmaceutical manufacturer in the United States when selling to
922 a wholesaler; and

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

926 (b) A state entity and health benefit plan shall, except as otherwise 927 required in any collective bargaining agreement affecting the state 928 employee health plan established pursuant to section 5-259 of the 929 general statutes, make available in a preferred tier with no copayment 930 or out-of-pocket cost an eligible insulin product at the lowest wholesale 931 acquisition cost to a beneficiary. Notwithstanding the provisions of this 932 section, if a state entity or health benefit plan determines that another 933 eligible insulin product has a lower net cost than the lowest wholesale 934 acquisition cost, such entity or health plan may offer that product with 935 no out-of-pocket payment to a beneficiary of such state entity or health 936 benefit plan. Nothing in this section shall prevent such entity or health 937 benefit plan from covering more than one eligible insulin product in a 938 preferred tier with no copayment or out-of-pocket cost to a beneficiary 939 of such entity or health benefit plan.

940 Sec. 21. Section 38a-492d of the general statutes is repealed and the941 following is substituted in lieu thereof (*Effective January 1, 2026*):

	sSB11 File No. 420
942	(a) For the purposes of this section:
943 944	(1) "Diabetes device" has the same meaning as provided in section 20- 616;
945 946	(2) "Diabetic ketoacidosis device" has the same meaning as provided in section 20-616;
947 948	(3) "Glucagon drug" has the same meaning as provided in section 20- 616;
949 950	(4) "High deductible health plan" has the same meaning as that term is used in subsection (f) of section 38a-493;
951 952	(5) "Insulin drug" has the same meaning as provided in section 20-616;
953 954 955 956	(6) "Noninsulin drug" means a drug, including, but not limited to, a glucagon drug, glucose tablet or glucose gel, that does not contain insulin and is approved by the federal Food and Drug Administration to treat diabetes; and
957 958	(7) "Prescribing practitioner" has the same meaning as provided in section 20-571.
959 960 961 962 963 964 965	(b) Notwithstanding the provisions of section 38a-492a, each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, issued for delivery, renewed, amended or continued in this state shall provide coverage for the treatment of all types of diabetes. Such coverage shall include, but need not be limited to, coverage for medically necessary:
966 967 968	(1) Laboratory and diagnostic testing and screening, including, but not limited to, hemoglobin A1c testing and retinopathy screening, for all types of diabetes;
969 970	(2) Insulin drugs (A) prescribed by a prescribing practitioner, or (B) prescribed and dispensed pursuant to subsection (d) of section 20-616 sSB11 / File No. 420 31

971 once during a policy year;

(3) Noninsulin drugs (A) prescribed by a prescribing practitioner, or
(B) prescribed and dispensed pursuant to subsection (d) of section 20616 once during a policy year if the noninsulin drug is a glucagon drug;

975 (4) Diabetes devices in accordance with the insured's diabetes
976 treatment plan, including, but not limited to, diabetes devices
977 prescribed and dispensed pursuant to subsection (d) of section 20-616
978 once during a policy year; and

979 (5) Diabetic ketoacidosis devices in accordance with the insured's
980 diabetes treatment plan, including, but not limited to, diabetic
981 ketoacidosis devices prescribed and dispensed pursuant to subsection
982 (d) of section 20-616 once during a policy year.

(c) Notwithstanding the provisions of section 38a-492a, no policy
described in subsection (b) of this section shall impose coinsurance,
copayments, deductibles and other out-of-pocket expenses on an
insured that exceed:

(1) Twenty-five dollars for each thirty-day supply of a medically
necessary covered insulin drug (A) prescribed to the insured by a
prescribing practitioner, or (B) prescribed and dispensed pursuant to
subsection (d) of section 20-616 once during a policy year;

(2) Twenty-five dollars for each thirty-day supply of a medically
necessary covered noninsulin drug (A) prescribed to the insured by a
prescribing practitioner, or (B) prescribed and dispensed pursuant to
subsection (d) of section 20-616 once during a policy year if such
noninsulin drug is a glucagon drug;

(3) One hundred dollars for a thirty-day supply of all medically
necessary covered diabetes devices and diabetic ketoacidosis devices for
such insured that are in accordance with such insured's diabetes
treatment plan, including, but not limited to, diabetes devices and
diabetic ketoacidosis devices prescribed and dispensed pursuant to
subsection (d) of section 20-616 once during a policy year.

	sSB11 File No. 420
1002	(d) Notwithstanding the provisions of subsection (c) of this section
1003	and section 38a-492a, on and after January 1, 2026, any policy described
1004	in subsection (b) of this section shall make available in a preferred tier
1005	with no copayment or out-of-pocket cost an eligible insulin product, as
1006	defined in section 20 of this act, at the lowest wholesale acquisition cost
1007	in accordance with section 20 of this act.
1008	[(d)] (e) The provisions of [subsection (c)] subsections (c) and (d) of
1009	this section shall apply to a high deductible health plan to the maximum
1010	extent permitted by federal law, except if such plan is used to establish
1011	a medical savings account or an Archer MSA pursuant to Section 220 of
1012	the Internal Revenue Code of 1986, or any subsequent corresponding
1013	internal revenue code of the United States, as amended from time to
1014	time, or a health savings account pursuant to Section 223 of said Internal
1015	Revenue Code, as amended from time to time, the provisions of said
1016	[subsection (c)] <u>subsections</u> shall apply to such plan to the maximum
1017	extent that (1) is permitted by federal law, and (2) does not disqualify
1018	such account for the deduction allowed under said Section 220 or 223,
1019	as applicable.
1020	Sec. 22. Section 38a-518d of the general statutes is repealed and the
1021	following is substituted in lieu thereof (<i>Effective January 1, 2026</i>):
1022	(a) For the purposes of this section:
1023	(1) "Diabetes device" has the same meaning as provided in section 20-
1024	616;
1025	(2) "Diabetic ketoacidosis device" has the same meaning as provided
1026	in section 20-616;
1027	(3) "Glucagon drug" has the same meaning as provided in section 20-
1028	616;
1029	(4) "High deductible health plan" has the same meaning as that term
1030	is used in subsection (f) of section 38a-520;
1031	(5) "Insulin drug" has the same meaning as provided in section 20-

1032 616;

(6) "Noninsulin drug" means a drug, including, but not limited to, a
glucagon drug, glucose tablet or glucose gel, that does not contain
insulin and is approved by the federal Food and Drug Administration
to treat diabetes; and

1037 (7) "Prescribing practitioner" has the same meaning as provided in1038 section 20-571.

1039 (b) Notwithstanding the provisions of section 38a-518a, each group 1040 health insurance policy providing coverage of the type specified in 1041 subdivisions (1), (2), (4), (11) and (12) of section 38a-469 delivered, 1042 issued for delivery, renewed, amended or continued in this state shall 1043 provide coverage for the treatment of all types of diabetes. Such 1044 coverage shall include, but need not be limited to, coverage for 1045 medically necessary:

1046 (1) Laboratory and diagnostic testing and screening, including, but
1047 not limited to, hemoglobin A1c testing and retinopathy screening, for
1048 all types of diabetes;

(2) Insulin drugs (A) prescribed by a prescribing practitioner, or (B)
prescribed and dispensed pursuant to subsection (d) of section 20-616
once during a policy year;

(3) Noninsulin drugs (A) prescribed by a prescribing practitioner, or
(B) prescribed and dispensed pursuant to subsection (d) of section 20616 once during a policy year if the noninsulin drug is a glucagon drug;

(4) Diabetes devices in accordance with the insured's diabetes
treatment plan, including, but not limited to, diabetes devices
prescribed and dispensed pursuant to subsection (d) of section 20-616
once during a policy year; and

(5) Diabetic ketoacidosis devices in accordance with the insured's
diabetes treatment plan, including, but not limited to, diabetic
ketoacidosis devices prescribed and dispensed pursuant to subsection

1062 (d) of section 20-616 once during a policy year.

(c) Notwithstanding the provisions of section 38a-518a, no policy
described in subsection (b) of this section shall impose coinsurance,
copayments, deductibles and other out-of-pocket expenses on an
insured that exceed:

(1) Twenty-five dollars for each thirty-day supply of a medically
necessary covered insulin drug (A) prescribed to the insured by a
prescribing practitioner, or (B) prescribed and dispensed pursuant to
subsection (d) of section 20-616 once during a policy year;

1071 (2) Twenty-five dollars for each thirty-day supply of a medically 1072 necessary covered noninsulin drug (A) prescribed to the insured by a 1073 prescribing practitioner, or (B) prescribed and dispensed pursuant to 1074 subsection (d) of section 20-616 once during a policy year if such 1075 noninsulin drug is a glucagon drug;

(3) One hundred dollars for a thirty-day supply of all medically
necessary covered diabetes devices and diabetic ketoacidosis devices for
such insured that are in accordance with such insured's diabetes
treatment plan, including, but not limited to, diabetes devices and
diabetic ketoacidosis devices prescribed and dispensed pursuant to
subsection (d) of section 20-616 once during a policy year.

(d) Notwithstanding the provisions of subsection (c) of this section
and section 38a-518a, on and after January 1, 2026, any policy described
in subsection (b) of this section shall make available in a preferred tier
with no copayment or out-of-pocket cost an eligible insulin product, as
defined in section 20 of this act, at the lowest wholesale acquisition cost
in accordance with section 20 of this act.

1088 [(d)] (e) The provisions of [subsection (c)] <u>subsections (c) and (d)</u> of 1089 this section shall apply to a high deductible health plan to the maximum 1090 extent permitted by federal law, except if such plan is used to establish 1091 a medical savings account or an Archer MSA pursuant to Section 220 of 1092 the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to
time, or a health savings account pursuant to Section 223 of said Internal
Revenue Code, as amended from time to time, the provisions of said
[subsection (c)] <u>subsections</u> shall apply to such plan to the maximum
extent that (1) is permitted by federal law, and (2) does not disqualify
such account for the deduction allowed under said Section 220 or 223,
as applicable.

1100 Sec. 23. (NEW) (*Effective October 1, 2025*) (a) Any pharmacy benefits 1101 manager shall owe a fiduciary duty to any health carrier, as defined in 1102 section 38a-591a of the general statutes, or other health benefit plan 1103 sponsor.

(b) Any pharmacy benefits manager shall notify the health carrier or
other health benefit plan sponsor, in writing, of any activity, policy or
practice of such pharmacy benefits manager that directly or indirectly
presents any conflict of interest with the duties imposed by this section.

(c) Any pharmacy benefits manager shall have an obligation of good
faith and fair dealing in performing such pharmacy benefits manager's
duties with all parties, including, but not limited to, a health carrier or
other health benefit plan sponsor with whom such pharmacy benefits
manager interacts in the performance of pharmacy benefit management
services.

(d) Notwithstanding any provision of title 38a of the general statutes and to the maximum extent permitted by applicable law, no contract entered into or amended by a health carrier shall contain any provision that permits or requires any party to such contract to violate the fiduciary duty that such health carrier owes to such health carrier's covered persons.

(e) Any violation of the provisions of this section shall constitute aviolation of sections 38a-815 to 38a-819, inclusive, of the general statutes.

1122 (f) The Insurance Commissioner may adopt regulations, in 1123 accordance with the provisions of chapter 54 of the general statutes, to 1124 implement the provisions of this section.

1125 Sec. 24. Section 38a-477cc of the general statutes is repealed and the 1126 following is substituted in lieu thereof (*Effective January 1, 2026*):

(a) No contract for pharmacy services entered into in the state
between a health carrier, as defined in section 38a-591a, or pharmacy
benefits manager, as defined in section 38a-479aaa, and a pharmacy or
pharmacist shall:

(1) On and after January 1, 2018, contain a provision prohibiting or
penalizing, including through increased utilization review, reduced
payments or other financial disincentives, a pharmacist's disclosure to
an individual purchasing prescription medication of information
regarding:

1136 (A) The cost of the prescription medication to the individual; or

(B) The availability of any therapeutically equivalent alternative medications or alternative methods of purchasing the prescription medication, including, but not limited to, paying a cash price, that are less expensive than the cost of the prescription medication to the individual; [and]

(2) On and after January 1, 2020, contain a provision permitting the health carrier or pharmacy benefits manager to recoup, directly or indirectly, from a pharmacy or pharmacist any portion of a claim that such health carrier or pharmacy benefits manager has paid to the pharmacy or pharmacist, unless such recoupment is permitted under section 38a-479iii or required by applicable law;

(3) On and after January 1, 2026, contain a provision permitting the
pharmacy benefits manager to charge a health benefit plan in this state
a contracted price for any pharmacy services that differs from the
amount such pharmacy benefits manager, directly or indirectly, pays
the pharmacy for such pharmacy services; and

1153 (4) On and after January 1, 2026, contain a provision permitting the

1154	pharmacy benefits manager to charge a health benefit plan, directly or
1155	indirectly, a fee that is conditioned on the (A) wholesale acquisition cost
1156	or any other price metric for a prescription drug, (B) amount of savings,
1157	rebates or other fees charged, realized, collected by or generated based
1158	on the business practices of such pharmacy benefits manager, or (C)
1159	amount of premiums charged or cost-sharing requirements pursuant to
1160	such health benefit plan that are realized or collected by such pharmacy
1161	benefits manager from covered persons. For the purposes of this
1162	subdivision, "wholesale acquisition cost" means the price of a
1163	medication set by a pharmaceutical manufacturer in the United States
1164	when selling to a wholesaler.
1165	(b) (1) On and after January 1, 2018, no health carrier or pharmacy
1166	benefits manager shall require an individual to make a payment at the
1167	point of sale for a covered prescription medication in an amount greater

- 1168 than the lesser of:
- 1169 (A) The applicable copayment for such prescription medication;
- 1170 (B) The allowable claim amount for the prescription medication; or

1171 (C) The amount an individual would pay for the prescription 1172 medication if the individual purchased the prescription medication 1173 without using a health benefit plan, as defined in section 38a-591a, or 1174 any other source of prescription medication benefits or discounts.

- (2) For the purposes of this subsection, "allowable claim amount"
 means the amount the health carrier or pharmacy benefits manager has
 agreed to pay the pharmacy for the prescription medication.
- (c) Any provision of a contract that violates the provisions of this
 section shall be void and unenforceable. Any general business practice
 that violates the provisions of this section shall constitute an unfair trade
 practice pursuant to chapter 735a. The invalidity or unenforceability of
 any contract provision under this subsection shall not affect any other
 provision of the contract.
- 1184 (d) The Insurance Commissioner may:

	sSB11 File No. 420
1185	(1) Enforce the provisions of this section pursuant to chapter 697; and
1186	(2) Upon request, audit a contract for pharmacy services for
1187	compliance with the provisions of this section.
1188	Sec. 25. (NEW) (Effective July 1, 2025) (a) The Insurance Commissioner
1189	shall require any health carrier, as defined in section 38a-591a of the
1190	general statutes, to report to the commissioner annually on pricing
1191	offered to and profit generated between such carrier and any pharmacy
1192	benefits manager or mail-order pharmacy doing business with such
1193	carrier.
1194	(b) The commissioner shall post a link on the Internet web site of the
1195	Insurance Department to the reports filed pursuant to subsection (a) of
1196	this section.
1197	Sec. 26. (Effective July 1, 2025) For the purposes of this section and
1198	sections 27 to 35, inclusive, of this act, unless the context otherwise
1199	requires:
1200	(1) "Canadian supplier" means a manufacturer or wholesale drug
1201	distributor that is licensed or permitted under applicable Canadian law
1202	to manufacture or distribute prescription drugs;
1203	(2) "Canadian prescription drug importation program" or "program"
1204	means a program under which the state would seek federal approval to
1205	import prescription drugs from Canada that have the highest potential
1206	for cost savings in the state;
1207	(3) "Department" means the Department of Consumer Protection;
1208	(4) "Drug" means an article that is (A) recognized in the official United
1209	States Pharmacopoeia, official Homeopathic Pharmacopoeia of the
1210	United States or official National Formulary, or any supplement thereto,
1211	(B) intended for use in the diagnosis, cure, mitigation, treatment or
1212	prevention of disease in humans, (C) not food and intended to affect the
1213	structure or any function of the human body, and (D) not a device and
1214	intended for use as a component of any article specified in

1215	subparagraphs (A) to (C), inclusive, of this subdivision;		
1216	(5) "Drug Quality and Security Act" means the federal Drug Quality		
1217	and Security Act, 21 USC 351, et seq., as amended from time to time;		
1218	(6) "Food, Drug and Cosmetic Act" means the federal Food, Drug and		
1219	Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and		
1220	Security Act, as both may be amended from time to time;		
1221	(7) "Qualifying laboratory" has the same meaning as provided in 21		
1222	CFR 251.2;		
1223	(8) "Laboratory testing" means a quantitative and qualitative analysis		
1224	of a drug consistent with the applicable provisions of the official United		
1225	States Pharmacopoeia;		
1226	(9) "Participating Canadian supplier" means a Canadian supplier that		
1227	is exporting prescription drugs, in the manufacturer's original		
1228	container, to a participating wholesaler for distribution in this state		
1229	under the program;		
1230	(10) "Participating wholesaler" means a wholesaler that is (A)		
1231	designated by the Department of Consumer Protection to distribute		
1232	prescription drugs in the manufacturer's original container, obtained		
1233	from a participating Canadian supplier, and (B) participating in the		
1234	program;		
1235	(11) "Recall" means a person's removal or correction of a marketed		
1236	product that the department determines is in violation of this section,		
1237	but "recall" does not include a market withdrawal or a stock recovery,		
1238	as such terms are defined in 21 CFR 7.3;		
1239	(12) "Relabeler" has the same meaning as provided in 21 CFR 207.1;		
1240	(13) "Repacker" has the same meaning as provided in 21 CFR 207.1;		
1241	(14) "Track-and-trace" means the product tracing process for the		
1242	components of the pharmaceutical distribution supply chain as		
1243	described in Title II of the Drug Quality and Security Act; and		

(15) "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.

1247 Sec. 27. (Effective July 1, 2025) The Commissioner of Consumer 1248 Protection shall hire, within available resources, a consultant to study 1249 the feasibility of establishing a Canadian prescription drug importation 1250 program to reduce prescription drug costs in the state. Not later than 1251 October 1, 2027, the commissioner shall file a report, in accordance with 1252 the provisions of section 11-4a of the general statutes, with the joint 1253 standing committees of the General Assembly having cognizance of 1254 matters relating to appropriations and the budgets of state agencies, 1255 general law and human services and the Office of Policy and 1256 Management on the results of the feasibility study.

1257 Sec. 28. (*Effective October 1, 2027*) (a) If after completion of the study 1258 described in section 27 of this act, the Commissioner of Consumer 1259 Protection, in consultation with the Secretary of the Office of Policy and 1260 Management, determines a Canadian prescription drug importation 1261 program is feasible, the Commissioner of Consumer Protection may 1262 submit a request to the federal Food and Drug Administration seeking 1263 approval for the program under Section 804 of the federal Food, Drug 1264 and Cosmetic Act, 21 USC 384(b) to 21 USC 384(h), inclusive, as 1265 amended from time to time. If submitted, such request shall, at a 1266 minimum:

(1) Describe the state's plans for operating the program and describe
any opportunities to coordinate or operate the program in coordination
with other states;

1270 (2) Demonstrate that any prescription drug that is imported and1271 distributed in this state under the program would:

1272 (A) Meet all applicable federal and state standards for safety and1273 effectiveness; and

1274 (B) Comply with all federal tracing procedures; and

	sSB11 File No. 420
1275	(3) State the estimated costs of implementing the program.
1276 1277	(b) If the federal Food and Drug Administration approves the request, the Commissioner of Consumer Protection shall:
1278 1279 1280 1281	(1) Submit to the Secretary of the Office of Policy and Management, and the Commissioners of Social Services and Health Strategy, a notice disclosing that the federal Food and Drug Administration approved such request; and
1282 1283 1284 1285 1286	(2) Submit to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law, human services and public health a notice disclosing that the federal Food and Drug Administration approved such request.
1287 1288 1289 1290 1291	(c) The Commissioner of Consumer Protection shall not operate the program unless the federal Food and Drug Administration approves the request. Notwithstanding the provisions of this subsection, the department may expend resources in advance of such approval to ensure efficient implementation.
1292 1293 1294 1295	Sec. 29. (<i>Effective October 1, 2027</i>) If the Canadian prescription drug importation program is established, each participating wholesaler may import and distribute a prescription drug in this state from a participating Canadian supplier under the program if:
1296 1297 1298	(1) Such drug meets the federal Food and Drug Administration's standards concerning drug safety, effectiveness, misbranding and adulteration;
1299	(2) Importing such drug would not violate federal patent laws; and
1300	(3) Such drug is not:
1301 1302	(A) A controlled substance, as defined in 21 USC 802, as amended from time to time;
1303	(B) A biological product, as defined in 42 USC 262, as amended from sSB11 / File No. 420 42

1304	time to time;
1305	(C) An infused drug;
1306	(D) An intravenously injected drug;
1307	(E) A drug that is inhaled during surgery; or
1308 1309 1310	(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.
1311 1312 1313 1314 1315	Sec. 30. (<i>Effective October 1, 2027</i>) If a Canadian prescription drug importation program is established, participating wholesalers may, subject to the provisions of sections 31 and 32 of this act, import and distribute drugs in this state from a participating Canadian supplier under the program to:
1316 1317	(1) A pharmacy or institutional pharmacy, as defined in section 20- 571 of the general statutes; and
1318	(2) A qualifying laboratory.
1319 1320 1321 1322 1323 1324 1325 1326 1327	Sec. 31. (<i>Effective October 1, 2027</i>) If a Canadian prescription drug importation program is established, the Commissioner of Consumer Protection shall require that each participating Canadian supplier and participating wholesaler (1) comply with all applicable track-and-trace requirements, and shall not distribute, dispense or sell outside of this state any prescription drug that is imported into this state under the program, and (2) make available to the commissioner all track-and-trace records not later than forty-eight hours after the commissioner requests such records.
1328 1329 1330 1331 1332	Sec. 32. (<i>Effective October 1, 2027</i>) (a) A participating wholesaler in any approved Canadian prescription drug importation program shall ensure the safety and quality of all drugs that may be imported and distributed in this state under the program. The participating wholesaler shall, if such program is established:

(1) For each initial shipment of a drug that is imported into this state
by a participating wholesaler, ensure that a qualifying 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 qualifying 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) Only import drugs into this state that are (A) approved for
marketing in the United States, (B) not adulterated or misbranded, and
(C) meet all of the labeling requirements under 21 USC 352, as amended
from time to time;

(4) Maintain qualifying laboratory records, including, but not limited
to, complete data derived from all tests necessary to ensure that each
drug imported into this state under any approved Canadian
prescription drug importation 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 qualifying laboratory in accordance
with the Food, Drug and Cosmetic Act and all other applicable federal
and state laws and regulations concerning qualifying laboratory
qualifications.

(b) The participating wholesaler shall maintain all information and
documentation pursuant to this section for a period of not less than three
years from the date of submission of such information and
documentation to the participating wholesaler by a qualifying
laboratory.

1364	(c) Each participating wholesaler shall maintain all of the following
1365	information for each drug that such participating wholesaler imports
1366	and distributes in this state under the program, and submit such
1367	information to the Commissioner of Consumer Protection upon request
1368	by the commissioner:
1369	(1) The name and quantity of the active ingredient of such drug;
1370	(2) A description of the dosage form of such drug;
1371	(3) The date on which such participating wholesaler received such
1372	drug;
1373	(4) The quantity of such drug that such participating wholesaler
1374	received;
1375	(5) The point of origin and destination of such drug;
1376	(6) The price paid by such participating wholesaler for such drug;
1377	(7) A report regarding any drug that fails qualifying laboratory
1378	testing; and
1379	(8) Such additional information and documentation that the
1380	commissioner deems necessary to ensure the protection of the public
1381	health.
1382	(d) The Commissioner of Consumer Protection shall require each
1383	participating Canadian supplier in any approved Canadian prescription
1384	drug importation program to maintain the following information and
1385	documentation and, upon request by the commissioner, submit such
1386	information and documentation to the commissioner for each drug that
1387	such participating Canadian supplier exports into this state under the
1388	program:
1389	(1) The original source of such drug, including, but not limited to:
1390	(A) The name of the manufacturer of such drug;

	sSB11 File No. 420
1391	(B) The date on which such drug was manufactured; and
1392	(C) The location where such drug was manufactured;
1393	(2) The date on which such drug was shipped;
1394	(3) The quantity of such drug that was shipped;
1395 1396	(4) The quantity of each lot of such drug originally received and the source of such lot;
1397 1398	(5) The lot or control number and the batch number assigned to such drug by the manufacturer; and
1399 1400 1401	(6) Such additional information and documentation that the Commissioner of Consumer Protection deems necessary to ensure the protection of the public health.
1402 1403 1404 1405 1406 1407 1408 1409 1410 1411 1412 1413 1414 1415	Sec. 33. (<i>Effective October 1, 2027</i>) (a) If the Commissioner of Consumer Protection determines that public health, safety or welfare requires emergency action, the commissioner may order a participating Canadian supplier, participating wholesaler, relabeler, repacker and qualifying laboratory to cease and desist from actions specified in the order that create the need for such emergency action pending administrative proceedings. Such cease and desist order shall be (1) in writing; (2) signed by the Commissioner of Consumer Protection; and (3) effective upon delivery to the respondent. An administrative proceeding in accordance with chapter 54 of the general statutes shall be promptly instituted following a cease and desist order. The commissioner may impose a civil penalty, in an amount not to exceed ten thousand dollars, after a hearing conducted pursuant to chapter 54 of the general statutes.
1416 1417 1418 1419 1420	(b) The commissioner may require the recall, embargo or destruction, pursuant to section 21a-96 of the general statutes, 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.

(c) In the event of a cease and desist, recall, embargo or destruction
order, the person adversely impacted by such order shall provide
written notice to all other businesses participating in the program,
informing them of the order.

Sec. 34. (*Effective October 1, 2027*) If a Canadian prescription drug importation program is established, the Commissioner of Consumer Protection may adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 29 to 33, inclusive, of this act.

1430 Sec. 35. (Effective October 1, 2027) Not later than one hundred eighty 1431 days after the first importation of any Canadian prescription drug under 1432 the importation program begins, and biannually thereafter, the 1433 Commissioner of Consumer Protection shall submit a report, in 1434 accordance with the provisions of section 11-4a of the general statutes, 1435 to the joint standing committees of the General Assembly having 1436 cognizance of matters relating to appropriations and the budgets of state 1437 agencies, general law, human services and public health. Such report 1438 shall describe (1) the operation of the program, if established, and (2) 1439 any violation of sections 29 to 33, inclusive, of this act that resulted in 1440 any action taken by the commissioner pursuant to section 33 of this act 1441 and the status of the investigation into such violation.

Sec. 36. (NEW) (*Effective from passage*) (a) There is established a task force to study emergency preparedness and mitigation strategies for prescription drug shortages. The task force shall identify prescription drugs at risk of shortage in this state and make recommendations pursuant to subsection (g) of this section.

1447 (b) The task force shall consist of the following members:

(1) Two appointed by the speaker of the House of Representatives,
one of whom has expertise in prescription drug supply chains and one
of whom has expertise in federal law concerning prescription drug
shortages;

	sSB11 File No. 420
1452 1453 1454	(2) Two appointed by the president pro tempore of the Senate, one of whom represents hospitals and one of whom represents health care providers who treat patients with rare diseases;
1455 1456 1457	(3) One appointed by the majority leader of the House of Representatives, who represents one of the two federally recognized Indian tribes in the state;
1458 1459	(4) One appointed by the majority leader of the Senate, who represents one of the two federally recognized Indian tribes in the state;
1460 1461	(5) One appointed by the minority leader of the House of Representatives;
1462	(6) One appointed by the minority leader of the Senate;
1463 1464	(7) The Commissioner of Health Strategy, or the commissioner's designee;
1465 1466	(8) The Commissioner of Consumer Protection, or the commissioner's designee;
1467 1468	(9) The Commissioner of Social Services, or the commissioner's designee;
1469 1470	(10) The Commissioner of Public Health, or the commissioner's designee;
1471 1472	(11) The chief executive officer of The University of Connecticut Health Center, or the chief executive officer's designee;
1473 1474	(12) The Insurance Commissioner, or the commissioner's designee; and
1475 1476	(13) The Commissioner of Economic and Community Development, or the commissioner's designee.
1477 1478	(c) Any member of the task force appointed under subdivision (1), (2), (3), (4), (5) or (6) of subsection (b) of this section may be a member

1479 of the General Assembly.

1480	(d) All initial appointments to the task force shall be made not later
1481	than thirty days after the effective date of this section. Any vacancy shall
1482	be filled by the appointing authority.

(e) The speaker of the House of Representatives and the president pro
tempore of the Senate shall select the chairpersons of the task force from
among the members of the task force. Such chairpersons shall schedule
the first meeting of the task force, which shall be held not later than sixty
days after the effective date of this section.

(f) The administrative staff of the joint standing committee of the
General Assembly having cognizance of matters relating to human
services shall serve as administrative staff of the task force.

1491 (g) Not later than January 1, 2026, and annually thereafter, the task 1492 force shall submit a report on its findings and recommendations to the 1493 joint standing committees of the General Assembly having cognizance 1494 of matters relating to general law, human services, insurance and real 1495 estate and public health, in accordance with the provisions of section 11-1496 4a of the general statutes, including, but not limited to, identification of 1497 prescription drugs the task force determines are at risk of shortage and 1498 strategies that would mitigate these shortages, including methods to 1499 increase in-state production of such drugs deemed both at risk of 1500 shortage and critically necessary for the provision of health care within 1501 the state.

Sec. 37. (NEW) (*Effective July 1, 2025*) (a) As used in this section, "Strategic Supply Chain Initiative" means a program administered by the Department of Economic and Community Development to help state-based companies to increase their production capacity to win new business and attract out-of-state and international supply chain operations.

(b) The Commissioner of Economic and Community Developmentshall expand the Strategic Supply Chain Initiative to include efforts to

prevent or mitigate prescription drug shortages, including, but not
limited to, incorporating recommendations to prevent or mitigate
prescription drug shortages by the task force established pursuant to
section 36 of this act.

Sec. 38. (NEW) (*Effective from passage*) (a) The Commissioner of Public
Health shall establish and convene a Vaccines and Related Biological
Products Advisory Committee for the purpose of coordinating seasonal
vaccine production in coordination with pharmaceutical drug
manufacturers.

1519 (b) The commissioner shall appoint to the advisory committee 1520 representatives of (1) pharmaceutical manufacturers, including one 1521 large such manufacturer and one small or start-up such manufacturer; 1522 (2) health systems, including, but not limited to, one large or state-wide 1523 hospital system and one federally qualified health center; and (3) 1524 physicians, including, but not limited to, one expert each in infectious 1525 disease epidemiology, disease ecology, biostatistics or infectious disease 1526 modeling, and an expert in immunology or virology.

(c) The advisory committee shall be appointed and meet not later
than thirty days after the effective date of this act. The chairpersons shall
be the commissioner, or the commissioner's designee, and a member of
the committee elected by the committee. Any vacancy shall be filled by
the commissioner.

1532 (d) Not later than September 1, 2025, and annually thereafter, the 1533 commissioner shall file a report, in accordance with the provisions of 1534 section 11-4a of the general statutes, with the joint standing committees 1535 of the General Assembly having cognizance of matters relating to 1536 human services and public health on the activities and 1537 recommendations of the advisory committee and impact on state 1538 preparedness for the annual flu season.

This act shall take effect as follows and shall amend the following sections:

Section 1	July 1, 2025	New section
Sec. 2	July 1, 2025	New section
Sec. 3	July 1, 2025	New section
Sec. 4	July 1, 2025	New section
Sec. 5	July 1, 2025	New section
Sec. 6	from passage	New section
Sec. 7	July 1, 2025	17b-340d(a)
Sec. 8	July 1, 2025	New section
Sec. 9	July 1, 2025	New section
Sec. 10	January 1, 2026	New section
Sec. 11	January 1, 2026	New section
Sec. 12	January 1, 2026	New section
Sec. 13	from passage	New section
Sec. 14	from passage	New section
Sec. 15	July 1, 2025	17b-278 <i>l</i>
Sec. 16	October 1, 2025	38a-479ttt
Sec. 17	from passage	New section
Sec. 18	from passage	New section
Sec. 19	July 1, 2025	New section
Sec. 20	January 1, 2026	New section
Sec. 21	January 1, 2026	38a-492d
Sec. 22	January 1, 2026	38a-518d
Sec. 23	October 1, 2025	New section
Sec. 24	January 1, 2026	38a-477cc
Sec. 25	July 1, 2025	New section
Sec. 26	July 1, 2025	New section
Sec. 27	July 1, 2025	New section
Sec. 28	October 1, 2027	New section
Sec. 29	October 1, 2027	New section
Sec. 30	October 1, 2027	New section
Sec. 31	October 1, 2027	New section
Sec. 32	October 1, 2027	New section
Sec. 33	October 1, 2027	New section
Sec. 34	October 1, 2027	New section
Sec. 35	October 1, 2027	New section
Sec. 36	from passage	New section
Sec. 37	July 1, 2025	New section
Sec. 38	from passage	New section

Statement of Legislative Commissioners:

In Section 2(b)(1), "Commissioner of Consumer Protection" was changed to "Commissioner of Revenue Services" for accuracy; in Section 2(c)(1)(A)(i), "Commissioner of Consumer Protection" was changed to "commissioner" for accuracy; in Section 4(a), "section 5" was changed to "sections 5 and 6" for accuracy; in Sections 4(b) and 6, "executive director" was changed to "chief executive officer" for accuracy; in Section 5(b), "or section 4 of this act" was inserted for accuracy; in Section 6, the effective date was changed for accuracy; in Section 6(f), a reference to "task force" was changed to "council" for consistency; in Section 14(a)(2), "concerning implementation of the strategic plan developed pursuant to section 13 of this act" was inserted after "recommendations" for clarity; in Section 22(d), the statutory citation was changed for accuracy; in Section 23(e), "the Connecticut Unfair Insurance Practices Act established pursuant to section" was changed to "sections 38a-815 to 38a-819, inclusive," for clarity; and in Section 28(c), "foregoing" was changed to "provisions of this subsection" for consistency with standard drafting conventions.

HS Joint Favorable Subst.

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 26 \$	FY 27 \$
Social Services, Dept.	GF - Cost	at least \$97	at least \$185
		million	million
Consumer Protection, Dept.	GF - Cost	373,552	266,052
Public Health, Dept.	GF - Cost	134,700	130,750
Department of Revenue Services	GF - Cost	32,990	131,958
Consumer Protection, Dept.	GF - Potential	None	84,010
	Cost		
State Comptroller - Fringe	GF - Cost	208,383	248,673
Benefits ¹			
State Comptroller - Fringe	GF - Potential	See Below	At least
Benefits	Cost		31,147
Social Services, Dept.	GF - Revenue	at least	See Below
	Gain	125,000	
Resources of the General Fund	GF - Potential	See Below	See Below
	Revenue Gain		
Correction, Dept.; Judicial Dept.	GF - Potential	Minimal	Minimal
(Probation)	Cost		
Treasurer, Debt Serv.	GF - Potential	See Below	See Below
	Cost		
Social Services, Dept.	GF - Potential	See Below	See Below
	Savings		
UConn Health Ctr.	GF - Potential	See Below	See Below
	Savings		
Various State Agencies	GF - Potential	See Below	See Below
	Savings		

Note: GF=General Fund

Municipal Impact:

Municipalities	Effect	FY 26 \$	FY 27 \$
Various Municipalities	Cost	Potential	Potential

¹The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 40.71% of payroll in FY 26.

sSB11

Explanation

The bill makes various changes regarding prescription drugs resulting in the impacts described below.

Sections 1 and 2 establish a prescription drug cost containment initiative to be administered by the Department of Revenue Services (DRS). This results in a General Fund cost of \$46,420 in FY 26 (partial year) and \$185,678 in FY 27. The cost is associated with two Revenue Examiner positions within DRS to administer the program (\$65,979 and \$26,860 each for salary and fringe benefit costs, respectively).

Section 2 imposes a civil penalty for violation of the price cap provision which results in a potential General Fund revenue gain beginning in FY 26, the magnitude of which is dependent on the violator's price differential in excess of the price cap.

Section 2 also creates a new class D felony for willfully providing certain false or fraudulent material, which results in a potential cost to the Department of Correction and the Judicial Department for incarceration or probation and a potential revenue gain to the General Fund from fines. On average, the marginal cost to the state for incarcerating an offender for the year is \$3,300² while the average marginal cost for supervision in the community is less than \$600³ each year for adults.

Sections 3 and 19 make requirements regarding withdrawing a prescription drug from sale in the state and requiring a manufacturer to report pay to delay agreements resulting in a cost to the Department of Consumer Protection (DCP). To meet the requirements of these sections DCP will need to hire one processing technician for a salary and other

²Inmate marginal cost is based on increased consumables (e.g., food, clothing, water, sewage, living supplies, etc.) This does not include a change in staffing costs or utility expenses because these would only be realized if a unit or facility opened.

³Probation marginal cost is based on services provided by private providers and only includes costs that increase with each additional participant. This does not include a cost for additional supervision by a probation officer unless a new offense is anticipated to result in enough additional offenders to require additional probation officers.

expenses cost of \$57,748 in FY 26 and \$55,248 in FY 27, along with associated fringe benefit costs of \$22,491 per year.

Section 3 also creates a civil penalty of \$500,000 for violations resulting in a potential revenue gain to the state to the extent that violations occur.

Sections 4 – 5 result in potential savings annually beginning in FY 26 to UConn Health Center, the Judicial Department, and the Departments of Mental Health and Addiction Services, Children and Families (DCF), Developmental Services and Public Health (which the bill terms "drug purchasing agencies"). Section 4 requires UConn Health to negotiate bulk prescription drug purchases on behalf of such agencies. Section 5 additionally allows such agencies to join interstate prescription drug purchasing compacts.

To the extent that bulk prescription drug purchasing results in lower prescription drug costs to drug purchasing agencies, there is a savings that will vary based on the amount of drugs purchased, and the change in per unit costs.

It should be noted that DCF does not operate a stand-alone pharmacy. Rather, the agency obtains medicines utilized at the Solnit Children's Center through a state contract that includes pharmacist services. Under this contract a combined cost of approximately \$682,600 was incurred in FY 24 for medications, pharmacy services and distribution. A need for DCF to reestablish pharmacist services may result from the bill, should it be deemed that a new drug procurement system will be cost beneficial for the agency. This would require either retention of direct outside professional services or the creation of an inhouse pharmacy. As discussed above, associated costs would be mitigated to the extent that savings are achieved through lower prescription drug prices, as well as from ending current contractual obligations.

Development of an in-house pharmacy would require DCF to hire at a minimum 1.5 FTE Pharmacists, at an annualized salary of \$140,000 combined. Additional minimal salary costs would be incurred for 24/7 on-call coverage. Other expenses, which could be significant in magnitude, would be associated with installation of an automated medication dispensing and inventory management system, disposal of expired medicines, and enhanced security around drug storage. Annualized fringe benefits costs of \$57,000 would be incurred by the Office of the State Comptroller.

Section 6 establishes a Prescription Drug Affordability Council to advise the UConn Health Center on bulk prescription drug purchasing efforts and provide annual reports. This has no fiscal impact, as it is anticipated the council can complete its duties with existing resources.

Section 7 results in a cost to the Department of Social Services (DSS) associated with requiring nursing homes to spend at least 80% of payment sources, including Medicaid and Medicare, on direct care. DSS will incur costs to reflect an additional associate accounts examiner (annual salary of \$90,300 with associated fringe of approximately \$36,800) to meet the requirements of the bill. To the extent DSS requires system modifications, the agency could experience additional costs.

Beginning in FY 28, DSS may incur savings related to lower Medicaid rates paid to any nursing homes not meeting the provisions of the bill. For context, the state share of Medicaid payments to nursing homes is approximately \$700 million annually.

Section 8 results in a cost to the Department of Social Services (DSS) associated with expanding coverage of emergency Medicaid services and requiring DSS to establish an administrative system for individuals to apply in advance for emergency Medicaid coverage by 7/1/26.

DSS will incur administrative costs of at least \$250,000 in FY 26 to establish a registration system for individuals with qualifying emergency medical conditions that can be treated in outpatient settings rather than in hospital emergency departments. These costs are anticipated to be funded under Other Expenses and eligible for federal reimbursement, resulting in a federal grants revenue gain of at least

\$125,000.

The fiscal impact of expanding the definition of emergency medical condition cannot be determined at this time. For context, the state currently spends approximately \$27.5 million on emergency Medicaid services (representing a 50% share of total expenditures), which are generally emergent in nature and include outpatient dialysis for individuals with end-stage renal disease. Emergency Medicaid coverage is available to all individuals, regardless of immigration status, who meet Medicaid income and asset limits.

Section 9 results in a cost to the Department of Social Services (DSS) of approximately \$42 million in FY 26 and \$150 million in FY 27 associated with expanding eligibility for HUSKY C. The bill increases the asset limit each year until eliminating the threshold on 7/1/29. Currently, the asset limit for HUSKY C is \$1,600 for an individual and \$2,400 for a married couple. The bill increases the asset limit to \$10,000 for an individual and \$15,000 for a couple effective 7/1/25, and to \$25,000 and \$40,000, respectively, effective 7/1/26. Estimates are based on coverage of similar members in other states and used as a proxy for estimating the potential increase in coverage for Connecticut. For context, this assumes an average cost of approximately \$570 per member per month. This also assumes costs of approximately \$1.2 million in FY 26 and \$200,000 in FY 27 to support system change and maintenance costs, which result in a federal grants revenue gain of at least \$600,000 in FY 26 and \$100,000 in FY 27.

Sections 10 – 11 result in a potential revenue gain to UConn Health Center annually beginning in FY 26. The sections prohibit insurance companies from putting time limits on covered anesthesia for specific procedures. To the extent such time limits are used currently, there is a revenue gain that would vary based on the procedures, and the reimbursement rates paid by insurers.

Sections 10-11 prohibit health insurance policies from placing time limits on general anesthesia coverage which does not result in a fiscal impact to the state or municipalities because carriers do not currently impose these restrictions.

Section 12 sets stop loss requirements for self-funded employee health benefit plans and does not result in a fiscal impact to the state because the state employee health plan meets the requirements outlined in the bill. Municipalities with self-funded employee health benefit plans face an indeterminate fiscal impact dependent on their current stop-loss policy or current coverage levels and how the outlined requirements impact premiums.

Sections 13 – 15 make changes to DSS policies regarding Medicaid coverage for glucagon-like peptide (GLP-1) prescription drugs approved by the federal Food and Drug Administration (FDA) to treat obesity or diabetes. Under current practice, DSS covers weight loss drugs for Medicaid members with type 2 diabetes and Wegovy when prescribed to reduce the risk of a major adverse cardiac event.

Section 15 specifies that DSS cover weight loss drugs and requires such coverage to continue for beneficiaries, with physician approval, if their body mass index (BMI) drops below 35. State Medicaid costs for drugs used solely for the purpose of weight loss is anticipated to cost at least \$55 million in FY 26 and \$35 million in FY 27. As this reflects costs for members with a BMI of 35 and above, the actual costs will be higher after considering members whose BMI drops below that level and remain eligible.

Section 13 requires DSS to petition the federal Department of Health and Human Services to authorize generic, lower cost forms of GLP-1 prescription drugs to treat obesity or diabetes. If approved, the bill requires DSS to contract for such generic GLP-1 drugs to support HUSKY Health members. DSS will experience a savings to the extent a generic form of drugs otherwise utilized for those purposes are approved.

Section 14, which establishes an advisory committee to study ways to maximize access to cost-effective, FDA approved prescription drugs for the treatment of obesity and make recommendations, has no fiscal impact.

Sections 17-18 require DCP to regulate the 340b marketplace resulting in a cost to the state. DCP does not currently regulate this marketplace or have the expertise to do so and will have to hire two employees to meet the requirements of the bill. DCP will need to hire one drug control agent and one staff attorney for a salary and other expenses cost of \$215,804 in FY 26 and \$210,804 in FY 27, along with associated fringe benefit costs of \$82,562 per year.

Section 18 also creates a civil penalty of \$50,000 for every violation resulting in a potential revenue gain to the state to the extent that violations occur.

Sections 17 – 18 results in a potential savings to UConn Health Center annually beginning in FY 26. The sections restrict the ability of prescription drug manufacturers to limit the purchasing of 340B drugs by covered entities, which includes UConn Health. Any savings will vary based on any increase in the purchase of 340B drugs that occurs as a result of the bill. In FY 22, UConn Health saved \$13 million via the purchase of 340B drugs.

Sections 20-22 result in a potential cost to fully insured municipalities that currently impose cost sharing on insulin products to the extent cost sharing is imposed. Additional costs to municipalities can be incurred if they do not offer insulin products at the lowest wholesale acquisition cost. There is no fiscal impact to the state to impose these provisions as insulin products are currently covered under the state employee health plan with no cost sharing.

Sections 26-35 create a Canadian Prescription Drug Importation Program (CPDIP) resulting in costs to the DCP and the Office of the State Comptroller (OSC). The bill requires DCP to hire a consultant to study the feasibility of establishing a CPDIP resulting in a cost of \$100,000 in FY 26.

If the consultant reports that it's feasible to establish the CPDIP and

the program is approved by the federal Food and Drug Administration there is a cost to DCP and OSC. To run the program, DCP will need to hire two drug control agents and one staff attorney beginning in the last three months of FY 27, for a partial year salary and other expenses costs of \$84,010 along with associated fringe benefit costs of \$31,147 in FY 27.

Section 36 creates an emergency preparedness and mitigation strategies for prescription drug shortages task force resulting in no fiscal impact to the state because the task force has the expertise to meet the requirements of the bill.

Section 37 expands the Strategic Supply Chain Initiative program, which is funded by General Obligation (GO) bond funds, to include efforts to prevent or mitigate prescription drug shortages.

Future General Fund debt service costs may be incurred sooner under the bill to the degree that it causes authorized GO bond funds to be expended more rapidly than they otherwise would have been.

As of March 1, 2025, there is \$25 million in previously allocated bond funds from Manufacturing Assistance Act program that have been set aside by the Department of Economic and Community Development to fund the Strategic Supply Chain Initiative program.

The bill does not change GO bond authorizations relevant to the program.

Section 38 requires the Department of Public Health (DPH) to convene a Vaccines and Related Biological Products Advisory Committee to coordinate seasonal vaccine production and annually issue a report to the legislature.

DPH will incur costs of \$134,700 in FY 26 and \$130,750 in FY 27 (and annually thereafter), with an estimated cost to the Office of the State Comptroller for associated fringe benefits of \$53,100 in both FY 26 and FY 27 (and annually thereafter). The Department does not currently have the staff necessary to support this advisory committee and would

need to hire additional personnel to meet the bill's requirements.⁴

The costs to DPH reflect the need for one new full-time Epidemiologist 3 to administer the Advisory Committee, at an annualized salary of \$87,000 (plus \$35,400 annualized fringe benefits). Additionally, a half-time (0.5 FTE) Epidemiologist 3 will be responsible for gathering, reviewing, analyzing, and preparing the requisite information needed by the Committee to address the proposed legislation, at an annualized salary of \$43,500 (plus \$17,700 annualized fringe benefits). Further costs associated with these positions are: (1) a one-time equipment cost of \$3,950 in FY 26 for a laptop and related hardware; and (2) an ongoing cost of \$250 in both FY 26 and FY 27 for general office supplies (which continues with inflation into the out years).

The bill also makes various other prescription drug related changes resulting in no fiscal impact to the state.

The Out Years

The full-year potential costs to run the CPDIP (see sections 26-35 above) will begin in FY 28. To run the program there is a potential annual cost to DCP of \$313,538 for salaries and other expenses, along with an associated fringe benefit potential cost of \$124,588.

The annualized ongoing fiscal impact identified above would continue into the future subject to if the CPDIP is implemented, to Medicaid coverage and associated utilization of GLP-1 prescription drugs, emergency Medicaid services, and qualifying individuals under HUSKY C, the number of violations, and inflation.

⁴ It should be noted that current DPH Immunization Program staff are funded through either federal grants or the Insurance Fund. The activities required by the bill are outside the scope of allowable work for these funding sources.

OLR Bill Analysis

sSB 11

AN ACT CONCERNING PRESCRIPTION DRUG ACCESS AND AFFORDABILITY.

TABLE OF CONTENTS:

SUMMARY

<u>§§ 1-3 — IDENTIFIED PRESCRIPTION DRUGS</u>

Caps the price for the sale of identified prescription drugs in the state; generally imposes a civil penalty on pharmaceutical manufacturers and wholesale distributors who violate the cap and requires the DRS commissioner to impose and collect it; and creates a process for penalty disputes

<u>§§ 4 & 5 — STATE DRUG PURCHASING AGENCY PRICE</u> <u>NEGOTIATIONS</u>

Requires UConn Health to negotiate bulk prices for prescription drugs on behalf of the state's drug purchasing agencies in order to buy them at lower cost; requires drug purchasing agencies, when negotiating drug prices with manufacturers, to incorporate the maximum fair price negotiated by CMS; allows drug purchasing agencies to enter compacts with other states for these purposes

<u>§ 6 — PRESCRIPTION DRUG AFFORDABILITY COUNCIL</u>

Creates a council to advise the UConn Health Executive Director and drug purchasing agencies on prescription drug negotiations

<u>§ 7 — NURSING HOME SPENDING ON DIRECT CARE</u>

Generally requires nursing homes, starting in FY 26, to spend at least 80% of their funding on direct resident care provided by nursing personnel; starting in FY 28, allows DSS to decrease Medicaid rates for nursing homes that do not comply

<u>§ 8 — EMERGENCY MEDICAID EXPANSION</u>

Requires DSS to expand emergency Medicaid coverage for certain conditions and create a system allowing people to apply in advance for emergency coverage for treatment in outpatient settings for these conditions

<u>§ 9 — PHASEOUT OF HUSKY C ASSET LIMIT</u>

Requires DSS to increase and then eliminate the HUSKY C asset limit over a five-year period

<u>§§ 10 & 11 — REIMBURSEMENT FOR GENERAL ANESTHESIA</u>

Prohibits health insurance policies from imposing (1) arbitrary time limits on reimbursement for medically necessary general anesthesia or (2) unilateral arbitrary limitations on reimbursement for medically necessary ancillary services

<u>§ 12 — STOP-LOSS INSURANCE POLICIES WITH SELF-FUNDED</u> <u>EMPLOYEE HEALTH PLANS</u>

Requires any stop-loss insurance policies used in conjunction with self-funded employee health benefit plans to either (1) provide specified benefits or (2) have a set minimum individual and aggregate attachment point

<u>§ 13 — GENERIC GLP-1 DRUGS FOR WEIGHT LOSS</u>

Requires DSS to take certain steps to increase access to generic, lower cost forms of GLP-1 drugs

<u>§ 14 — OBESITY DRUG ADVISORY COMMITTEE</u>

Creates an advisory committee to study and make recommendations on ways to maximize access to cost-effective, FDA-approved prescription drugs to treat obesity

§ 15 — MEDICAID COVERAGE OF WEIGHT LOSS DRUGS

Expands Medicaid coverage for weight loss drugs by requiring DSS to cover glucagon-like peptide 1 (GLP-1) prescription drugs to treat obesity under certain circumstances

<u>§ 16 — HEALTH CARRIER REBATE ANNUAL REPORTING</u>

Expands the contents of the insurance commissioner's annual report on health carrier rebates to include certain information on how rebates affected cost sharing

<u>§§ 17 & 18 — 340B PROGRAM</u>

Generally prohibits drug manufacturers from (1) limiting access to 340B drugs for pharmacies contracting with covered entities and (2) requiring pharmacies or covered entities to submit claims or utilization data as a condition for receiving 340B drugs; establishes a hearing process and penalties for violators

<u>§ 19 — "PAY TO DELAY" REPORTING</u>

Requires pharmaceutical manufacturers to annually report to DCP any agreements with a competitor to delay the launch of generic drugs; allows DCP to set penalties for the failure to report

<u> §§ 20-22 — INSULIN PRODUCT INSURANCE COVERAGE</u>

Requires state entities and health benefit plans to cover certain insulin products at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost; allows plans to cover and offer more than one insulin product

<u>§ 23 — PHARMACY BENEFITS MANAGER FIDUCIARY DUTY AND</u> <u>HEALTH CARRIER CONTRACTS</u>

Provides that PBMs owe a fiduciary duty to health carriers or other health plan sponsors and generally prohibits carrier contracts from allowing or requiring a party to violate the carrier's fiduciary duty to insureds

<u>§ 24 — PHARMACY SERVICES CONTRACTS</u>

Prohibits certain provisions in pharmacy services contracts, such as those allowing a PBM to charge a health plan a contracted price that differs from what the PBM pays the pharmacy for the services

<u>§ 25 — HEALTH CARRIER PRICING AND PROFIT REPORTING</u> <u>REQUIREMENTS</u>

Requires the insurance commissioner to require carriers to annually report on pricing offered to, and profit generated between, the carrier and any PBM or mail-order pharmacy

<u>§§ 26-35 — CANADIAN PRESCRIPTION DRUG IMPORTATION</u> <u>PROGRAM</u>

Establishes a Canadian prescription drug importation program; requires the DCP commissioner, on behalf of the state, to seek federal approval to import prescription drugs from Canada for distribution in the state; establishes testing, safety, and quality requirements; drug standards and tracking; establishes requirements for participating suppliers and wholesalers, including documentation, records retention, administrative proceedings, and penalties for violations; and authorizes DCP emergency actions (e.g., recalls), regulations, and reporting

§ 36 — PRESCRIPTION DRUG SHORTAGES TASK FORCE

Creates a task force to study prescription drug shortage preparedness and mitigation

<u>§ 37 — STRATEGIC SUPPLY CHAIN INITIATIVE</u>

Requires DECD to incorporate prescription drug shortage prevention or mitigation into its Strategic Supply Chain Initiative

<u>§ 38 — VACCINES AND RELATED BIOLOGICAL PRODUCTS</u> <u>ADVISORY COMMITTEE</u>

Requires DPH to convene an advisory committee to coordinate seasonal vaccine production along with drug manufacturers

SUMMARY

This bill includes several provisions on prescription drugs, including setting manufacturer and wholesaler price caps for certain drugs, requiring UConn Health to negotiate bulk prices for state agencies, restricting limits on 340B drugs, expanding required reporting, and establishing a Canadian Prescription Drug Importation program, a prescription drug affordability council, a prescription drug shortage task force, and a vaccine and related biological products advisory committee.

It also makes several changes in Medicaid laws, including on nursing home spending requirements, emergency Medicaid expansions, HUSKY C asset limits, and weight loss drugs and treatments.

And, it makes changes in insurance laws, including provisions addressing private insurance coverage of anesthesia, stop-loss insurance policies, reporting requirements, insulin coverage, and pharmacy benefit managers.

These provisions are described in the section-by-section analysis below.

EFFECTIVE DATE: Various; see below.

§§ 1-3 — IDENTIFIED PRESCRIPTION DRUGS

Caps the price for the sale of identified prescription drugs in the state; generally imposes a civil penalty on pharmaceutical manufacturers and wholesale distributors who violate the cap and requires the DRS commissioner to impose and collect it; and creates a process for penalty disputes

The bill sets a (1) cap on the prices for which pharmaceutical manufacturers and wholesale distributors can sell an identified

prescription drug in the state and (2) civil penalty for violators, except for those that made less than \$250,000 in total annual sales in the state for the calendar year for which the penalty is being imposed. It also creates a process by which an aggrieved person can request a hearing to dispute the penalty. An "identified prescription drug" is a (1) brandname drug or biological product for which the patent has expired for at least 24 months, or (2) generic drug or interchangeable biological product.

EFFECTIVE DATE: July 1, 2025

Price Cap on Identified Prescription Drugs (§§ 1 & 2(a))

Increase Based on Consumer Price Index. Starting January 1, 2026, regardless of state statute, the bill prohibits pharmaceutical manufacturers and wholesale distributors from selling an identified prescription drug in the state for more than its reference price, adjusted for any increase in the consumer price index.

Under the bill a "pharmaceutical manufacturer" is a person that manufactures a prescription drug and sells it, directly or through another person, for distribution in the state.

A "wholesale distributor" is a person engaged in the wholesale distribution of prescription drugs. This includes a repacker, own-label distributor, private-label distributor, or independent wholesale drug trader.

A "reference price" is the drug or biological product's wholesale acquisition price. For brand-name drugs or biological products, the reference price is the wholesale acquisition cost on January 1, 2025, or the date the patent expires, whichever is later. For generic drugs or interchangeable biological products, the reference price is the wholesale acquisition cost on January 1, 2025, or the date the drug or product is first commercially marketed in the U.S., whichever is later.

Drug Shortage. The bill makes one exception by allowing manufacturers and distributors to exceed this price, starting January 1,

2026, if the federal Health and Human Services secretary determines that there is a shortage of the drug in the United States and includes it on the drug shortage list.

Civil Penalty for Violating Price Cap (§ 2(b))

The bill imposes a civil penalty on pharmaceutical manufacturers and wholesale distributors that violate the price cap provision above. The civil penalty must be imposed, calculated, and collected by the state on a calendar year basis by the Department or Revenue Services (DRS) commissioner.

Penalty Calculation. The civil penalty amount for a calendar year must be equal to 80% of the difference between the revenue that the pharmaceutical manufacturer or wholesale distributor:

- 1. earned from all sales of the identified prescription drug in the state during the calendar year; and
- 2. would have earned from these sales if the manufacturer or distributor had not sold the drug at a price over the bill's price cap.

Exception. The bill exempts from liability for the above civil penalty, pharmaceutical manufacturers or wholesale distributors of an identified prescription drug that made less than \$250,000 in total annual sales in the state for the calendar year for which the civil penalty would otherwise be imposed.

Penalty Payment and Statement Filing (§ 2(c))

For calendar years starting January 1, 2026, each pharmaceutical manufacturer or wholesale distributor that violates the identified prescription drug price cap during any calendar year must, by March 1 immediately following the end of the calendar year:

- 1. pay the DRS commissioner the civil penalty for that calendar year; and
- 2. file with the DRS commissioner a statement for that calendar

year.

The commissioner must prescribe the statement's form and manner and required information.

Electronic Filing and Wire Transfer. The manufacturer and distributor must file the statement electronically and pay the penalty by electronic funds transfer in the same way as filing and paying tax returns, regardless of whether they would have otherwise been required to do so under the law.

If no statement is filed as required above, the bill allows the DRS commissioner to make the statement at any time according to the best obtainable information and the prescribed form.

Record Examination and Retention (§ 2(d) & (e))

DRS Commissioner's Examination. The commissioner may, as he deems necessary, examine the records of any pharmaceutical manufacturer or wholesale distributor subject to the civil penalty imposed for an identified prescription drug price cap violation described above.

Billing Due to Failure to Pay. After the examination, if the DRS commissioner determines that the pharmaceutical manufacturer or wholesale distributor failed to pay the full amount of the civil penalty, he must bill the pharmaceutical manufacturer or wholesale distributor for the full amount of the civil penalty.

Records Retention. Under the bill, to provide or secure information pertinent to the civil penalty enforcement and collection, the DRS commissioner may require each pharmaceutical manufacturer or wholesale distributor subject to penalty to (1) keep records as the commissioner may prescribe and (2) produce books, papers, documents, and other data.

Investigation. To verify the accuracy of any statement made or, to determine the amount of the civil penalty due if a statement was not

made, the DRS commissioner or his authorized representative may (1) examine the books, papers, records, and equipment of anyone subject to the identified prescription drug price cap provisions and (2) investigate the character of their business.

Aggrieved Company's Request for a Hearing (§ 2(f))

Hearing Application. Any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty and aggrieved by the DRS commissioner's actions above (i.e. making a statement, billing, records examination, and investigation) may apply to the commissioner for a hearing. This must be done in writing within 60 days after the notice of the action is delivered or mailed to the manufacturer or distributor.

The aggrieved pharmaceutical manufacturer or wholesale distributor must state in the application (1) why the hearing should be granted and (2) if they believe they are not liable for the civil penalty or the full amount of the civil penalty, the (a) grounds for the belief and (b) amount by which they believe the civil penalty should be reduced.

Hearing Denied or Granted. The DRS commissioner must promptly consider each application and notify the pharmaceutical manufacturer or wholesale distributor (1) immediately of a hearing denial or (2) of the date, time, and place for a hearing that is granted.

DRS Commissioner's Orders. After the hearing, the commissioner may make orders as appears just and lawful to him and must give a copy to the pharmaceutical manufacturer or wholesale distributor.

Hearing on the DRS Commissioner's Initiative. By notice and in writing, the commissioner may order a hearing on his own initiative and require a pharmaceutical manufacturer or wholesale distributor, or any other person the commissioner believes has relevant information, to appear before him, or his authorized agent, with any specified books of account, papers, or other documents for examination under oath.

Aggrieved Company's Appeal to Superior Court (§ 2(g))

Time Period to Appeal. Within 30 days after the aggrieved pharmaceutical manufacturer or wholesale distributor is served notice of the DRS commissioner's order, decision, determination, or disallowance, the manufacturer or distributor may appeal to the Superior Court for the New Britain judicial district.

Accompanying Citation. The appeal must be accompanied by a citation to the DRS commissioner to appear before the court. The citation must be signed by the same authority and the appeal must be returnable at the same time and served and returned in the same way as required for a summons in a civil action.

Bond or Recognizance With Surety. The authority issuing the citation must take from the appellant a bond or recognizance to the state, with surety, to prosecute the appeal to effect and to comply with the court's orders and decrees.

Equitable Relief. Unless there is a reason otherwise, the appeals must be preferred cases and heard at the first session by the court or by a committee it appoints. The court may (1) grant equitable relief, and (2) if the civil penalty was paid before the relief was granted, order the state treasurer to pay the amount of the relief.

Costs Taxed. If the appeal was made without probable cause, the court may tax double or triple costs, as appropriate. For appeals that are denied, costs may be taxed against the pharmaceutical manufacturer or wholesale distributor, but not against the state, at the court's discretion.

DRS Commissioner's Authority (§ 2(h))

Administer Oaths. The commissioner may administer oaths and take testimony under oath for any inquiry or investigation. The commissioner's agent duly authorized to conduct any inquiry, investigation, or hearing under the provisions above also has these powers.

Subpoena Witnesses and Require Record Production. At any hearing the commissioner ordered, he may subpoena witnesses and require the production of books, papers, and documents relevant to the inquiry or investigation. The commissioner's agent authorized to conduct the hearing and having authority by law to issue the process also has these powers.

A witness under any subpoena authorized to be issued under these provisions must not be excused from testifying or from producing books, papers, or documentary evidence on the ground that the testimony or the production would tend to incriminate the witness, but the books, papers, or documentary evidence produced must not be used in any criminal proceeding against the witness.

Commitment to Community Correctional Center. If anyone disobeys the process or appears but refuses to answer the commissioner's or his agent's questions, the commissioner or the agent may apply to the Superior Court of the judicial district where the pharmaceutical manufacturer or wholesale distributor resides or where the business was conducted, or to any judge of the court if it is not in session, stating the disobedience to process or refusal to answer.

The court or judge must cite the person to appear to answer the question or produce the books, papers, or other documentary evidence and, if they refuse to do so, must commit the person to a community correctional center until they testify, but not for more than 60 days.

Regardless of the person serving the term of commitment, the DRS commissioner may continue the inquiry and examination as if the witness had not previously been called to testify.

Fees and Compensation. Officers who serve subpoenas issued by the DRS commissioner or under his authority and witnesses attending hearings conducted by the commissioner under this provision must receive fees and compensation at the same rates as officers and witnesses in the state courts. This must be paid on vouchers of the DRS commissioner on order of the state comptroller from the proper appropriation for the administration of this provision.

State Collection and Attorney General's Lien Foreclosure (§ 2(i))

State Collection Agency Process. The amount of any unpaid civil penalty under the bill's price cap violations-related provisions may be collected using the process under existing law used by the state collection agency (i.e. the state treasurer; DRS commissioner; any other state official, board, or commission authorized to collect taxes payable to the state; and their duly authorized agents). Under the bill, the warrant issued under the collection process must be signed by the DRS commissioner or his authorized agent.

Lien on Real Property. The amount of the civil penalty must be a lien on the pharmaceutical manufacturer's or wholesale distributor's real property from the last day of the month next preceding the civil penalty's due date until it is paid.

The DRS commissioner may record the lien in the records of the town in which the real property is located, but the lien is not enforceable against a bona fide purchaser or qualified encumbrancer of the real property.

Certificate of Discharge. When the civil penalty for which a lien was recorded is satisfied, the DRS commissioner must, upon request of any interested party, issue a certificate discharging the lien. The discharge certificate must be recorded in the same office in which the lien was recorded.

Foreclosure of the Lien. Any action for the foreclosure of the lien must be brought by the attorney general in the name of the state in the Superior Court for the judicial district in which the real property subject to the lien is located. If the real property is in two or more judicial districts, the action must be brought in the Superior Court for any one of the judicial districts.

The court may limit the time for redemption or order the sale of the real property or make any other decree as it judges equitable.

All civil penalties imposed under this provision can generally be

applied as a reduction against any amount payable by the state to the person, as under existing law related to penalties due from taxpayers.

Officer's and Employee's Liability (§ 2(j))

Willful Failure to Perform. An officer or employee of a pharmaceutical manufacturer or wholesale distributor, who (1) owes a duty, on the manufacturer's or distributor's behalf, to pay the civil penalty, file the required statement with the commissioner, keep records, or supply information to the commissioner and (2) willfully fails to do so must, in addition to any other penalty provided by law, be fined up to \$1,000, imprisoned up to one year, or both.

Regardless of existing limitations of prosecution for certain violations or offenses, the bill sets a three-year statute of limitations for prosecuting officers or employees for violations of these provisions committed on or after January 1, 2026.

Willful Delivery or Disclosure of Fraudulent or False Material. Any officer or employee of a pharmaceutical manufacturer or wholesale distributor who owes a duty, on the manufacturer's or distributor's behalf, to deliver or disclose to the commissioner, or his authorized agent, any list, statement, return, account statement, or other document and willfully delivers or discloses one the officer or employee knows is fraudulent or false in any material matter is guilty of a class D felony, in addition to any other penalty provided by law. (A class D felony is punishable by a fine up to \$5,000, up to five years in prison, or both.)

Under the bill, an officer or employee may not be charged with an offense under both provisions above in relation to the same civil penalty but may be charged and prosecuted for both offenses based on the same information.

Waiver and Tax Credit Prohibited (§ 2(k))

The civil penalty imposed under the bill for violating the identified prescription drug price cap:

1. is excluded from Medicaid provider tax calculations,

- 2. cannot be waived by the Penalty Review Committee under existing law or any other applicable law, and
- 3. cannot be reduced by applying a tax credit.

List of Violators and Implementing Regulations (§ 2(I) & (m))

Starting by July 1, 2027, the bill requires the DRS commissioner to (1) annually prepare a list of the pharmaceutical manufacturers or wholesale distributors that violated the identified prescription drug price cap-related provisions during the preceding calendar year and (2) make each annual list publicly available.

The bill authorizes the commissioner to adopt regulations to implement its provisions related to identified prescription drug pricing and sales.

Withdrawal of Identified Prescription Drug (§ 3)

Required Notice to OHS. If a pharmaceutical manufacturer or wholesale distributor intends to withdraw an identified prescription drug from sale in the state, it must send written notice to the Office of Health Strategy (OHS) disclosing that intention at least 180 days before the withdrawal.

Withdrawal to Avoid Penalty Prohibited. The bill prohibits a pharmaceutical manufacturer or wholesale distributor of an identified prescription drug from withdrawing the identified prescription drug from sale in the state to avoid the bill's civil penalty.

Penalty. Any pharmaceutical manufacturer or wholesale distributor that violates the withdrawal provisions above is liable to the state for a \$500,000 civil penalty.

Background — Related Bill

sSB 6870 (File 308), §§ 11-13, favorably reported by the Insurance and Real Estate Committee, has substantially similar provisions on the sale of identified prescription drugs by pharmaceutical manufacturers and wholesale distributors in the state, including establishing a price cap and civil penalties for violating it.

§§ 4 & 5 — STATE DRUG PURCHASING AGENCY PRICE NEGOTIATIONS

Requires UConn Health to negotiate bulk prices for prescription drugs on behalf of the state's drug purchasing agencies in order to buy them at lower cost; requires drug purchasing agencies, when negotiating drug prices with manufacturers, to incorporate the maximum fair price negotiated by CMS; allows drug purchasing agencies to enter compacts with other states for these purposes

The bill requires the UConn Health Center to negotiate bulk prices for prescription drugs on behalf of itself and other drug purchasing agencies, including the judicial branch and the departments of Children and Families (DCF), Developmental Services, Mental Health and Addiction Services, and Public Health (DPH). UConn Health must do so with the goal to buy these drugs at lower prices than if the agencies each purchased them. The UConn Health Executive Director or his designee must report by September 1, 2025, to the General Law, Human Services, and Public Health committees on any savings achieved through bulk purchasing.

The bill requires these drug purchasing agencies, when negotiating with drug manufacturers to supply drugs for state-subsidized health care programs, to incorporate by reference the maximum fair price negotiated by the federal Centers for Medicare and Medicaid Services (CMS) for certain drugs under the federal Inflation Reduction Act (see *Background — Maximum Fair Price*).

The bill allows these drug purchasing agencies, either when negotiating bulk prices or referencing CMS's maximum fair price, to enter into a compact with officials in other states to increase the state's purchasing power in negotiations.

It also requires these drug purchasing agencies to consider the Prescription Drug Affordability Council's recommendations (see § 6) in these negotiations.

EFFECTIVE DATE: July 1, 2025

Background — Maximum Fair Price

Federal law requires the CMS secretary to negotiate with manufacturers on the maximum fair price of certain drugs covered under Medicare. The secretary must do so for 10 drugs starting in 2026, 15 more for each of the next two years, and 20 additional per year starting in 2028. For the first two years, this only applies to certain drugs under Medicare Part D; in the third year, it extends to Medicare Part B (42 U.S.C. § 1320f et seq.).

§ 6 — PRESCRIPTION DRUG AFFORDABILITY COUNCIL

Creates a council to advise the UConn Health Executive Director and drug purchasing agencies on prescription drug negotiations

The bill establishes a Prescription Drug Affordability Council to advise the UConn Health executive director and drug purchasing agencies on drug negotiations (see §§ 4 & 5).

EFFECTIVE DATE: Upon passage

Council Members, Administration, and Reporting Requirement

The council includes eight members appointed by legislative leaders, as shown in the following table.

Appointing Authority	Appointee Qualifications
House speaker	Hospital organization representative
	Physician organization representative
Senate president pro	Academic who has researched prescription drug affordability
tempore	Representative of organization representing the state's seniors
House majority leader	Representative of physicians who treat patients with rare diseases
Senate majority leader	Unspecified qualifications
House minority leader	Unspecified qualifications
Senate minority leader	Unspecified qualifications

Table: Counc	il Appointed	Members
--------------	--------------	---------

The council also includes the DCF, Consumer Protection (DCP), OHS, Insurance, and Social Services (DSS) commissioners or their designees.

Any of the legislative leaders' appointed members may be legislators.

Appointing authorities must make their initial appointments within 30 days after the bill's passage and fill any vacancy.

The House speaker and Senate president pro tempore must select the task force chairpersons from among its members. The chairpersons must schedule and hold the first meeting within 60 days after the bill's passage. The Human Services Committee's administrative staff must serve in that capacity for the council.

The bill requires the council, starting by January 1, 2026, to annually report its findings and recommendations to the OHS commissioner and the General Law, Human Services, and Public Health committees.

§ 7 — NURSING HOME SPENDING ON DIRECT CARE

Generally requires nursing homes, starting in FY 26, to spend at least 80% of their funding on direct resident care provided by nursing personnel; starting in FY 28, allows DSS to decrease Medicaid rates for nursing homes that do not comply

The bill requires the DSS commissioner, beginning with fiscal year 2026, to require nursing homes to spend at least 80% of their funding from Medicaid, Medicare, and all other payment sources on residents' direct care. However, it allows the commissioner to adjust this percentage for nursing homes with a capital improvement project or fair rent increase DSS approved. Beginning with fiscal year 2028, the commissioner may decrease Medicaid reimbursement for any nursing home that does not comply.

Under the bill, "direct care" means hands-on care nursing personnel provide to facility residents (e.g., help with feeding, bathing, toileting, dressing, lifting or moving residents, or administering medication). It also includes nursing personnel's salary and fringe benefits and the cost of supplies to provide hands-on care. Nursing personnel include advanced practice registered nurses, registered or practical nurses, and nurse's aides.

EFFECTIVE DATE: July 1, 2025

Background — Related Bills

SB 805, favorably reported by the Human Services Committee, also

requires nursing homes to spend at least 80% of their funding on residents' direct care.

SB 1417, favorably reported by the Human Services Committee, establishes a nursing home workforce standards board to set standards for wages and other matters for nursing home employees.

sSB 1415, favorably reported by the Human Services Committee, requires nursing homes to increase the minimum hourly wage for certain employees to \$22.50 by January 1, 2026, and \$25.00 by January 1, 2027.

§ 8 — EMERGENCY MEDICAID EXPANSION

Requires DSS to expand emergency Medicaid coverage for certain conditions and create a system allowing people to apply in advance for emergency coverage for treatment in outpatient settings for these conditions

The bill requires the DSS commissioner to expand, in a way consistent with federal law, Medicaid coverage for treating emergency medical conditions (i.e. emergency Medicaid, see *Background — Emergency Medicaid Coverage*). Under the bill, an "emergency medical condition" is a medical condition, including emergency labor and delivery, with acute symptoms severe enough that it can be expected to result in the following without treatment:

- 1. placing the patient's health in serious jeopardy,
- 2. serious impairment to bodily functions, or
- 3. serious dysfunction of an organ or body part.

The bill lists several conditions that must qualify for emergency Medicaid coverage under the expansion.

The bill also requires the DSS commissioner, by July 1, 2026, to create an administrative system for people to apply in advance for emergency Medicaid coverage for outpatient treatment for emergency medical conditions. The commissioner must include (1) a link to the application and list of covered emergency medical conditions on the DSS website and (2) information about advance applications for emergency Medicaid and a list of covered conditions in DSS forms and policy manuals.

EFFECTIVE DATE: July 1, 2025

Emergency Medical Conditions

Under the bill, DSS's emergency Medicaid expansion must include coverage for the following conditions to the extent allowed by federal law:

- 1. high-risk pregnancy;
- 2. type 1 diabetes in people under age 21;
- 3. diabetic emergencies, including diabetic ketoacidosis;
- 4. renal failure requiring ongoing dialysis;
- 5. a skull, arm, neck, leg, spine, or pelvis fracture that occurred in the two-month period before an emergency Medicaid request;
- 6. hypertensive emergencies in people with symptoms of end organ damage and systolic blood pressure of at least 180 or diastolic blood pressure of at least 120;
- 7. unstable seizure disorder with at least five minutes of uncontrollable seizures or at least two discrete seizures where the person does not regain consciousness between them;
- 8. active cancer treatment;
- 9. ventilator dependency;
- 10. labor and delivery; and

11. acute inpatient or outpatient psychiatric treatment.

Background — Emergency Medicaid Coverage

Under current state policy, emergency Medicaid coverage is

generally limited to treatment after the sudden onset of a medical emergency. It does not cover treatment for chronic conditions, even if the condition may be life threatening. Emergency Medicaid cannot be preapproved, and instead a bill for emergency treatment is submitted to DSS for review.

However, federal law gives states flexibility to define what treatments or conditions qualify for emergency Medicaid coverage within the parameters of the "emergency medical condition" definition above. For example, in 2021 DSS determined that ongoing dialysis for end stage renal disease qualifies for emergency Medicaid coverage because without dialysis, the condition will likely become a medical emergency.

Emergency Medicaid allows hospitals to receive federal Medicaid reimbursement for care that may otherwise be uncompensated. Any person, regardless of immigration status, can qualify for emergency Medicaid coverage if he or she meets Medicaid income and asset limits.

Background — Related Bill

SB 806, favorably reported by the Human Services Committee, also requires DSS to expand Medicaid coverage for treating emergency medical conditions.

§ 9 — PHASEOUT OF HUSKY C ASSET LIMIT

Requires DSS to increase and then eliminate the HUSKY C asset limit over a five-year period

The bill requires the DSS commissioner to increase and then eliminate the HUSKY C asset limit over a five-year period, as shown in the table below. HUSKY C provides Medicaid coverage to people who are age 65 or older, blind, or living with a disability.

Time Period	Single Person	Married Couple
Current law	\$1,600	\$2,400
FY 26	\$10,000	\$15,000

Table: HUSKY C Asset Limit Changes Under the Bill

Time Period	Single Person	Married Couple
FY 27	\$25,000	\$40,000
FY 28	\$75,000	\$100,000
FY 29	\$100,000	\$150,000
FY 30	No Limit	No Limit

The bill also requires the commissioner to allow a person to spend down income that exceeds HUSKY C income limits on incurred medical bills in accordance with federal regulations on Medicaid spend-downs, so long as the person otherwise qualifies for HUSKY C, generally conforming to current practice.

Lastly, the bill requires the commissioner, starting by July 1, 2026, to report annually to the Appropriations and Human Services committees on (1) the number of people eligible for HUSKY C for the prior fiscal year and (2) any increased costs incurred by the state that are attributable to the bill's changes in asset limits.

EFFECTIVE DATE: July 1, 2025

Background — Related Bills

SB 807, favorably reported by the Human Services Committee, also requires DSS to eliminate the asset limit for HUSKY C over a five-year period.

SB 981, favorably reported by the Human Services Committee, requires DSS to disregard certain Social Security income for disabled adult children when determining income eligibility for HUSKY C.

sHB 6911 (File 110), favorably reported by the Aging Committee, requires DSS, starting July 1, 2025, to increase HUSKY C asset limits by at least the same percentage increase as the national consumer price index.

§§ 10 & 11 — REIMBURSEMENT FOR GENERAL ANESTHESIA

Prohibits health insurance policies from imposing (1) arbitrary time limits on reimbursement for medically necessary general anesthesia or (2) unilateral arbitrary limitations on reimbursement for medically necessary ancillary services

The bill prohibits certain individual and group health insurance policies that cover general anesthesia from (1) imposing arbitrary time limits on reimbursement for general anesthesia during a medically necessary procedure or (2) denying, reducing, terminating, or not providing reimbursement for general anesthesia solely because its duration exceeded the insurer's predetermined time limit for the care. It also prohibits the policies from imposing unilateral arbitrary limitations on reimbursement for medically necessary ancillary services.

The bill requires the attending board-certified anesthesiologist to determine the medical necessity of general anesthesia during a medical procedure.

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut on or after January 1, 2026, that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including those provided under an HMO plan. Because of the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: January 1, 2026

Background — Related Bill

sSB 10, §§ 17 & 18, favorably reported by the Insurance and Real Estate Committee, includes the same requirements for medically necessary general anesthesia and ancillary services reimbursements as this bill.

§ 12 — STOP-LOSS INSURANCE POLICIES WITH SELF-FUNDED EMPLOYEE HEALTH PLANS

Requires any stop-loss insurance policies used in conjunction with self-funded employee health benefit plans to either (1) provide specified benefits or (2) have a set minimum individual and aggregate attachment point Generally, employers use stop-loss insurance policies under selffunded plans to protect against catastrophic losses. The threshold for stop-loss coverage is generally referred to as the "attachment point."

The bill requires any stop-loss insurance policy used along with a self-funded employee health benefit plan to either:

- 1. provide essential health benefits required under the federal Affordable Care Act and the group state-mandated coverage requirements under state health insurance laws or
- 2. have a minimum individual attachment point of at least \$75,000 and an aggregate attachment point of at least \$250,000.

(It is unclear whether the first provision above could be enforced, because federal law (ERISA) preempts the state from regulating a self-insured plan's benefits.)

Current Insurance Department guidelines (Bulletin HC-126) prohibit a stop-loss policy from:

- 1. having an annual individual attachment point less than \$20,000;
- 2. for a small employer (i.e. 50 or fewer group members), having an annual aggregate attachment point less than the greater of \$20,000, \$4,000 times the number of covered individuals, or 120% of expected claims;
- 3. for a large employer, having an annual aggregate attachment point less than 110% of expected claims; or
- 4. providing direct coverage for an individual's health care or medical expenses.

EFFECTIVE DATE: January 1, 2026

§ 13 — GENERIC GLP-1 DRUGS FOR WEIGHT LOSS

Requires DSS to take certain steps to increase access to generic, lower cost forms of GLP-1 drugs

The bill requires DSS, within 30 days after the bill's passage, to petition the federal Department of Health and Human Services (HSS) secretary to authorize generic, lower cost forms of glucagon-like peptide GLP-1 drugs (e.g., Ozempic) that are FDA approved to treat obesity or diabetes. (Currently, there are two generic versions of GLP-1 drugs approved to treat diabetes, but none specifically approved to treat obesity.)

Under the bill, if HHS approves the petition, the DSS commissioner must contract with a manufacturer to supply the state with a generic form of these drugs for HUSKY Health members. The commissioner may enter into a consortium with other states in such a contract.

The bill requires the commissioner to develop a strategic plan to maximize access to these drugs and minimize their cost. By December 31, 2025, she must report on the plan to the Human Services Committee and the Obesity Drug Advisory Committee created under the bill (see below).

EFFECTIVE DATE: Upon passage

§ 14 — OBESITY DRUG ADVISORY COMMITTEE

Creates an advisory committee to study and make recommendations on ways to maximize access to cost-effective, FDA-approved prescription drugs to treat obesity

The bill establishes an advisory committee to study ways to maximize access to cost-effective, FDA-approved prescription drugs to treat obesity and make recommendations to DSS.

The committee includes six members, as shown in the following table.

Appointing Authority	Appointee Qualifications
Council on Medical Assistance Program Oversight chairperson	Two patient advocates
DSS commissioner	Two Medicaid-enrolled pharmacists
Human Services	Two medical professionals, including at least one doctor

Table: Obesity	Drug Advisory	Committee Members
----------------	----------------------	--------------------------

Appointing Authority	Appointee Qualifications
Committee chairpersons	certified by the American Board of Obesity Medicine

The bill requires the committee to meet within 30 days after the bill's passage, choose a chairperson, and meet at least bimonthly.

Under the bill, the committee must review DSS's strategic plan on generic GLP-1 drugs (see § 13) and make recommendations to DSS on implementing the plan and the results of its study by January 31, 2026. The committee ends when it submits its recommendations to DSS or on January 31, 2026, whichever is later.

EFFECTIVE DATE: Upon passage

§ 15 — MEDICAID COVERAGE OF WEIGHT LOSS DRUGS

Expands Medicaid coverage for weight loss drugs by requiring DSS to cover glucagon-like peptide 1 (GLP-1) prescription drugs to treat obesity under certain circumstances

Current law requires DSS to provide medical assistance for medical services for Medicaid and HUSKY B beneficiaries with a body mass index over 35, so long as the beneficiaries otherwise meet conditions set by CMS. By law, medical services include FDA-approved prescription drugs to treat obesity on an outpatient basis and nutritional counseling provided by a registered dietitian.

The bill expands this coverage by (1) removing the requirement that beneficiaries meet CMS conditions and (2) specifying that medical services include GLP-1 prescription drugs approved by the FDA for weight loss or commonly used for weight loss, sleep apnea, or to reduce risks of cardiovascular disease. The bill requires the DSS commissioner to continue providing Medicaid coverage for beneficiaries treated with GLP-1 prescription drugs in cases where their BMI drops below 35 if a physician certifies that their BMI would increase above 35 if GLP-1 drugs were discontinued. Existing law and the bill authorize DSS to amend the Medicaid state plan or the Children's Health Insurance Program state plan if needed to implement this coverage.

EFFECTIVE DATE: July 1, 2025

Background — Related Bills

sSB 1474, favorably reported by the Human Services Committee, also expands Medicaid coverage for weight loss drugs.

§ 16 — HEALTH CARRIER REBATE ANNUAL REPORTING

Expands the contents of the insurance commissioner's annual report on health carrier rebates to include certain information on how rebates affected cost sharing

Existing law requires the insurance commissioner to annually report on health carrier rebate practices for the prior year and publish the report on the department's website. The bill expands the required contents of this report to include the (1) percentage of rebate dollars health carriers used to reduce cost-sharing requirements and (2) an evaluation of rebate practices to reduce cost-sharing for health care plans delivered, issued, renewed, amended, or continued.

Under existing law, the report must include (1) an explanation of how carriers accounted for rebates when calculating premiums, (2) a statement disclosing whether and how carriers made rebates available to insureds at the point of purchase, (3) any other way carriers applied rebates, and (4) any other information the commissioner deems relevant.

EFFECTIVE DATE: October 1, 2025

Background — Related Bill

sHB 7192, § 3, favorably reported by the Human Services Committee, has identical provisions on rebate annual reporting.

§§ 17 & 18 — 340B PROGRAM

Generally prohibits drug manufacturers from (1) limiting access to 340B drugs for pharmacies contracting with covered entities and (2) requiring pharmacies or covered entities to submit claims or utilization data as a condition for receiving 340B drugs; establishes a hearing process and penalties for violators

Section 340B of the federal Public Health Service Act (i.e. the 340B Drug Pricing Program) requires drug manufacturers participating in Medicaid to sell certain outpatient prescription drugs at discounted prices to health care organizations that care for uninsured and low-income patients. Pharmacies may contract with 340B-participating

healthcare organizations to also purchase reduced-price outpatient drugs.

The bill prohibits drug manufacturers (including biologics manufacturers), and their agents or affiliates, from directly or indirectly taking any of the following actions:

- 1. denying or limiting access to 340B drugs for a pharmacy contracting or otherwise working with a covered entity (see below) to obtain them on the entity's behalf, unless the pharmacy's receipt of a drug is federally prohibited, or
- 2. requiring a covered entity, or pharmacy contracted with a covered entity, to submit claims or utilization data as a condition for acquiring a 340B drug, unless the claims or data sharing is federally required.

For these restrictions, "covered entities" are the UConn Health Center, federally qualified health centers, family planning clinics, and Ryan White clinics (i.e. clinics that receive specified HIV and AIDSrelated federal funding). (Federal law allows other organizations to participate in the 340B program, such as hospitals that serve a disproportionate number of low-income patients.)

Also, under these provisions, 340B drugs are those that a covered entity (1) purchases under the program and that are subject to the program's pricing requirements or (2) would purchase except for the prohibited conduct.

The bill subjects violators to civil penalties (see below). It also requires the DCP commissioner to adopt implementing regulations.

The bill specifies that its 340B provisions must not be applied in a way that conflicts with, or is less restrictive than, applicable state and federal laws (including the federal law on drug risk evaluation and mitigation strategies (REMSs); see *Background* — *REMS*).

EFFECTIVE DATE: Upon passage

Violations

Beginning July 1, 2025, the bill subjects manufacturers (or their agents or affiliates) to a civil penalty of up to \$50,000 per violation if the DCP commissioner has a reasonable belief, based on received information, that they have violated these provisions or regulations.

The commissioner must issue the violation notice by first-class mail or personal service, and it must include:

- 1. a reference to the law or regulation that has allegedly been violated;
- 2. a short and plain language statement of the matter;
- 3. a description of the activity to cease;
- 4. the penalty amount that may be imposed; and
- 5. an explanation of the right to request, in writing to DCP, a hearing within 10 business days after receiving the notice.

Under the bill, DCP must hold requested hearings as contested case hearings under the Uniform Administrative Procedure Act (UAPA). If after a hearing, DCP finds, by a preponderance of the evidence, that a violation has occurred or that the entity has violated any DCP order, the department must issue a final cease and desist order in addition to any civil penalty imposed.

If the manufacturer, agent, or affiliate does not timely request a hearing, DCP must issue a cease and desist order or impose a civil penalty.

Background — REMS

Federal law authorizes the FDA to require a drug safety program (called "REMS") for certain prescription medications with serious safety concerns to ensure that the medications are used safely and the risks of serious or life-threatening side effects are minimized for patients, pharmacies, and providers (21 U.S.C. § 355-1).

sSB11

§ 19 — "PAY TO DELAY" REPORTING

Requires pharmaceutical manufacturers to annually report to DCP any agreements with a competitor to delay the launch of generic drugs; allows DCP to set penalties for the failure to report

The bill requires pharmaceutical manufacturers doing business in the state to annually report to DCP any "pay to delay" agreements with a competitor and the prescription drugs included in the agreement. Under the bill, these are agreements between a pharmaceutical manufacturer and a competitor to delay launching a generic drug based on an expiring or expired patent for one of the manufacturer's drugs. Manufacturers must report in a form and manner DCP sets.

The bill also requires DCP to adopt implementing regulations. The department also may establish penalties and an administrative hearing process under the UAPA for manufacturers that violate the reporting requirement.

EFFECTIVE DATE: July 1, 2025

§§ 20-22 — INSULIN PRODUCT INSURANCE COVERAGE

Requires state entities and health benefit plans to cover certain insulin products at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost; allows plans to cover and offer more than one insulin product

The bill requires state entities and health benefit plans to make available to beneficiaries an eligible insulin product at the lowest wholesale acquisition cost in a preferred tier with no copayment or other out-of-pocket cost. This applies unless a collective bargaining agreement requires otherwise for the state employee plan. An "eligible insulin product" is an insulin product, including pens or vials, for which at least two licenses have been issued and that continues to be marketed.

Under current law, commercial health benefit plans generally must cap the out-of-pocket cost of insulin at \$25 per 30-day supply.

The bill also allows state entities and health benefit plans to (1) cover more than one eligible insulin product in a preferred tier with no outof-pocket costs and (2) offer, with no out-of-pocket costs, another eligible insulin product if it has a net cost lower than the lowest wholesale acquisition cost. Under the bill, an insulin product's net cost takes into account rebates or discounts, excluding those required under state or federal law or those related to portfolio agreements for purchasing multiple insulin products or other drugs.

For commercial plans, the bill applies the above requirement to high deductible health plans (HDHP) to the maximum extent permitted by federal law. If the HDHP is used to establish a health savings or similar account, the bill applies to the maximum extent permitted by federal law that does not affect the account's tax preferred status.

Because of ERISA, state insurance benefit mandates do not apply to self-insured benefit plans.

EFFECTIVE DATE: January 1, 2026

§ 23 — PHARMACY BENEFITS MANAGER FIDUCIARY DUTY AND HEALTH CARRIER CONTRACTS

Provides that PBMs owe a fiduciary duty to health carriers or other health plan sponsors and generally prohibits carrier contracts from allowing or requiring a party to violate the carrier's fiduciary duty to insureds

The bill provides that pharmacy benefits managers (PBMs) owe a fiduciary duty to any heath carriers (e.g., insurers) or other health benefit plan sponsors (in other words, have the legal duty to act in the carriers' or sponsors' interests). It also provides that PBMs have an obligation of good faith and fair dealing in performing their duties with all parties, including carriers or other plan sponsors they interact with in performing their management services.

Under the bill, a PBM must notify the carrier or other plan sponsor, in writing, if any of the PBM's activities, policies, or practices directly or indirectly present a conflict of interest with its duties under the bill.

The bill also prohibits any health carrier contracts entered into or amended after October 1, 2025, from allowing or requiring a party to violate the fiduciary duty that the carrier owes to the carrier's covered persons (i.e. insureds). This applies despite any contrary provisions in the state's insurance laws and to the maximum extent allowed by law. Under the bill, a violation of any of these provisions is an unfair insurance practice (see *Background — Connecticut Unfair Insurance Practices Act*).

The bill allows the insurance commissioner to adopt implementing regulations.

EFFECTIVE DATE: October 1, 2025

Background — Connecticut Unfair Insurance Practices Act

The law prohibits engaging in unfair or deceptive acts or practices in the business of insurance. It authorizes the insurance commissioner to conduct investigations and hearings, issue cease and desist orders, impose fines, revoke or suspend licenses, and order restitution for per se violations (i.e. violations specifically listed in statute). The law also allows the commissioner to ask the attorney general to seek injunctive relief in Superior Court if he believes someone is engaging in other unfair or deceptive acts not specifically defined in statute.

Fines may be up to (1) \$5,000 per violation to a \$50,000 maximum or (2) \$25,000 per violation to a \$250,000 maximum in any six-month period if the violation was knowingly committed. The law also imposes a fine of up to \$50,000, in addition to or in place of a license suspension or revocation, for violating a cease and desist order (CGS §§ 38a-815 to - 819).

Background — Related Bill

sHB 7192, § 1, favorably reported by the Human Services Committee, contains the same provisions on PBMs' fiduciary duty and carrier contracts.

§ 24 — PHARMACY SERVICES CONTRACTS

Prohibits certain provisions in pharmacy services contracts, such as those allowing a PBM to charge a health plan a contracted price that differs from what the PBM pays the pharmacy for the services

The bill prohibits a pharmacy services contract between a pharmacist or pharmacy and health carrier or PBM from allowing the PBM to charge an in-state health benefit plan a contracted price for any pharmacy services that differs from what the PBM pays the pharmacy (directly or indirectly) for these services (sometimes called a "spread pricing" arrangement).

It further prohibits these contracts from allowing the PBM to charge a health benefit plan, directly or indirectly, a fee that depends on any of the following:

- 1. a prescription drug's wholesale acquisition cost or another price metric for these drugs;
- 2. the amount of savings, rebates, or other fees charged, collected, or generated based on the PBM's business practices; or
- 3. the amount of charged premiums or cost-sharing requirements under the plan that the PBM collects from covered persons.

As under existing law for prohibited provisions in these contracts:

- 1. any contract provision that violates the bill is void and unenforceable, but a provision rendered invalid or unenforceable does not affect remaining provisions;
- 2. any general business practice that violates the bill's provisions is an unfair trade practice under the Connecticut Unfair Trade Practices Act (CUTPA, see *Background — Connecticut Unfair Trade Practices Act*); and
- 3. the insurance commissioner may enforce the bill's provisions and upon request, audit pharmacy services contracts for compliance.

EFFECTIVE DATE: January 1, 2026

Background — Connecticut Unfair Trade Practices Act

By law, CUTPA prohibits businesses from engaging in unfair and deceptive acts or practices. It allows the DCP commissioner, under specified procedures, to issue regulations defining an unfair trade practice, investigate complaints, issue cease and desist orders, order restitution in cases involving less than \$10,000, impose civil penalties of up to \$5,000, enter into consent agreements, ask the attorney general to seek injunctive relief, and accept voluntary statements of compliance. It also allows individuals to sue. Courts may issue restraining orders; award actual and punitive damages, costs, and reasonable attorney's fees; and impose civil penalties of up to \$5,000 for willful violations and up to \$25,000 for a restraining order violation.

Background — Related Bill

sHB 7192, § 2, favorably reported by the Human Services Committee, has identical provisions on pharmacy services contracts.

§ 25 — HEALTH CARRIER PRICING AND PROFIT REPORTING REQUIREMENTS

Requires the insurance commissioner to require carriers to annually report on pricing offered to, and profit generated between, the carrier and any PBM or mail-order pharmacy

Under the bill, the insurance commissioner must require health carriers to annually report on pricing offered to, and profit generated between, the carrier and any PBM or mail-order pharmacy doing business in Connecticut. The commissioner must post a link on the department's website to these reports.

EFFECTIVE DATE: July 1, 2025

Background — Related Bill

sHB 7192, § 4, favorably reported by the Human Services Committee, also requires this annual reporting on carrier pricing.

§§ 26-35 — CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

Establishes a Canadian prescription drug importation program; requires the DCP commissioner, on behalf of the state, to seek federal approval to import prescription drugs from Canada for distribution in the state; establishes testing, safety, and quality requirements; drug standards and tracking; establishes requirements for participating suppliers and wholesalers, including documentation, records retention, administrative proceedings, and penalties for violations; and authorizes DCP emergency actions (e.g., recalls), regulations, and reporting

The bill establishes a Canadian prescription drug importation program under which the DCP commissioner, on behalf of the state, sSB11

would seek federal approval to import prescription drugs from Canada that have the highest potential for cost savings in the state. ("Prescription drug" is a legend drug approved by the federal Food and Drug Administration (FDA), or any successor agency, and prescribed by a health care provider to an individual in the state.)

EFFECTIVE DATE: October 1, 2027, except July 1, 2025, for the provisions that define the applicable terms and require the DCP feasibility study.

Feasibility Study and Report (§ 27)

The bill requires the DCP commissioner to:

- 1. hire, within available resources, a consultant to study the feasibility of establishing a Canadian prescription drug importation program to reduce prescription drug costs in the state; and
- 2. by October 1, 2027, report the findings to the Appropriations, General Law, and Human Services committees and the Office of Policy and Management (OPM).

Food and Drug Administration Approval (§ 28)

Request for FDA Approval. If the DCP commissioner, in consultation with the OPM secretary, determines the program is feasible, the bill authorizes the commissioner to request program approval from the FDA.

At a minimum, the request to the FDA must do the following:

- 1. describe (a) the state's plans for operating the program and (b) any opportunities to coordinate with other states,
- demonstrate that any prescription drug imported and distributed in this state under the program would (a) meet all applicable federal and state standards for safety and effectiveness and (b) comply with all federal tracing procedures, and

- sSB11
- 3. state the estimated program implementation costs.

The bill authorizes the DCP commissioner to spend resources before FDA approval to ensure efficient implementation, but it prohibits the commissioner from actually operating the program without FDA approval.

FDA-Approval Received. If the FDA approves the request, the DCP commissioner must submit a notice disclosing it to the OPM secretary; Social Services and Health Strategy commissioners; and Appropriations, General Law, Human Services, and Public Health committees.

Prescription Drug Importation, Distribution, and Standard (§§ 26, 29 & 30)

Importation and Distribution. If a Canadian prescription drug importation program is established under the bill, participating wholesalers may, subject to the bill's provisions and under the program, import and distribute drugs in this state from a participating Canadian supplier to pharmacies, institutional pharmacies, and qualifying laboratories.

Drug. For purposes of the Canadian prescription drug importation program, "drug" means an article that is:

- 1. recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any of their supplements;
- 2. intended to diagnose, cure, mitigate, treat, or prevent disease in humans;
- 3. not food and intended to affect the structure or any function of the human body; and
- 4. not a device and intended for use as a component of any article specified in those listed above.

Participating Wholesaler. A "participating wholesaler" in the program is designated by DCP to distribute prescription drugs in the manufacturer's original container, obtained from a participating Canadian supplier.

Participating Canadian Supplier. A "participating Canadian supplier" in the program is a Canadian supplier that is exporting prescription drugs, in the manufacturer's original container, to a participating wholesaler for distribution in the state under the program.

Canadian Supplier. A "Canadian supplier" is a manufacturer or wholesale drug distributor licensed or permitted under applicable Canadian law to manufacture or distribute prescription drugs.

An "institutional pharmacy" is the area within a care-giving, correctional, or juvenile training institution where drugs are stored and dispensed under the direct charge of a pharmacist. This area is commonly known as the pharmacy.

Drug Standards. Under the program, participating wholesalers may import and distribute prescription drugs in this state from a participating Canadian supplier under the program if doing so would not violate federal patent laws and the drug meets the FDA's drug safety, effectiveness, misbranding, and adulteration standards.

A drug cannot be imported under the program if it is:

- 1. considered a controlled substance under federal law;
- 2. a biological product (e.g., a virus, therapeutic serum, vaccine, blood, or blood component applied to prevent, treat, or cure a human disease or condition);
- 3. one that is infused, intravenously injected, or inhaled during surgery; or
- 4. a parenteral drug that the federal Health and Human Services secretary determines would pose a threat to the public health if

imported.

Track-and-Trace-Related Requirements (§§ 26 & 31)

Under the program, the DCP commissioner must require participating Canadian suppliers and participating wholesalers to (1) comply with all applicable track-and-trace requirements and (2) make all track-and-trace records available within 48 hours after the commissioner requests them.

"Track-and-trace" is the product tracing process in the federal Drug Quality and Security Act for the components of the pharmaceutical distribution supply chain.

The DCP commissioner must prohibit the distribution, dispensing, or sale outside the state of any prescription drug imported under the program.

Safety and Quality Requirements (§§ 26 & 32(a))

A participating wholesaler under the program must ensure the safety and quality of all drugs imported and distributed in the state under the program.

Drug Requirements. The drugs must (1) be approved for marketing in the United States; (2) not be adulterated or misbranded; and (3) meet all labeling requirements (e.g., content, prominence of information, and designation of established names) under federal law.

Laboratory Testing. Under the bill, "laboratory testing" is a quantitative and qualitative analysis of a drug consistent with the applicable provisions of the official United States Pharmacopoeia.

The bill requires a participating wholesaler to engage a qualifying laboratory (i.e. one in the United States approved by the FDA for purposes of the federal Food Drug and Cosmetic Act) to test for authenticity and degradation a (1) statistically valid sample size for each batch of each drug in the initial shipment and (2) statistically valid sample of the shipment. The laboratory must do testing consistent with the federal Food, Drug and Cosmetic Act.

Laboratory Records Maintenance and Retention Requirements (§ 32(a) & (b))

Under the program, a participating wholesaler must maintain:

- 1. qualifying laboratory records, including complete data derived from all tests necessary to ensure that each drug imported under the program complies with the bill's safety and quality requirements; and
- 2. documentation demonstrating that the required testing was done at a qualifying laboratory consistent with the federal Food, Drug and Cosmetic Act and all other applicable federal and state laws and regulations on qualifying laboratory qualifications.

After a qualifying laboratory submits information and documentation to the participating wholesaler, the wholesaler must keep them for at least three years from the submission date.

Participating Wholesaler Documentation Requirements (§ 32(c))

A participating wholesaler must also maintain the following information for each drug the wholesaler imports and distributes in the state under the program:

- 1. the name and quantity of the drug's active ingredient and a description of the drug's dosage form,
- 2. the date the participating wholesaler received the drug and the price the wholesaler paid,
- 3. the quantity the participating wholesaler received and the drug's point of origin and destination,
- 4. a report on any drug that fails qualifying laboratory testing, and
- 5. any additional information and documentation that the commissioner deems necessary to protect public health.

Participating Supplier Documentation Requirements (§ 32(d))

The DCP commissioner must require each participating Canadian supplier to maintain the following information and documentation for each drug the supplier exports into the state under the program:

- 1. the original source of the drug, including the manufacturer's name and manufacture date and location;
- 2. the shipping date and quantity;
- 3. the quantity of each lot of the drug originally received and the source of the lot;
- 4. the lot or control number and batch number the manufacturer assigned to the drug; and
- 5. any additional information and documentation that the DCP commissioner deems necessary to ensure public health protection.

The supplier must submit the above information and documentation to the commissioner, upon the commissioner's request.

Authorized Emergency Actions for Public Health or Welfare (§ 33)

The bill authorizes the DCP commissioner to issue cease and desist, recall, embargo, or destruction orders to program participants when warranted and subject to administrative proceedings and penalties.

Cease and Desist Order. If the DCP commissioner determines that public health, safety, or welfare requires emergency action, the commissioner may order a participating Canadian supplier, participating wholesaler, relabeler, repacker, and qualifying laboratory to cease and desist from actions specified in the order pending administrative proceedings. The cease and desist order must be in writing and signed by the commissioner and is effective upon delivery

to the respondent.

Administrative Proceeding and Civil Penalty. After a cease and desist order is issued, an administrative proceeding, done according to the Uniform Administrative Procedures Act, must begin promptly. After a hearing, the commissioner may impose a civil penalty up to \$10,000.

Recall, Embargo, or Destruction. The commissioner may require the recall, embargo, or destruction of any drug that was imported and distributed under the program that has been identified as adulterated or misbranded. Any such action must be done according to DCP's process for food, drug, and cosmetic seizures and embargoes in existing law, which includes a hearing and possible civil penalty.

Generally, a drug is deemed adulterated under several circumstances. For example, if it consists of any filthy, putrid, or decomposed substance; or has been produced, prepared, packed, or held under insanitary conditions so that it may have been contaminated with filth or made injurious to health.

Written Notice to Impacted Businesses. If a cease and desist, recall, embargo, or destruction order is issued, the person adversely impacted by the order must notify all other businesses participating in the program of the order. The notice must be in writing.

DCP Regulations and Report to the General Assembly (§§ 34 & 35)

If a Canadian prescription drug importation program is established, the bill allows the DCP commissioner to adopt implementing regulations.

By 180 days after the first importation and biannually after that, the commissioner must submit a report to the Appropriations, General Law, Human Services, and Public Health committees describing the program operation, any violations that resulted in action being taken by the commissioner, and the status of any violation investigations.

Background — Related Bills

sHB 6870 (File 308), §§ 1-10, favorably reported by the Insurance and Real Estate Committee, and sHB 7192, §§ 5-14, favorably reported by the Human Services Committee, both have substantially similar provisions related to establishing a Canadian prescription drug importation program.

§ 36 — PRESCRIPTION DRUG SHORTAGES TASK FORCE

Creates a task force to study prescription drug shortage preparedness and mitigation

The bill creates an ongoing task force to study emergency preparedness and mitigation strategies for prescription drug shortages. The task force must identify drugs at risk of shortage in this state and recommend ways to address that (see below).

EFFECTIVE DATE: Upon passage

Task Force Members, Administration, and Reporting Requirement

The task force includes eight members appointed by the legislative leaders, as shown in the following table. Appointees may be legislators.

Appointing Authority	Appointee Qualifications
House speaker	Expert in prescription drug supply chains
	Expert in federal law on prescription drug shortages
Senate president pro	Representative of hospitals
tempore	Representative of providers who treat patients with rare diseases
House majority leader	Representative of the Mohegan or Mashantucket Pequot tribe
Senate majority leader	Representative of the Mohegan or Mashantucket Pequot tribe
House minority leader	Unspecified qualifications
Senate minority leader	Unspecified qualifications

Table: Task Force Appointed Members

The task force also includes the following officials or their designees: the DCP, economic and community development (DECD), health strategy, insurance, public health, and social services commissioners and UConn Health Center's chief executive officer. Appointing authorities must make their initial appointments within 30 days after the bill's passage and fill any vacancy.

The House speaker and Senate president pro tempore must select the task force chairpersons from among its members. The chairpersons must schedule and hold the first meeting within 60 days after the bill's passage. The Human Services Committee's administrative staff serves in that capacity for the task force.

The bill requires the task force, starting by January 1, 2026, to annually report its findings and recommendations to the General Law, Human Services, Insurance and Real Estate, and Public Health committees. The reports must identify (1) those drugs the task force determines are at risk of shortage and (2) strategies to mitigate these shortages, including ways to increase in-state production of drugs that are at risk of shortage and critically necessary for health care in the state.

Background — Related Bill

sHB 7192, § 15, favorably reported by the Human Services Committee, has substantially similar provisions creating a prescription drug shortages task force.

§ 37 — STRATEGIC SUPPLY CHAIN INITIATIVE

Requires DECD to incorporate prescription drug shortage prevention or mitigation into its Strategic Supply Chain Initiative

The bill requires the DECD commissioner to expand the department's Strategic Supply Chain Initiative to include efforts to prevent or mitigate prescription drug shortages. This must include incorporating the task force's recommendations (see § 36).

Under the bill, this initiative is a DECD-administered program to help state-based companies increase their production capacity to win new business and attract out-of-state and international supply chain operations.

EFFECTIVE DATE: July 1, 2025

Background — Related Bill

HB 7192, § 16, favorably reported by the Human Services Committee, has identical provisions on DECD's Strategic Supply Chain Initiative.

§ 38 — VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Requires DPH to convene an advisory committee to coordinate seasonal vaccine production along with drug manufacturers

The bill requires the public health commissioner to establish and convene a Vaccines and Related Biological Products Advisory Committee to coordinate seasonal vaccine production with pharmaceutical manufacturers.

Under the bill, the commissioner must appoint representatives of the following groups:

- 1. pharmaceutical manufacturers, including one large manufacturer and one small or start-up one;
- 2. health systems, including at least one large or statewide hospital system and one federally qualified health center; and
- 3. physicians, including at least one expert each in infectious disease epidemiology, disease ecology, biostatistics or infectious disease modeling, and an expert in immunology or virology.

The bill requires the committee to meet within 30 days after the bill's passage. The committee has two chairpersons: the DPH commissioner or her designee, and another elected by the committee. The commissioner must fill any vacancy.

Starting by September 1, 2025, the commissioner must annually file a report with the Human Services and Public Health committees on the advisory committee's activities and recommendations and its impact on state preparedness for the annual flu season.

EFFECTIVE DATE: Upon passage

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute Yea 15 Nay 7 (03/13/2025)