

## General Assembly

## Substitute Bill No. 11

January Session, 2025



## 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;
- 11 (4) "Consumer price index" means the consumer price index, annual
- 12 average, for all urban consumers: United States city average, all items,
- 13 published by the United States Department of Labor, Bureau of Labor
- 14 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,
- 16 a comparable index published by the United States Department of

17 Labor, Bureau of Labor Statistics;

LCO 5928 **1** of 52

- (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;
- 25 (6) "Identified prescription drug" means (A) a brand-name drug or 26 biological product for which the patent has expired for at least twenty-27 four months, or (B) a generic drug or interchangeable biological 28 product;
- 29 (7) "Interchangeable biological product" has the same meaning as 30 provided in section 20-619 of the general statutes;
- 31 (8) "Person" has the same meaning as provided in section 12-1 of the 32 general statutes;
- 33 (9) "Pharmaceutical manufacturer" means a person that 34 manufactures a prescription drug and sells, directly or through another 35 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;
- 40 (11) "Reference price" means the wholesale acquisition cost, as 41 defined in 42 USC 1395w-3a, as amended from time to time, of (A) a 42 brand-name drug or biological product (i) on January 1, 2025, if the 43 patent for the brand-name drug or biological product expired on or 44 before said date, or (ii) if the patent for the brand-name drug or 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

LCO 5928 **2** of 52

commercially marketed in the United States after January 1, 2025, on the date such generic drug or interchangeable biological product is first commercially marketed in the United States; and

52

53

54

55

70

71

72

73

74

75

76

- (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.
- Sec. 2. (NEW) (*Effective July 1, 2025*) (a) (1) Notwithstanding any provision of the general statutes and except as provided in subdivision (2) of this subsection, no pharmaceutical manufacturer or wholesale distributor shall, 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.
- (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:
- 77 (A) The revenue that the pharmaceutical manufacturer or wholesale 78 distributor earned from all sales of the identified prescription drug in 79 this state during the calendar year; and

LCO 5928 **3** of 52

(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.
- (c) (1) (A) For calendar years commencing on or after January 1, 2026, each pharmaceutical manufacturer or wholesale distributor that violated the provisions of subsection (a) of this section during any calendar year shall, not later than the first day of March immediately following the end of such calendar year:
- (i) Pay to the commissioner the civil penalty imposed under subsection (b) of this section for such calendar year; and
- (ii) File with the commissioner a statement for such calendar year in a form and manner, and containing all information, prescribed by the commissioner.
- (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 manner provided by chapter 228g of the general statutes, irrespective of whether the pharmaceutical manufacturer or wholesale distributor would have otherwise been required to electronically file such statement or make such payment by electronic funds transfer under

LCO 5928 **4** of 52

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.
- (d) The commissioner may examine the records of any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section as the commissioner deems necessary. If the commissioner determines from such examination that the pharmaceutical manufacturer or wholesale distributor failed to pay the full amount of such civil penalty, the commissioner shall bill such pharmaceutical manufacturer or wholesale 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.
- (2) The commissioner, or the commissioner's authorized representative, may examine the books, papers, records and equipment of any person who is subject to the provisions of this section and may investigate the character of the business of such person to verify the accuracy of any statement made or, if no statement is made by such person, to ascertain and determine the amount of the civil penalty due under subsection (b) of this section.
- (f) Any pharmaceutical manufacturer or wholesale distributor that is subject to the civil penalty imposed under subsection (b) of this section and aggrieved by any action of the commissioner under subdivision (2) of subsection (c) of this section or subsection (d) of this section may apply to the commissioner, in writing and not later than sixty days after the notice of such action is delivered or mailed to such pharmaceutical

LCO 5928 **5** of 52

manufacturer or wholesale distributor, for a hearing, setting forth the reasons why such hearing should be granted and if such pharmaceutical manufacturer or wholesale distributor believes that pharmaceutical manufacturer or wholesale distributor is not liable for such civil penalty or the full amount of such civil penalty, the grounds for such belief and the amount by which such pharmaceutical manufacturer or wholesale distributor believes such civil penalty should be reduced. The commissioner shall promptly consider each such application and may grant or deny the hearing requested. If the hearing request is denied, the commissioner shall immediately notify the pharmaceutical manufacturer or wholesale distributor. If the hearing request is granted, the commissioner shall notify the pharmaceutical manufacturer or wholesale distributor of the date, time and place for such hearing. After such hearing, the commissioner may make such order as appears just and lawful to the commissioner and shall furnish a copy of such order to the pharmaceutical manufacturer or wholesale distributor. The commissioner may, by notice in writing, order a hearing on the commissioner's own initiative and require a pharmaceutical manufacturer or wholesale distributor, or any other person who the commissioner believes to be in possession of relevant information concerning such pharmaceutical manufacturer wholesale distributor, to appear before the commissioner or the commissioner's authorized agent with any specified books of account, papers or other documents for examination under oath.

144

145

146

147148

149

150

151

152

153

154

155

156157

158

159

160

161

162

163

164

165166

167

168

169

170

171

172

173

174

175

176

177

(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 court. Such citation shall be signed by the same authority and such appeal shall be returnable at the same time and served and returned in the same manner as is required in case of a summons in a civil action.

LCO 5928 **6** of 52

The authority issuing the citation shall take from the appellant a bond or recognizance to this state, with surety, to prosecute the appeal to effect and to comply with the orders and decrees of the court. Such appeals shall be preferred cases, to be heard, unless cause appears to the contrary, at the first session, by the court or by a committee appointed by the court. Said court may grant such relief as may be equitable and, if the civil penalty was paid prior to the granting of such relief, may order the Treasurer to pay the amount of such relief. If the appeal was taken without probable cause, the court may tax double or triple costs, as the case demands and, upon all such appeals that are denied, costs may be taxed against such pharmaceutical manufacturer or wholesale distributor at the discretion of the court but no costs shall be taxed against this state.

178

179

180

181

182

183

184

185

186

187

188

189

190

191

192

193

194

195

196

197

198

199

200

201202

203

204

205

206

207

208

209

210

211

(h) The commissioner, and any agent of the commissioner duly authorized to conduct any inquiry, investigation or hearing pursuant to this section, shall have power to administer oaths and take testimony under oath relative to the matter of inquiry or investigation. At any hearing ordered by the commissioner, the commissioner, or the commissioner's agent authorized to conduct such hearing and having authority by law to issue such process, may subpoena witnesses and require the production of books, papers and documents pertinent to such inquiry or investigation. No witness under any subpoena authorized to be issued under the provisions of this section shall be excused from testifying or from producing books, papers or documentary evidence on the ground that such testimony or the production of such books, papers or documentary evidence would tend to incriminate such witness, but such books, papers or documentary evidence so produced shall not be used in any criminal proceeding against such witness. If any person disobeys such process or, having appeared in obedience thereto, refuses to answer any pertinent question put to such person by the commissioner, or the commissioner's authorized agent, or to produce any books, papers or other documentary evidence pursuant thereto, the commissioner, or such agent, may apply to the superior court of the judicial district wherein

LCO 5928 **7** of 52

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

212

213

214

215

216

217

218

219

220

221

222

223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242

243

244

245

(i) The amount of any civil penalty unpaid under the provisions of this section may be collected under the provisions of section 12-35 of the general statutes. The warrant provided under section 12-35 of the general statutes shall be signed by the commissioner or the commissioner's authorized agent. The amount of any such civil penalty shall be a lien on the real property of the pharmaceutical manufacturer or wholesale distributor from the last day of the month next preceding the due date of such civil penalty until such civil penalty is paid. The commissioner may record such lien in the records of any town in which the real property of such pharmaceutical manufacturer or wholesale distributor is situated, but no such lien shall be enforceable against a bona fide purchaser or qualified encumbrancer of such real property. When any civil penalty with respect to which a lien was recorded under the provisions of this subsection is satisfied, the commissioner shall, upon request of any interested party, issue a certificate discharging such lien, which certificate shall be recorded in the same office in which such

LCO 5928 **8** of 52

lien was recorded. Any action for the foreclosure of such lien shall be brought by the Attorney General in the name of this state in the superior court for the judicial district in which the real property subject to such lien is situated, or, if such property is located in two or more judicial districts, in the superior court for any one such judicial district, and the court may limit the time for redemption or order the sale of such real property or make such other or further decree as the court judges equitable. The provisions of section 12-39g of the general statutes shall apply to all civil penalties imposed under this section.

246

247

248

249

250

251

252

253

254

255

256

257

258

259

260

261

262

263

264

265

266

267

268

269

270

271

272

273

274

275

276

277

278

279

(j) (1) Any officer or employee of a pharmaceutical manufacturer or wholesale distributor, who owes a duty to the pharmaceutical manufacturer or wholesale distributor to pay the civil penalty imposed under subsection (b) of this section on behalf of such pharmaceutical manufacturer or wholesale distributor, shall file a statement with the commissioner pursuant to subsection (c) of this section on behalf of such pharmaceutical manufacturer or wholesale distributor and keep records or supply information to the commissioner on behalf of such pharmaceutical manufacturer or wholesale distributor pursuant to this section. Any such officer or employee who wilfully fails, at the time required under this section, to pay such civil penalty, file such statement, keep such records or supply such information on behalf of such pharmaceutical manufacturer or wholesale distributor shall, in addition to any other penalty provided by law, be fined not more than one thousand dollars or imprisoned not more than one year, or both. Notwithstanding the provisions of section 54-193 of the general statutes, no such officer or employee shall be prosecuted for a violation of the provisions of this subdivision committed on or after January 1, 2026, 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

LCO 5928 **9** of 52

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 (b) of this section.
  - (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.
  - (m) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the 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.
- 310 (b) Any pharmaceutical manufacturer or wholesale distributor that

LCO 5928 **10** of 52

- 311 intends to withdraw an identified prescription drug from sale in this
- state shall, at least one hundred eighty days before such withdrawal,
- 313 send advance written notice to the Office of Health Strategy disclosing
- 314 such pharmaceutical manufacturer's or wholesale distributor's
- 315 intention.
- 316 (c) Any pharmaceutical manufacturer or wholesale distributor that
- violates the provisions of subsection (a) or (b) of this section shall be
- 318 liable to this state for a civil penalty in the amount of five hundred
- 319 thousand dollars.
- Sec. 4. (NEW) (Effective July 1, 2025) (a) As used in this section and
- 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
- 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
- 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
- purchases of prescription drugs pursuant to subsection (a) of this
- 336 section.
- 337 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
- 339 Medicare and Medicaid Services for certain prescription drugs under
- 340 the Inflation Reduction Act, P.L. 117-69, and (2) "drug purchasing
- 341 agency" has the same meaning as provided in section 4 of this act. A
- drug purchasing agency shall incorporate by reference maximum fair

LCO 5928 11 of 52

- 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;
  - (2) Two appointed by the president pro tempore of the Senate, one of whom represents an academic who has conducted research into the affordability of prescription drugs and one of whom represents an organization representing senior citizens in the state;
- 367 (3) One appointed by the majority leader of the House of Representatives, who represents physicians who treat patients with rare diseases;
- 370 (4) One appointed by the majority leader of the Senate;

360

361

362

363

364

365

366

371 (5) One appointed by the minority leader of the House of 372 Representatives;

LCO 5928 **12** of 52

- 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
  - 399 shall submit a report on its findings and recommendations to the 400 Commissioner of Health Strategy and the joint standing committees of

(g) Not later than January 1, 2026, and annually thereafter, the council

services shall serve as administrative staff of the council.

397

398

LCO 5928 **13** of 52

- 401 the General Assembly having cognizance of matters relating to general
- 402 law, human services and public health, in accordance with the
- 403 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,
- 406 2025):
- 407 (a) The Commissioner of Social Services shall implement an acuity-
- 408 based methodology for Medicaid reimbursement of nursing home
- services effective July 1, 2022. Notwithstanding section 17b-340, for the
- 410 fiscal year ending June 30, 2023, and annually thereafter, the
- 411 Commissioner of Social Services shall establish Medicaid rates paid to
- 412 nursing home facilities based on cost years ending on September
- 413 thirtieth in accordance with the following:
- 414 (1) Case-mix adjustments to the direct care component, which will be
- based on Minimum Data Set resident assessment data as well as cost
- 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
- 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
- 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
- 426 transition to the new methodology on July 1, 2022. This evaluation may
- 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.
- 430 (2) Beginning July 1, 2022, facilities [will be required to] shall comply
- with collection and reporting of quality metrics as specified by the
- Department of Social Services, after consultation with the nursing home

LCO 5928 **14** of 52

industry, consumers, employees and the Department of Public Health. Rate adjustments based on performance on quality metrics [will] shall be phased in, beginning July 1, 2022, with a period of reporting only. Effective July 1, 2023, the Department of Social Services shall issue individualized reports annually to each nursing home facility showing the impact to the Medicaid rate for such home based on the quality metrics program. A nursing home facility receiving an individualized quality metrics report may use such report to evaluate the impact of the quality metrics program on said facility's Medicaid reimbursement. Not later than June 30, 2025, the department shall submit a report, in accordance with the provisions of section 11-4a, to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies and human services on the quality metrics program. Such report shall include information regarding individualized reports and the anticipated impact on nursing homes if the state were to implement a rate withhold 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 components: (A) Direct costs, which shall include salaries for nursing personnel, related fringe benefits and costs for nursing personnel supplied by a temporary nursing services agency; (B) indirect costs, which shall include professional fees, dietary expenses, housekeeping expenses, laundry expenses, supplies related to patient care, salaries for indirect care personnel and related fringe benefits; (C) fair rent, which shall be defined in regulations adopted in accordance with subsection (b) of this section; (D) capital-related costs, which shall include property taxes, insurance expenses, equipment leases and equipment depreciation; and (E) administrative and general costs, which shall include maintenance and operation of plant expenses, salaries for administrative and maintenance personnel and related fringe benefits. For (i) direct costs, the maximum cost shall be equal to one hundred

LCO 5928 **15** of 52

thirty-five per cent of the median allowable cost of that peer grouping; (ii) indirect costs, the maximum cost shall be equal to one hundred fifteen per cent of the state-wide median allowable cost; (iii) fair rent, the amount shall be calculated utilizing the amount approved pursuant to section 17b-353; (iv) capital-related costs, there shall be no maximum; and (v) administrative and general costs, the maximum shall be equal to the state-wide median allowable cost. For purposes of this subdivision, "temporary nursing services agency" and "nursing personnel" have the 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.
- (6) On or after June 30, 2022, the commissioner may, in the commissioner's discretion and within available appropriations, provide pro rata fair rent increases to facilities which have documented fair rent additions placed in service in the most recently filed cost report that are not otherwise included in the rates issued. The commissioner may provide, within available appropriations, pro rata fair rent increases, which may, at the discretion of the commissioner, include increases for facilities which have undergone a material change in circumstances related to fair rent additions in the most recently filed cost report. The commissioner may allow minimum fair rent as the basis upon which reimbursement associated with improvements to real property is added.
- (7) For the purpose of determining allowable fair rent, a facility with allowable fair rent less than the twenty-fifth percentile of the state-wide allowable fair rent shall be reimbursed as having allowable fair rent 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 excess of eleven per cent shall have such allowance revised to eleven per

LCO 5928 **16** of 52

cent. Any facility or its related realty affiliate which finances or refinances debt through bonds issued by the Connecticut Health and Education Facilities Authority shall report the terms and conditions of such financing or refinancing to the Commissioner of Social Services not later than thirty days after completing such financing or refinancing. The commissioner may revise the facility's fair rent component of its rate to reflect any financial benefit the facility or its related realty affiliate received as a result of such financing or refinancing. The commissioner shall determine allowable fair rent for real property other than land based on the rate of return for the cost year in which such bonds were issued. The financial benefit resulting from a facility financing or refinancing debt through such bonds shall be shared between the state and the facility to an extent determined by the commissioner on a case-by-case basis and shall be reflected in an adjustment to the facility's 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 be determined by the commissioner in accordance with the provisions of this 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,

LCO 5928 **17** of 52

532 2023, unless otherwise authorized under subdivision (1) of this 533 subsection. Notwithstanding section 17-311-52 of the regulations of 534 Connecticut state agencies, for the fiscal years ending June 30, 2024, and June 30, 2025, there shall be no inflationary increases to rates beyond 535 536 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

548

549

550

551

552

553

554

555

556

557558

559

560

561

562563

564

565

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

[(12)] (13) For purposes of computing minimum allowable patient

LCO 5928 **18** of 52

days, utilization of a facility's certified beds shall be determined at a minimum of ninety per cent of capacity, except for facilities that have undergone a change in ownership, new facilities, and facilities which are certified for additional beds which may be permitted a lower occupancy rate for the first three months of operation after the effective date of licensure.

[(13)] (14) Rates determined under this section shall comply with 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.
- Sec. 8. (NEW) (*Effective July 1, 2025*) (a) As used in this section, (1) "emergency medical condition" means a medical condition, including emergency labor and delivery, manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in (A) placing the patient's health in serious jeopardy, (B) serious impairment to bodily functions, or (C) serious dysfunction of any bodily organ or part; and (2) "emergency Medicaid coverage" means Medicaid coverage for treatment of an emergency medical condition.
- (b) The Commissioner of Social Services shall expand emergency Medicaid coverage consistent with federal law for treatment of emergency medical conditions, including, but not limited to, emergency medical conditions related to (1) a high-risk pregnancy, (2) diabetes type 1 in persons under the age of twenty-one, (3) diabetic emergencies, including, but not limited to, diabetic ketoacidosis, (4) renal failure requiring ongoing dialysis, (5) fracture of a bone in the skull, arm, neck, leg, spine or pelvis occurring in the two-month period prior to a request for emergency Medicaid coverage, (6) hypertensive emergencies involving persons presenting with signs or symptoms of end organ damage and systolic blood pressure equaling or exceeding one hundred

LCO 5928 **19** of 52

eighty or diastolic blood pressure equaling or exceeding one hundred twenty, (7) unstable seizure disorder characterized by at least five minutes of uncontrollable seizures or at least two discrete seizures 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

606

607

608

609

610

611

612

613

614

615

620

621

622

623

624

625

626

627

628629

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

LCO 5928 **20** of 52

- 630 dollars;
- 631 (4) For the fiscal year ending June 30, 2029, the commissioner shall 632
- 633 thousand dollars, and (B) married persons to one hundred fifty

increase the asset limit for (A) an unmarried person to one hundred

- 634 thousand dollars; and
- 635 (5) For the fiscal year ending June 30, 2030, and each fiscal year
- 636 thereafter, there shall be no asset limit for unmarried or married
- 637 persons.
- 638 (b) The Commissioner of Social Services shall allow any person,
- 639 whose income exceeds the income limits for the HUSKY C health
- 640 program but who otherwise qualifies, to qualify for the program by
- 641 spending down such person's excess income over the program income
- 642 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:
- 652 (1) "General anesthesia" has the same meaning as provided in section
- 653 20-123a of the general statutes; and
- 654 (2) "Medical necessity" has the same meaning as provided in section
- 655 38a-482a of the general statutes.
- 656 (b) No individual health insurance policy providing coverage of the
- 657 type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469
- 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

LCO 5928 **21** of 52

- policy provides coverage for general anesthesia, (A) impose an arbitrary 660 661 time limit on reimbursement for general anesthesia provided during any medically necessary procedure, or (B) deny, reduce, terminate or 662 663 fail to provide such reimbursement, in whole or in part, for general 664 anesthesia solely because the duration of care exceeded a predetermined 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:
- (1) "General anesthesia" has the same meaning as provided in section
   20-123a of the general statutes; and

674

675

676

677

678

679

680

681

682

683

684

685

686

687

688

689

690

- (2) "Medical necessity" has the same meaning as provided in section 38a-482a of the general statutes.
- (b) No group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state on or after January 1, 2026, shall (1) if such policy provides coverage for general anesthesia, (A) impose an arbitrary time limit on reimbursement for general anesthesia provided during any medically necessary procedure, or (B) deny, reduce, terminate or fail to provide such reimbursement, in whole or in part, for general anesthesia solely because the duration of care exceeded a predetermined time limit as determined by the insurer, or (2) impose unilateral arbitrary limitations on reimbursement for medically necessary 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.

LCO 5928 **22** of 52

Sec. 12. (NEW) (Effective January 1, 2026) Any stop loss insurance policy used in conjunction with a self-funded employee health benefit plan shall: (1) Provide coverage for (A) essential health benefits as 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.

691

692

693

694 695

696

697

698

699

700

701 702

703

704

705

706

707

708

709

710

711

712

713

714

715

716

717

718

719

721

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.
- 720 Sec. 14. (Effective from passage) (a) There is established an advisory committee to (1) study ways to maximize access to cost-effective 722 prescription drugs approved by the federal Food and Drug

LCO 5928 **23** of 52

- 723 Administration for the treatment of obesity, and (2) make
- 724 recommendations concerning implementation of the strategic plan
- developed pursuant to section 13 of this act to the Commissioner of
- 726 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
- 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
- by the American Board of Obesity Medicine, appointed by the Senate
- 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
- shall make recommendations to the commissioner on implementation
- 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.
- Sec. 15. Section 17b-278l of the general statutes is repealed and the
- 747 following is substituted in lieu thereof (*Effective July 1, 2025*):
- 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

LCO 5928 **24** of 52

- dividing an individual's weight in kilograms by the individual's height in meters squared;
- 754 (3) "Medical services" means (A) prescription drugs approved by the 755 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

764

769

770

771

772

773

774 775

776

777

778

779

780

781

- (B) Thirty-five or more if an individual has been diagnosed with a comorbid disease or condition, including, but not limited to, a cardiopulmonary condition, diabetes, hypertension or sleep apnea; [and]
  - (5) "Obesity" means a body mass index of thirty or higher; and
- 765 (6) "Weight loss drugs" means glucagon-like peptide 1 (GLP-1)
  766 prescription drugs approved by the federal Food and Drug
  767 Administration for weight loss or commonly used for weight loss, sleep
  768 appea or to reduce risks of cardiovascular disease.
  - (b) The Commissioner of Social Services shall provide medical assistance for (1) bariatric surgery and related medical services for Medicaid and HUSKY B beneficiaries with severe obesity, and (2) medical services for Medicaid and HUSKY B beneficiaries with a body mass index greater than thirty-five, [provided such beneficiaries otherwise meet conditions set by the Centers for Medicare and Medicaid Services for such surgery and medical services] including weight loss drugs. The commissioner shall continue to provide Medicaid coverage for beneficiaries treated with weight loss drugs if their BMI drops below thirty-five and a licensed physician certifies, in writing, that their BMI would increase above thirty-five if such drugs were discontinued. If necessary, the commissioner may amend the Medicaid state plan and the state plan for the Children's Health Insurance Program to implement

LCO 5928 **25** of 52

782 the provisions of this section.

805

806

807

808

809

810

- Sec. 16. Section 38a-479ttt of the general statutes is repealed and the 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.
- Sec. 17. (NEW) (*Effective from passage*) As used in this section and 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 of 812 the general statutes;

LCO 5928 **26** of 52

- (3) "Covered entity" means The University of Connecticut Health Center, a federally qualified health center, a family planning clinic and a Ryan White clinic;
- (4) "Manufacturer" has the same meaning as provided in section 21a-817 70 of the general statutes, except that such definition shall include 818 manufacturers of biologics;
- 819 (5) "Package" has the same meaning as provided in 21 USC 820 360eee(11)(A); and
- 821 (6) "Pharmacy" has the same meaning as provided in section 20-571 of the general statutes.
- Sec. 18. (NEW) (*Effective from passage*) (a) A manufacturer, or an agent or affiliate of such manufacturer, shall not, either directly or indirectly:
- (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

837

838

839

840

841

842

- (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.
- (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

LCO 5928 **27** of 52

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.

- (2) The manufacturer, or an agent or affiliate of such manufacturer, to whom such notice is provided pursuant to subparagraph (A) of subdivision (1) of this subsection may, not later than ten business days after receipt of such notice, make written application to the Department of Consumer Protection to request a hearing to demonstrate that such violation did not occur. The failure to make a timely request for a hearing shall result in the issuance of a cease and desist order or imposition of a civil penalty by the department. All hearings held under this subsection shall be conducted in accordance with the provisions for contested cases under chapter 54 of the general statutes.
- (3) Following any hearing before the Department of Consumer Protection pursuant to subdivision (2) of this subsection, if the department finds, by a preponderance of the evidence, that any manufacturer, or an agent or affiliate of such manufacturer, violated or is violating any provision of this subsection, any regulation adopted thereunder or any order issued by the department, the department shall issue a final cease and desist order in addition to any civil penalty the department imposes.
- (c) Nothing in this section shall be construed or applied to be in conflict with or less restrictive than:

LCO 5928 **28** of 52

- (1) Applicable federal law and related regulations, including 21 USC
  355-1, as amended from time to time; or
- 877 (2) Other laws of this state to the extent such laws are compatible with applicable federal law.

879

880

881

887

888

889

890

891

892

893

894

895

896

897

898

- (d) The Commissioner of Consumer Protection shall adopt regulations in accordance with the provisions of chapter 54 of the general 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 section 901 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;

LCO 5928 **29** of 52

(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;

905

908

909

910

911

912

913

914

915

916

917

918

919

923

924

925

926

927

928

929

930

931

932

933

934

935

936

- (4) "Net cost" means the cost of an insulin product taking into account rebates or discounts for that specific product, excluding (A) rebates or discounts required by state or federal law, including Medicaid, Medicare and Section 340B of the Public Health Service Act, 42 USC 256b, as amended from time to time, and (B) rebates or discounts related to portfolio agreements that relate to purchase of multiple insulin 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
  - (7) "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.
  - (b) A state entity and health benefit plan shall, except as otherwise required in any collective bargaining agreement affecting the state employee health plan established pursuant to section 5-259 of the general statutes, make available in a preferred tier with no copayment or out-of-pocket cost an eligible insulin product at the lowest wholesale acquisition cost to a beneficiary. Notwithstanding the provisions of this section, if a state entity or health benefit plan determines that another eligible insulin product has a lower net cost than the lowest wholesale acquisition cost, such entity or health plan may offer that product with no out-of-pocket payment to a beneficiary of such state entity or health benefit plan. Nothing in this section shall prevent such entity or health

LCO 5928 **30** of 52

- 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
- of such entity or health benefit plan.
- 940 Sec. 21. Section 38a-492d of the general statutes is repealed and the
- 941 following is substituted in lieu thereof (*Effective January 1, 2026*):
- 942 (a) For the purposes of this section:
- 943 (1) "Diabetes device" has the same meaning as provided in section 20-
- 944 616;
- 945 (2) "Diabetic ketoacidosis device" has the same meaning as provided
- 946 in section 20-616;
- 947 (3) "Glucagon drug" has the same meaning as provided in section 20-
- 948 616;
- 949 (4) "High deductible health plan" has the same meaning as that term
- 950 is used in subsection (f) of section 38a-493;
- 951 (5) "Insulin drug" has the same meaning as provided in section 20-
- 952 616;
- 953 (6) "Noninsulin drug" means a drug, including, but not limited to, a
- 954 glucagon drug, glucose tablet or glucose gel, that does not contain
- 955 insulin and is approved by the federal Food and Drug Administration
- 956 to treat diabetes; and
- 957 (7) "Prescribing practitioner" has the same meaning as provided in
- 958 section 20-571.
- 959 (b) Notwithstanding the provisions of section 38a-492a, each
- 960 individual health insurance policy providing coverage of the type
- 961 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.
- 964 Such coverage shall include, but need not be limited to, coverage for

LCO 5928 **31** of 52

medically necessary:

965

975

976

977

978

987

988

989

990

991

992

993

994

- 966 (1) Laboratory and diagnostic testing and screening, including, but 967 not limited to, hemoglobin A1c testing and retinopathy screening, for 968 all types of diabetes;
- 969 (2) Insulin drugs (A) prescribed by a prescribing practitioner, or (B) 970 prescribed and dispensed pursuant to subsection (d) of section 20-616 971 once during a policy year;
- 972 (3) Noninsulin drugs (A) prescribed by a prescribing practitioner, or 973 (B) prescribed and dispensed pursuant to subsection (d) of section 20-974 616 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
- 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

LCO 5928 **32** of 52

noninsulin drug is a glucagon drug;

995

996

997

998

999

1000

1001

- (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-492a, 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.
- 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)] subsections 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.
- Sec. 22. Section 38a-518d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2026*):
- 1022 (a) For the purposes of this section:
- 1023 (1) "Diabetes device" has the same meaning as provided in section 20-1024 616;

LCO 5928 **33** of 52

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; 1033 (6) "Noninsulin drug" means a drug, including, but not limited to, a 1034 glucagon drug, glucose tablet or glucose gel, that does not contain 1035 insulin and is approved by the federal Food and Drug Administration 1036 to treat diabetes; and 1037 (7) "Prescribing practitioner" has the same meaning as provided in 1038 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; 1049 (2) Insulin drugs (A) prescribed by a prescribing practitioner, or (B) 1050 prescribed and dispensed pursuant to subsection (d) of section 20-616 1051 once during a policy year;

1053 (B) prescribed and dispensed pursuant to subsection (d) of section 20-

1052

LCO 5928 **34** of 52

(3) Noninsulin drugs (A) prescribed by a prescribing practitioner, or

- 616 once during a policy year if the noninsulin drug is a glucagon drug;
- 1055 (4) Diabetes devices in accordance with the insured's diabetes 1056 treatment plan, including, but not limited to, diabetes devices 1057 prescribed and dispensed pursuant to subsection (d) of section 20-616 1058 once during a policy year; and

- 1059 (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 (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;
  - (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.
  - (d) Notwithstanding the provisions of subsection (c) of this section and section 38a-518a, on and after January 1, 2026, any policy described

LCO 5928 **35** of 52

1084 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 1087 in accordance with section 20 of this act.

1085

1086

1088

1089

1090

1091

1092

1093

1094

1095

1096

1097

1098

1099

1100

1101

1102

1103

1104

1105

1106

1107

1108

1109

1110

1111

1112

1113

1114

1115

[(d)] (e) The provisions of [subsection (c)] subsections (c) and (d) of this section shall apply to a high deductible health plan to the maximum extent permitted by federal law, except if such plan is used to establish a medical savings account or an Archer MSA pursuant to Section 220 of 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.

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

LCO 5928 **36** of 52

- entered into or amended by a health carrier shall contain any provision
- 1117 that permits or requires any party to such contract to violate the
- fiduciary duty that such health carrier owes to such health carrier's
- 1119 covered persons.
- (e) Any violation of the provisions of this section shall constitute a
- violation of sections 38a-815 to 38a-819, inclusive, of the general statutes.
- 1122 (f) The Insurance Commissioner may adopt regulations, in
- accordance with the provisions of chapter 54 of the general statutes, to
- implement the provisions of this section.
- 1125 Sec. 24. Section 38a-477cc of the general statutes is repealed and the
- following is substituted in lieu thereof (*Effective January 1, 2026*):
- 1127 (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
- 1130 pharmacist shall:
- 1131 (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
- 1134 an individual purchasing prescription medication of information
- 1135 regarding:
- 1136 (A) The cost of the prescription medication to the individual; or
- 1137 (B) The availability of any therapeutically equivalent alternative
- 1138 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
- 1141 individual; [and]
- 1142 (2) On and after January 1, 2020, contain a provision permitting the
- 1143 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

LCO 5928 **37** of 52

1146	pharmacy or pharmacist, unless such recoupment is permitted under
1147	section 38a-479iii or required by applicable law;
1148	(3) On and after January 1, 2026, contain a provision permitting the
1149	pharmacy benefits manager to charge a health benefit plan in this state
1150	a contracted price for any pharmacy services that differs from the
1151	amount such pharmacy benefits manager, directly or indirectly, pays
1152	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:
1100	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

LCO 5928 **38** of 52

(2) For the purposes of this subsection, "allowable claim amount"

any other source of prescription medication benefits or discounts.

1174

1175

- means the amount the health carrier or pharmacy benefits manager has agreed to pay the pharmacy for the prescription medication.
- 1178 (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:
- 1185 (1) Enforce the provisions of this section pursuant to chapter 697; and
- 1186 (2) Upon request, audit a contract for pharmacy services for compliance with the provisions of this section.
- Sec. 25. (NEW) (*Effective July 1, 2025*) (a) The Insurance Commissioner shall require any health carrier, as defined in section 38a-591a of the general statutes, to report to the commissioner annually on pricing offered to and profit generated between such carrier and any pharmacy benefits manager or mail-order pharmacy doing business with such 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.
- Sec. 26. (*Effective July 1, 2025*) For the purposes of this section and sections 27 to 35, inclusive, of this act, unless the context otherwise 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

LCO 5928 **39** of 52

- import prescription drugs from Canada that have the highest potential 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
- 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
- subparagraphs (A) to (C), inclusive, of this subdivision;
- 1216 (5) "Drug Quality and Security Act" means the federal Drug Quality
- 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
- 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)
- 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;

LCO 5928 **40** of 52

- (11) "Recall" means a person's removal or correction of a marketed product that the department determines is in violation of this section, but "recall" does not include a market withdrawal or a stock recovery, 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.
    - Sec. 27. (Effective July 1, 2025) The Commissioner of Consumer Protection shall 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. Not later than October 1, 2027, the commissioner shall file a report, in accordance with the provisions of section 11-4a of the general statutes, with the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, general law and human services and the Office of Policy and Management on the results of the feasibility study.
    - Sec. 28. (Effective October 1, 2027) (a) If after completion of the study described in section 27 of this act, the Commissioner of Consumer Protection, in consultation with the Secretary of the Office of Policy and Management, determines a Canadian prescription drug importation program is feasible, the Commissioner of Consumer Protection may submit a request to the federal Food and Drug Administration seeking approval for the program under Section 804 of the federal Food, Drug and Cosmetic Act, 21 USC 384(b) to 21 USC 384(h), inclusive, as amended from time to time. If submitted, such request shall, at a

LCO 5928 **41** of 52

1266	minimum		

1285

1286

1287

1288

1289

1290

1291

- 1267 (1) Describe the state's plans for operating the program and describe any opportunities to coordinate or operate the program in coordination 1269 with other states:
- 1270 (2) Demonstrate that any prescription drug that is imported and 1271 distributed in this state under the program would:
- 1272 (A) Meet all applicable federal and state standards for safety and 1273 effectiveness; and
- 1274 (B) Comply with all federal tracing procedures; and
- 1275 (3) State the estimated costs of implementing the program.
- 1276 (b) If the federal Food and Drug Administration approves the 1277 request, the Commissioner of Consumer Protection shall:
- 1278 (1) Submit to the Secretary of the Office of Policy and Management, 1279 and the Commissioners of Social Services and Health Strategy, a notice 1280 disclosing that the federal Food and Drug Administration approved 1281 such request; and
- 1282 (2) Submit to the joint standing committees of the General Assembly 1283 having cognizance of matters relating to appropriations and the budgets 1284 of state agencies, general law, human services and public health a notice disclosing that the federal Food and Drug Administration approved such request.
  - (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 Sec. 29. (Effective October 1, 2027) If the Canadian prescription drug 1293 importation program is established, each participating wholesaler may

LCO 5928 **42** of 52

- import and distribute a prescription drug in this state from a participating Canadian supplier under the program if:
- 1296 (1) Such drug meets the federal Food and Drug Administration's 1297 standards concerning drug safety, effectiveness, misbranding and 1298 adulteration;
- 1299 (2) Importing such drug would not violate federal patent laws; and
- 1300 (3) Such drug is not:
- 1301 (A) A controlled substance, as defined in 21 USC 802, as amended 1302 from time to time;
- 1303 (B) A biological product, as defined in 42 USC 262, as amended from 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 (F) A drug that is a parenteral drug, the importation of which is 1309 determined by the federal Secretary of Health and Human Services to
- pose a threat to the public health.
- 1311 Sec. 30. (Effective October 1, 2027) If a Canadian prescription drug
- 1312 importation program is established, participating wholesalers may,
- 1313 subject to the provisions of sections 31 and 32 of this act, import and
- 1314 distribute drugs in this state from a participating Canadian supplier
- 1315 under the program to:
- 1316 (1) A pharmacy or institutional pharmacy, as defined in section 20-
- 1317 571 of the general statutes; and
- 1318 (2) A qualifying laboratory.
- 1319 Sec. 31. (Effective October 1, 2027) If a Canadian prescription drug

LCO 5928 **43** of 52

- 1320 importation program is established, the Commissioner of Consumer 1321 Protection shall require that each participating Canadian supplier and 1322 participating wholesaler (1) comply with all applicable track-and-trace requirements, and shall not distribute, dispense or sell outside of this 1323 1324 state any prescription drug that is imported into this state under the 1325 program, and (2) make available to the commissioner all track-and-trace 1326 records not later than forty-eight hours after the commissioner requests 1327 such records.
- Sec. 32. (*Effective October 1, 2027*) (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:

13341335

1336

1337

1338

1339

1340

1341

1342

1343

1344

- (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;
- 1349 (4) Maintain qualifying laboratory records, including, but not limited 1350 to, complete data derived from all tests necessary to ensure that each 1351 drug imported into this state under any approved Canadian

LCO 5928 **44** of 52

1352	prescription	drug	importation	program	is	in	compliance	with	the
1353	requirements	of thi	s section; and	1					

- (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;

1360

1361

1362

1363

- 1371 (3) The date on which such participating wholesaler received such 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

LCO 5928 **45** of 52

	Gabattate Dii Noi 11
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;
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	(4) The quantity of each lot of such drug originally received and the
1396	source of such lot;
1397	(5) The lot or control number and the batch number assigned to such
1398	drug by the manufacturer; and
1399	(6) Such additional information and documentation that the
1400	Commissioner of Consumer Protection deems necessary to ensure the
1401	protection of the public health.
4.465	
1402	Sec. 33. (Effective October 1, 2027) (a) If the Commissioner of Consumer
1403	Protection determines that public health, safety or welfare requires

LCO 5928 **46** of 52

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

1404

1405

14061407

- 1408 administrative proceedings. Such cease and desist order shall be (1) in 1409 writing; (2) signed by the Commissioner of Consumer Protection; and 1410 (3) effective upon delivery to the respondent. An administrative 1411 proceeding in accordance with chapter 54 of the general statutes shall 1412 be promptly instituted following a cease and desist order. The 1413 commissioner may impose a civil penalty, in an amount not to exceed 1414 ten thousand dollars, after a hearing conducted pursuant to chapter 54 1415 of the general statutes.
- (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.

1422

1423

1424

1430

14311432

1433

1434

1435

1436

1437

14381439

- 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.
  - Sec. 35. (*Effective October 1, 2027*) Not later than one hundred eighty days after the first importation of any Canadian prescription drug under the importation program begins, and biannually thereafter, the Commissioner of Consumer Protection shall submit a report, in accordance with the provisions of section 11-4a of the general statutes, 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. Such report shall describe (1) the operation of the program, if established, and (2) any violation of sections 29 to 33, inclusive, of this act that resulted in

LCO 5928 **47** of 52

- any action taken by the commissioner pursuant to section 33 of this act 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
- 1444 prescription drug shortages. The task force shall identify prescription
- 1445 drugs at risk of shortage in this state and make recommendations
- 1446 pursuant to subsection (g) of this section.
- (b) The task force shall consist of the following members:
- 1448 (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
- 1451 shortages;
- 1452 (2) Two appointed by the president pro tempore of the Senate, one of
- 1453 whom represents hospitals and one of whom represents health care
- 1454 providers who treat patients with rare diseases;
- 1455 (3) One appointed by the majority leader of the House of
- Representatives, who represents one of the two federally recognized
- 1457 Indian tribes in the state;
- 1458 (4) One appointed by the majority leader of the Senate, who
- represents one of the two federally recognized Indian tribes in the state;
- 1460 (5) One appointed by the minority leader of the House of
- 1461 Representatives;
- 1462 (6) One appointed by the minority leader of the Senate;
- 1463 (7) The Commissioner of Health Strategy, or the commissioner's
- 1464 designee;
- 1465 (8) The Commissioner of Consumer Protection, or the commissioner's
- 1466 designee;
- 1467 (9) The Commissioner of Social Services, or the commissioner's

LCO 5928 **48** of 52

	Substitute Bill No. 11
1468	designee;
1469	(10) The Commissioner of Public Health, or the commissioner's
1470	designee;
1471	(11) The chief executive officer of The University of Connecticut
1472	Health Center, or the chief executive officer's designee;
1473	(12) The Insurance Commissioner, or the commissioner's designee;
1474	and
1475	(13) The Commissioner of Economic and Community Development,
1476	or the commissioner's designee.
1477	(c) Any member of the task force appointed under subdivision (1),
1478	(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.
1483	(e) The speaker of the House of Representatives and the president pro
1484	tempore of the Senate shall select the chairpersons of the task force from
1485	among the members of the task force. Such chairpersons shall schedule
1486	the first meeting of the task force, which shall be held not later than sixty
1487	days after the effective date of this section.
1488	(f) The administrative staff of the joint standing committee of the
1489	General Assembly having cognizance of matters relating to human
1490	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

LCO 5928 **49** of 52

of matters relating to general law, human services, insurance and real

estate and public health, in accordance with the provisions of section 11-4a of the general statutes, including, but not limited to, identification of

1494

1495

1496

- prescription drugs the task force determines are at risk of shortage and strategies that would mitigate these shortages, including methods to increase in-state production of such drugs deemed both at risk of shortage and critically necessary for the provision of health care within 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 Development shall 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.

1515

1516

1517

1518

1519

1520

1521

1522

1523

1524

1525

1526

1527

1528

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

LCO 5928 **50** of 52

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.

1529

1530

1531

1532

1533

1534

1535

1536

15371538

(d) Not later than September 1, 2025, and annually thereafter, the commissioner shall file a report, in accordance with the provisions of section 11-4a of the general statutes, with the joint standing committees of the General Assembly having cognizance of matters relating to human services and public health on the activities and recommendations of the advisory committee and impact on state 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		

LCO 5928 **51** of 52

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.

LCO 5928 **52** of 52