



# Senate

General Assembly

**File No. 577**

February Session, 2004

Substitute Senate Bill No. 295

*Senate, April 14, 2004*

The Committee on Public Health reported through SEN. MURPHY of the 16th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

**AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE  
LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS  
COMMITTEE RELATIVE TO PHARMACY BENEFITS.**

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

1 Section 1. Section 17b-274d of the general statutes, as amended by  
2 section 19 of public act 03-2, section 63 of public act 03-278 and section  
3 83 of public act 03-3 of the June 30 special session, is repealed and the  
4 following is substituted in lieu thereof (*Effective July 1, 2004*):

5 (a) Pursuant to 42 USC 1396r-8, there is established a Medicaid  
6 Pharmaceutical and Therapeutics Committee within the Department of  
7 Social Services. [Said committee shall convene on or before March 31,  
8 2003.] The Commissioner of Social Services shall report monthly, in  
9 accordance with section 11-4a, to the joint standing committees of the  
10 General Assembly having cognizance of matters relating to  
11 appropriations and the budgets of state agencies, public health and  
12 human services and to the Legislative Program Review and

13 Investigations Committee on the activities of the Medicaid  
14 Pharmaceutical and Therapeutics Committee. The commissioner shall  
15 continue to make such monthly reports until such time as a preferred  
16 drug list that includes three classes of drugs, including proton pump  
17 inhibitors and two other classes of drugs as determined by the  
18 commissioner, has been adopted in accordance with subsection (e) of  
19 this section.

20 (b) The Medicaid Pharmaceutical and Therapeutics Committee shall  
21 be comprised as specified in 42 USC 1396r-8 and shall consist of  
22 fourteen members appointed by the Governor. Five members shall be  
23 physicians licensed pursuant to chapter 370, including one general  
24 practitioner, one pediatrician, one geriatrician, one psychiatrist and  
25 one specialist in family planning, four members shall be pharmacists  
26 licensed pursuant to chapter 400j, two members shall be visiting  
27 nurses, one specializing in adult care and one specializing in  
28 psychiatric care, one member shall be a clinician designated by the  
29 Commissioner of Mental Health and Addiction Services, one member  
30 shall be a representative of pharmaceutical manufacturers and one  
31 member shall be a consumer representative. The committee may, on an  
32 ad hoc basis, seek the participation of other state agencies or other  
33 interested parties in its deliberations. The members shall serve for  
34 terms of two years from the date of their appointment. Members may  
35 be appointed to more than one term. The Commissioner of Social  
36 Services, or the commissioner's designee, shall convene the committee  
37 following the Governor's designation of appointments. The  
38 administrative staff of the Department of Social Services shall serve as  
39 staff for said committee and assist with all ministerial duties. The  
40 Governor shall ensure that the committee membership includes  
41 Medicaid participating physicians and pharmacists, with experience  
42 serving all segments of the Medicaid population.

43 (c) Committee members shall select a chairperson and vice-  
44 chairperson from the committee membership on an annual basis.

45 (d) The committee shall meet at least quarterly, and may meet at

46 other times at the discretion of the chairperson and committee  
47 membership. The committee shall comply with all regulations adopted  
48 by the department, including notice of any meeting of the committee,  
49 pursuant to the requirements of chapter 54.

50 (e) [On or before July 1, 2003, the] The Department of Social  
51 Services, in consultation with the Medicaid [and] Pharmaceutical and  
52 Therapeutics Committee, shall adopt a preferred drug list for use in  
53 the Medicaid, state-administered general assistance, HUSKY Plan, Part  
54 A, HUSKY Plan, Part B, Connecticut AIDS drug assistance and  
55 ConnPACE programs. To the extent feasible, the department shall  
56 review all drugs included in the preferred drug list at least every  
57 twelve months, and may recommend additions to, and deletions from,  
58 the preferred drug list, to ensure that the preferred drug list provides  
59 for medically appropriate drug therapies for Medicaid, state-  
60 administered general assistance, HUSKY Plan, Part A, HUSKY Plan,  
61 Part B, Connecticut AIDS drug assistance and ConnPACE patients. For  
62 the fiscal year ending June 30, 2004, such drug list shall be limited to  
63 use in the Medicaid and ConnPACE programs and cover three classes  
64 of drugs, including proton pump inhibitors and two other classes of  
65 drugs determined by the Commissioner of Social Services. [The  
66 commissioner shall notify the joint standing committees of the General  
67 Assembly having cognizance of matters relating to human services and  
68 appropriations of the classes of drugs on the list by January 1, 2004.]  
69 Not later than October 1, 2004, the Department of Social Services, in  
70 consultation with the Medicaid Pharmaceutical and Therapeutics  
71 Committee, shall expand such drug list to include all classes of drugs,  
72 except as provided in subsection (f) of this section.

73 (f) Except for mental-health-related drugs and antiretroviral drugs,  
74 reimbursement for a drug not included in the preferred drug list is  
75 subject to prior authorization. No prior authorization shall be required  
76 if the patient was using a drug not included in the preferred drug list  
77 for the treatment of a chronic illness prior to the adoption of the  
78 preferred drug list.

79 (g) The Department of Social Services shall publish and disseminate  
80 the preferred drug list to all Medicaid providers in the state.

81 (h) The committee shall ensure that the pharmaceutical  
82 manufacturers agreeing to provide a supplemental rebate pursuant to  
83 42 USC 1396r-8(c) have an opportunity to present evidence supporting  
84 inclusion of a product on the preferred drug list unless a court of  
85 competent jurisdiction, in a final decision, determines that the  
86 Secretary of Health and Human Services does not have authority to  
87 allow such supplemental rebates, provided the inability to utilize  
88 supplemental rebates pursuant to this subsection shall not impair the  
89 committee's authority to maintain a preferred drug list. Upon timely  
90 notice, the department shall ensure that any drug that has been  
91 approved, or had any of its particular uses approved, by the United  
92 States Food and Drug Administration under a priority review  
93 classification, will be reviewed by the Medicaid Pharmaceutical and  
94 Therapeutics Committee at the next regularly scheduled meeting. To  
95 the extent feasible, upon notice by a pharmaceutical manufacturer, the  
96 department shall also schedule a product review for any new product  
97 at the next regularly scheduled meeting of the Medicaid  
98 Pharmaceutical and Therapeutics Committee.

99 (i) Factors considered by the department and the Medicaid  
100 Pharmaceutical and Therapeutics Committee in developing the  
101 preferred drug list shall include, but not be limited to, clinical efficacy,  
102 safety and cost effectiveness of a product.

103 (j) The Medicaid Pharmaceutical and Therapeutics Committee may  
104 also make recommendations to the department regarding the prior  
105 authorization of any prescribed drug covered by Medicaid in  
106 accordance with the plan developed and implemented pursuant to  
107 section 17b-491a.

108 (k) Medicaid recipients may appeal any department preferred drug  
109 list determinations utilizing the Medicaid fair hearing process  
110 administered by the Department of Social Services established  
111 pursuant to chapter 54.

112 [(l) The provisions of this section shall apply to the state-  
113 administered general assistance program.]

114 (l) The Commissioner of Social Services shall contract with a  
115 pharmacy benefits organization or a single entity qualified to negotiate  
116 with pharmaceutical manufacturers for supplemental rebates,  
117 available pursuant to 42 USC 1396r-8(c), for drugs listed on the  
118 preferred drug list established pursuant to subsection (e) of this  
119 section.

120 Sec. 2. (NEW) (*Effective July 1, 2004*) (a) Subject to the provisions of  
121 subsection (b) of this section, the Commissioner of Social Services,  
122 upon the renewal of a contract between the Department of Social  
123 Services and a managed care organization providing comprehensive  
124 medical services to the HUSKY Plan, Part A, or HUSKY Plan, Part B,  
125 may assign and consolidate all responsibility for the administration of  
126 pharmacy benefits available under the HUSKY Plan, Parts A and B.  
127 Subject to the provisions of subsection (b) of this section, the  
128 administration of pharmacy benefits available under the HUSKY Plan,  
129 Parts A and B shall be consolidated with the fee-for-service pharmacy  
130 programs administered by the department.

131 (b) Prior to (1) taking any action pursuant to subsection (a) of this  
132 section, (2) issuing a request for proposal pursuant to this section, or  
133 (3) awarding a contract to a managed care organization for  
134 consolidated administration of pharmacy benefits, the commissioner  
135 shall submit the proposal for such action, request for proposal or  
136 contract award to the joint standing committees of the General  
137 Assembly having cognizance of matters relating to human services,  
138 public health and appropriations and the budgets of state agencies for  
139 their approval. Said joint standing committees may approve or  
140 disapprove such action, request for proposal or contract award at  
141 meetings held not later than sixty days after receipt by said joint  
142 standing committees of the proposed action, request for proposal or  
143 contract award. If said joint standing committees take no action with  
144 regard to such action, request for proposal or contract award during

145 such sixty-day period, it shall be deemed approved. Disapproval by  
146 any one of said joint standing committees shall be sufficient to  
147 disapprove the proposed action, request for proposal or contract  
148 award. After such sixty-day period, the chairpersons of the joint  
149 standing committees of the General Assembly having cognizance of  
150 matters relating to human services, public health and appropriations  
151 and the budgets of state agencies shall advise the commissioner of  
152 their approval or disapproval of the proposed action, request for  
153 proposal or contract award.

154 Sec. 3. Section 17b-363a of the general statutes, as amended by  
155 section 1 of public act 03-116 and section 146 of public act 03-6 of the  
156 June 30 special session, is repealed and the following is substituted in  
157 lieu thereof (*Effective July 1, 2004*):

158 (a) Each long-term care facility shall return to the vendor pharmacy  
159 which shall accept, for repackaging and reimbursement to the  
160 Department of Social Services, drug products that were dispensed to a  
161 patient and not used if such drug products are (1) prescription drug  
162 products that are not controlled substances, (2) sealed in individually  
163 packaged units, (3) returned to the vendor pharmacy within the  
164 recommended period of shelf life for the purpose of redispensing such  
165 drug products, (4) determined to be of acceptable integrity by a  
166 licensed pharmacist, and (5) oral and parenteral medication in single-  
167 dose sealed containers approved by the federal Food and Drug  
168 Administration, topical or inhalant drug products in units of use  
169 containers approved by the federal Food and Drug Administration or  
170 parenteral medications in multiple-dose sealed containers approved by  
171 the federal Food and Drug Administration from which no doses have  
172 been withdrawn.

173 (b) Notwithstanding the provisions of subsection (a) of this section:

174 (1) If such drug products are packaged in manufacturer's unit-dose  
175 packages, such drug products shall be returned to the vendor  
176 pharmacy for redispensing and [reimbursement to] such vendor  
177 pharmacy shall reimburse the Department of Social Services if such

178 drugs may be redispensed for use before the expiration date, if any,  
179 indicated on the package.

180 (2) If such drug products are repackaged in manufacturer's unit-  
181 dose or multiple-dose blister packs, such drug products shall be  
182 returned to the vendor pharmacy for redispensing and  
183 [reimbursement to] such vendor pharmacy shall reimburse the  
184 Department of Social Services if: (A) [the] The date on which such drug  
185 product was repackaged, such drug product's lot number and  
186 expiration date are indicated clearly on the package of such  
187 repackaged drug; (B) ninety days or fewer have elapsed from the date  
188 of repackaging of such drug product; and (C) a repackaging log is  
189 maintained by the pharmacy in the case of drug products repackaged  
190 in advance of immediate needs.

191 (3) No drug products dispensed in a bulk dispensing container may  
192 be returned to the vendor pharmacy.

193 (c) Each long-term care facility shall establish procedures for the  
194 return of unused drug products to the vendor pharmacy from which  
195 such drug products were purchased.

196 (d) A vendor pharmacy providing drug products to a long-term  
197 care facility shall provide such drug products in packaging that  
198 facilitates return of unused drug products to the vendor pharmacy in  
199 accordance with subsections (a) and (b) of this section.

200 [(d)] (e) The Department of Social Services (1) shall reimburse [to]  
201 the vendor pharmacy for the reasonable cost of services incurred in the  
202 operation of this section, as determined by the commissioner, and (2)  
203 may establish procedures, if feasible, for [reimbursement to]  
204 reimbursing non Medicaid payors for drug products returned  
205 pursuant to this section.

206 [(e)] (f) The Department of Agriculture and Consumer Protection, in  
207 consultation with the Department of Social Services, shall adopt  
208 regulations, in accordance with the provisions of chapter 54, which

209 shall govern the repackaging and labeling of drug products returned  
210 pursuant to subsections (a) and (b) of this section. The Department of  
211 Agriculture and Consumer Protection shall implement the policies and  
212 procedures necessary to carry out the provisions of this section until  
213 January 1, 2002, while in the process of adopting such policies and  
214 procedures in regulation form, provided notice of intent to adopt the  
215 regulations is published in the Connecticut Law Journal within twenty  
216 days after implementation.

217 [(f)] (g) Any long-term care facility that violates or fails to comply  
218 with the provisions of this section shall be fined [thirty] one thousand  
219 dollars for each incidence of noncompliance. The [commissioner]  
220 Commissioner of Social Services may offset payments due a facility to  
221 collect the penalty. Prior to imposing any penalty pursuant to this  
222 subsection, the commissioner shall notify the long-term care facility of  
223 the alleged violation and the accompanying penalty and shall permit  
224 such facility to request that the department review its findings. A  
225 facility shall request such review [within] not later than fifteen days  
226 [of] after receipt of the notice of violation from the department. The  
227 department shall stay the imposition of any penalty pending the  
228 outcome of the review. The commissioner may impose a penalty upon  
229 a facility pursuant to this subsection regardless of whether a change in  
230 ownership of the facility has taken place since the time of the violation,  
231 provided the department issued notice of the alleged violation and the  
232 accompanying penalty prior to the effective date of the change in  
233 ownership and record of such notice is readily available in a central  
234 registry maintained by the department. Payments of fines received  
235 pursuant to this subsection shall be deposited in the General Fund and  
236 credited to the Medicaid account.

237 [(g)] (h) The Commissioner of Social Services, in consultation with  
238 the pharmacy review panel established in section 17b-362a, as  
239 amended, shall update and expand by June 30, 2003, and annually  
240 thereafter, the list of drugs that are included in the drug return  
241 program. Such list shall include, but not be limited to, the fifty drugs  
242 with the highest average wholesale price that meet the requirements

243 for the program, as established in subsection (a) of this section.

244 Sec. 4. Subsection (a) of section 17b-491 of the general statutes, as  
245 amended by section 14 of public act 03-2, is repealed and the following  
246 is substituted in lieu thereof (*Effective July 1, 2004*):

247 (a) There shall be a "Connecticut Pharmaceutical Assistance  
248 Contract to the Elderly and the Disabled Program" which shall be  
249 within the Department of Social Services. The program shall consist of  
250 payments by the state to pharmacies for the reasonable cost of  
251 prescription drugs dispensed to eligible persons minus a copayment  
252 charge. The pharmacy shall collect the copayment charge from the  
253 eligible person at the time of each purchase of prescription drugs, and  
254 shall not waive, discount or rebate in whole or in part such amount.  
255 The copayment for each prescription shall be as follows:

256 (1) Ten dollars for generic prescription drugs if the participant is (A)  
257 not married and has an annual income of less than twenty thousand  
258 three hundred dollars, or (B) is married and has an annual income that,  
259 when combined with the participant's spouse, is less than twenty-  
260 seven thousand five hundred dollars.

261 ~~[(1) Sixteen dollars and twenty-five cents]~~ (2) Twelve dollars for  
262 brand name prescription drugs if the participant is (A) not married  
263 and has an annual income of less than twenty thousand three hundred  
264 dollars, or (B) is married and has an annual income that, when  
265 combined with the participant's spouse, is less than twenty-seven  
266 thousand five hundred dollars.

267 ~~[(2)]~~ (3) Upon the granting of a federal waiver to expand the  
268 program in accordance with section 17b-492, as amended, the  
269 copayment for brand name prescription drugs shall be [twenty] sixteen  
270 dollars for a participant who is (A) not married and has an annual  
271 income that equals or exceeds twenty thousand three hundred dollars,  
272 or (B) married and has an annual income that, when combined with  
273 the participant's spouse, equals or exceeds twenty-seven thousand five  
274 hundred dollars.

275 Sec. 5. (NEW) (*Effective July 1, 2004*) (a) As used in this section:

276 (1) "Prescription drugs" means (A) legend drugs, as defined in  
277 section 20-571 of the general statutes, as amended, (B) any other drugs  
278 which by state law or regulation require the prescription of a licensed  
279 practitioner for dispensing, except products prescribed for cosmetic  
280 purposes as specified in regulations adopted pursuant to section 17b-  
281 494 of the general statutes, diet pills, smoking cessation gum,  
282 contraceptives, multivitamin combinations, cough preparations and  
283 antihistamines, and (C) insulin, insulin syringes and insulin needles;

284 (2) "State agency" means each state board, authority, commission,  
285 department, office, institution, council or other agency of the state,  
286 including, but not limited to, each constituent unit of higher education  
287 and each public institution of higher education.

288 (b) On or before October 15, 2004, and annually thereafter, each state  
289 agency that purchases prescription drugs shall prepare and submit to  
290 the Office of Policy and Management a report that includes: (1) The  
291 total amounts spent by the state agency on prescription drugs for the  
292 preceding fiscal year, and (2) the total amount of any rebates or credits  
293 received by such agency from prescription drug manufacturers,  
294 wholesalers or group purchasing organizations of which the state is a  
295 participating member. Any state agency with multiple institutions that  
296 purchase prescription drugs shall provide the information required by  
297 this section for each institution.

298 Sec. 6. (NEW) (*Effective July 1, 2004*) (a) For purposes of this section,  
299 "state agency" means each state board, authority, commission,  
300 department, office, institution, council or other agency of the state,  
301 including, but not limited to, each constituent unit of higher education  
302 and each public institution of higher education.

303 (b) The Commissioner of Administrative Services shall require each  
304 state agency that obtains drug products through a contract negotiated  
305 by the Department of Administrative Services and dispenses such  
306 drug products directly to patients to return such drug products that

307 are unused to the vendor pharmacy. The vendor pharmacy shall  
308 accept, for repackaging and reimbursement to any such state agency,  
309 drug products that were dispensed to a patient and not used if such  
310 drug products are (1) prescription drug products that are not  
311 controlled substances, (2) sealed in individually packaged units, (3)  
312 returned to the vendor pharmacy within the recommended period of  
313 shelf life for the purpose of redispensing such drug products, (4)  
314 determined to be of acceptable integrity by a licensed pharmacist, and  
315 (5) oral and parenteral medication in single-dose sealed containers  
316 approved by the federal Food and Drug Administration, topical or  
317 inhalant drug products in units of use containers approved by the  
318 federal Food and Drug Administration or parenteral medications in  
319 multiple-dose sealed containers approved by the federal Food and  
320 Drug Administration from which no doses have been withdrawn.

321 (c) Notwithstanding the provisions of subsection (b) of this section:

322 (1) If such drug products are packaged in manufacturer's unit-dose  
323 packages, such drug products shall be returned to the vendor  
324 pharmacy for redispensing and such vendor pharmacy shall reimburse  
325 such state agency if such drugs may be redispensed for use before the  
326 expiration date, if any, indicated on the package.

327 (2) If such drug products are repackaged in manufacturer's unit-  
328 dose or multiple-dose blister packs, such drug products shall be  
329 returned to the vendor pharmacy for redispensing and such vendor  
330 pharmacy shall reimburse such state agency if: (A) The date on which  
331 such drug product was repackaged, such drug product's lot number  
332 and expiration date are indicated clearly on the package of such  
333 repackaged drug; (B) ninety days or fewer have elapsed from the date  
334 of repackaging of such drug product; and (C) a repackaging log is  
335 maintained by the pharmacy in the case of drug products repackaged  
336 in advance of immediate needs.

337 (3) No drug products dispensed in a bulk dispensing container may  
338 be returned to the vendor pharmacy.

339 (d) The Department of Administrative Services shall establish  
340 procedures for the return of unused drug products to the vendor  
341 pharmacy from which such drug products were purchased.

342 (e) A state agency that obtains and dispenses drug products, as  
343 provided in subsection (b) of this section, shall reimburse the vendor  
344 pharmacy for the reasonable cost of services incurred in the operation  
345 of this section, as determined by the Commissioner of Administrative  
346 Services.

347 (f) The Department of Agriculture and Consumer Protection, in  
348 consultation with the Department of Administrative Services, shall  
349 adopt regulations, in accordance with the provisions of chapter 54 of  
350 the general statutes, which shall govern the repackaging and labeling  
351 of drug products returned pursuant to subsections (b) and (c) of this  
352 section.

This act shall take effect as follows:	
Section 1	July 1, 2004
Sec. 2	July 1, 2004
Sec. 3	July 1, 2004
Sec. 4	July 1, 2004
Sec. 5	July 1, 2004
Sec. 6	July 1, 2004

**PH** Joint Favorable Subst.

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

**OFA Fiscal Note**

**State Impact:**

Agency Affected	Fund-Effect	FY 05 \$	FY 06 \$
Department of Social Services	GF - Savings	Significant	Significant
Various State Agencies	GF - Savings	Potential	Potential

**Municipal Impact:** None

**Explanation**

This bill implements some of the recommendations of the Program Review and Investigations Committee concerning state funded pharmacy benefits. The bill has the following impacts:

**Section one** requires the Department of Social Services (DSS) to report to the General Assembly monthly on the activities of the Medicaid Pharmaceutical and Therapeutics Committee. This requirement will result in additional minimal administrative costs to DSS.

**Sections one and two** require DSS, upon renewal of the current Medicaid Managed Care contracts, to carve out pharmaceutical expenditures for the managed care population and combine them with the current fee-for-service pharmacy expenditures. DSS is then required to contract with a single entity qualified to negotiate with pharmaceutical manufacturers for supplemental rebates through the preferred drug list (PDL). These sections also require DSS to extend the PDL to all eligible classes of drugs in FY05. The current FY05 budget reflects savings of \$15 million related to the implementation of the preferred drug list on three classes of drugs. It is estimated that expanding the PDL to all classes of drugs could result in an additional FY05 savings of up to \$25 million under the Medicaid and ConnPACE

programs. This estimate assumes that the combined savings from full implementation of the PDL will be approximately ten percent of the current services costs.

However, the bill specifies that no prior authorization will be required if a patient was already using a drug to treat a chronic illness that is not included on the preferred drug list prior to the adoption of the list. This provision may significantly reduce the potential savings of the preferred drug list depending upon the number of drugs that would be exempted from prior authorization, which is required if any savings are to be achieved. It is estimated that 60% to 70% of the drugs that would otherwise be subject to prior authorization would be exempt under this provision.

These sections further require DSS to extend the PDL currently being developed for the Medicaid program to the State Administered General Assistance and Connecticut AIDS Drug Assistance programs. The combined pharmaceutical expenditures under these programs are estimated to be \$37.5 million for FY05. Assuming that full implementation of the PDL results in savings of ten percent over current services expenditure levels, the extension of this list to SAGA and CADAP could result in additional savings of \$3.75 million in FY05.

Section 2 also requires DSS to submit proposals for any action related to the PDL to the Appropriations, Human Services and Public health committees of the General Assembly prior to implementation. Any one of these committees may disapprove of the proposal. This provision may delay, or if the committees disapprove of a proposal, eliminate a portion of the savings that can be achieved through the PDL.

**Section three** contains several initiatives intended to increase compliance, and therefore savings, under the nursing home drug return program. The bill requires that vendor pharmacies provide drugs to long term care facilities in packaging that facilitates the return of unused drugs. The bill further lowers the fine that can be assessed

on a nursing home for failure to participate in the drug return program from \$30,000 for each incidence to \$1,000 for each incidence. Since its inception in 1998, it is estimated that this program has saved \$1.4 million through the return of unused drugs. If the measures included in this section increase compliance under the program, additional savings will result. The extent of these savings cannot be determined at this time.

**Section four** establishes a two-tiered co-payment system (\$10 for generic drugs, \$12 for brand name drugs) for the ConnPACE Program, effective July 1, 2004. Participants currently pay a \$16.25 co-payment for each covered prescription. DSS will experience an annual cost of \$5.1 - \$6.0 million commencing in FY 05 in response to this policy change. This cost is primarily attributable to the agency having to pay an additional \$6.25 per prescription for the estimated forty six percent (46%) of prescriptions covered by ConnPACE that are generic (for a total of approximately \$3.3 million) and \$4.25 per prescription for the remaining fifty four percent (54%) that are brand name (approximately \$2.6 million).

These costs would be supplemented to the extent that generic drugs costing in excess of \$10 and brand name drugs costing in excess of \$12 but less than \$16.25, which previously would not have been subsidized by DSS, would now be (at a cost of approximately \$600,000). Offsetting savings of between \$500,000 - \$1.4 million would result based on an estimated two to six percent (2 - 6%) increase in the generic drug penetration rate, due to price differentials between brand name drugs having generic alternatives and those generic products.

**Section five** requires that any state agency that purchases prescription drugs must annually submit to the Office of Policy and Management (OPM) the total amount spent on such purchases and the total amount of rebates or credits generated by these purchases. This requirement will result in additional minimal administrative costs to any agency that purchases pharmaceuticals.

**Section six** requires the Department of Administrative Services

(DAS) to require each state agency that obtains drugs through a contract negotiated by DSS and that directly administers drugs to patients to return any unused products to the vendor pharmacy. This program would be similar to the nursing home drug return program. This provision is likely to lead to savings to any state agencies that participate. The extent of these savings will be dependent upon the volume of returned drugs as well as the compliance among agencies and vendors. These savings cannot be estimated at this time.

Under the bill, the DAS would be responsible for developing procedures for the return of unused or outdated drugs to the vendor pharmacy. This will result in a workload increase for DAS, which will not require additional funding.

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**OLR Bill Analysis**

sSB 295

**AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE RELATIVE TO PHARMACY BENEFITS****SUMMARY:**

This bill requires the Department of Social Services (DSS) to make several changes related to its preferred drug list (PDL). It must (1) expand the required three-drug-class PDL to include all classes of drugs by October 1, 2004 and apply the expanded list to all DSS-administered pharmacy assistance programs, (2) make monthly reports to legislative committees until the three-drug-class PDL is adopted, and (3) contract with a pharmacy benefits organization or other entity to negotiate for supplemental prescription rebates once the PDL is established. Under current law, drugs not on the PDL, with certain exceptions, will require prior authorization. The bill, in addition, exempts those drugs that a patient was using for a chronic illness before adoption of the PDL.

The bill also:

1. (a) allows the DSS commissioner, when renewing existing contracts for HUSKY A and B with managed care organizations, to consolidate the programs' pharmacy benefits administration and assign it to an entity at her discretion, (b) requires DSS to consolidate HUSKY A and B pharmacy benefits administration with all the DSS-administered fee-for-service pharmacy programs, and (c) prescribes procedures for legislative committees' approval or disapproval of DSS's consolidation proposals;
2. replaces the current \$16.25 per-prescription copayment under the Connecticut Pharmaceutical Assistance Contract to the Elderly and Disabled (ConnPACE) with a two-tiered system of a \$12 copay for brand name prescription drugs and \$10 for generics (it also lowers, from \$20 to \$16 for brand name drugs and \$10 for generics, the current law's potential copay for higher-income participants if the federal government approves a pending Medicaid waiver request to expand ConnPACE income limits (see BACKGROUND);

3. modifies certain aspects of the Nursing Home Drug Return Program and creates a new state agency drug return program; and
4. requires state agencies to submit reports to the Office of Policy and Management (OPM) on the prescription drug expenditures, rebates, and credits.

EFFECTIVE DATE: July 1, 2004

## **PREFERRED DRUG LIST**

### ***Preferred Drug List Applicability to DSS Programs and Monthly Reports***

The FY 2002-03 budget revision act (PA 03-2, § 19) required DSS to adopt a PDL for its medical assistance programs by July 1, 2003 in consultation with the recently created Medicaid Pharmaceutical and Therapeutics Committee. PA 03-3, § 83, June 30 Special Session, specified that the PDL is for use in the Medicaid, ConnPACE, and State-Administered General Assistance (SAGA) programs, but it limited the list for FY 2003-04 to three classes of drugs, including proton pump inhibitors and two other classes the DSS commissioner chooses. It required the commissioner to notify the Human Services and Appropriations committees of the drug classes chosen by January 1, 2004.

The bill requires the DSS commissioner, until a PDL has been adopted, to report monthly on the activities of the Medicaid Pharmaceutical and Therapeutics Committee to the Appropriations, Public Health, Human Services, and Legislative Program Review and Investigations committees.

The bill limits use of the three-drug-class PDL to the Medicaid and ConnPACE programs for FY 2003-04. Under current law, the list also applies to SAGA. By October 1, 2004, the bill requires DSS, in consultation with the Medicaid Pharmaceutical and Therapeutics Committee, to expand the list to include all classes of drugs, with certain exceptions, and to apply it to all the DSS pharmacy assistance programs (ConnPACE, Medicaid, HUSKY Parts A and B, SAGA, and the Connecticut AIDS Drug Assistance Program).

Under current law, all drugs not on the PDL will be subject to prior authorization, except for mental health-related drugs and antiretroviral drugs. The bill adds another exception for drugs not on the list that a patient was using for a chronic illness before the list was adopted.

### **Pharmacy Benefit Organization and Supplemental Rebate Negotiations**

The bill requires the commissioner to contract with a pharmacy benefits organization or a single entity qualified to negotiate with pharmaceutical manufacturers for supplemental rebates available under federal law for drugs on the PDL (42 U.S.C.A. § 1396r-8(c)).

### **HUSKY AND FEE-FOR-SERVICE PHARMACY BENEFITS ADMINISTRATION CONSOLIDATION**

The bill allows the commissioner, when renewing contracts between DSS and managed care organizations (MCOs) serving HUSKY A and B clients, to assign and consolidate all administrative responsibility for pharmacy benefits under the programs. And it requires DSS to consolidate the administration of HUSKY pharmacy benefits with the department's fee-for-service pharmacy programs. Currently, HUSKY A and B pharmacy benefits are administered by the individual MCOs.

Before undertaking any action to implement the consolidation, issuing a request for proposal under these provisions, or awarding a contract to a managed care organization for consolidated pharmacy benefits administration, the bill requires the DSS commissioner to submit the proposed actions to the Appropriations, Public Health, and Human Services committees. Under the bill, the committees may approve or disapprove the proposed actions within 60 days after receiving the proposals. If the committees take no action within the 60-day period, the proposal is considered approved. Disapproval by any one committee is sufficient to disapprove the proposal. After the 60-day period, the bill requires the committees' chairmen to advise the commissioner of their approval or disapproval.

### **NURSING HOME DRUG RETURN PROGRAM CHANGES**

With respect to the state's nursing home drug return program, the bill:

1. requires pharmacies providing drugs to nursing homes to do so in

- packaging that facilitates the return of unused drugs to the pharmacy under the drug return program;
2. reduces the per-incident fine for failure to return drugs or other violations of the law from \$30,000 to \$1,000;
  3. allows the commissioner to expand the number of unused drugs that must be returned to more than the current 50; and
  4. makes several technical changes and clarifications concerning the program.

### **NEW STATE AGENCY DRUG RETURN PROGRAM**

The bill creates a drug return program for state agencies similar to the existing nursing home drug return program and the Department of Corrections drug return program (which is run by the UConn Health Center). Specifically, the bill requires the Department of Administrative Services (DAS) commissioner to require each agency that obtains drugs through a DAS-negotiated contract and dispenses them directly to patients to return any unused drugs to the vendor pharmacy. It requires the vendor pharmacy to take the drugs back for repackaging and reimbursement to the agency if the drugs are:

1. not controlled substances;
2. sealed in individually packaged units;
3. returned so they can be redispensed within the recommended shelf life;
4. determined to be of acceptable integrity by a licensed pharmacist; and
5. oral and parenteral (such as injectable) medication in single-dose sealed containers approved by the federal Food and Drug Administration (FDA), topical or inhalant drug products in FDA-approved units of use containers, or parenteral medication in multiple-dose FDA-approved sealed containers from which no doses have been used.

But, regardless of the above requirements, the bill requires the agencies

to return these unused drugs to the vendor pharmacy for redispensing and the pharmacy to reimburse the agency if the drugs are:

1. packaged in manufacturer's unit-dose packages and can be redispensed for use before they expire or
2. repackaged in manufacturer's unit-dose or multiple-dose blister packs and (a) the repackaging date, the drug's lot number, and its expiration date are clearly marked on the repackaged drug; (b) 90 days or fewer have elapsed from the repackaging date; and (c) the pharmacy maintains a repackaging log for those repackaged in advance of immediate need.

The bill prohibits return of drugs dispensed in bulk dispensing containers.

It requires DAS to establish procedures for these drug returns and requires the state agencies to reimburse the vendor pharmacies for the reasonable cost of services incurred in the drug return program's operation, as the DAS commissioner determines.

The bill also requires the Department of Agriculture and Consumer Protection (DACP), in consultation with DAS, to adopt regulations governing the returned drugs' repackaging and labeling.

#### **STATE AGENCY DRUG PURCHASE REPORTING REQUIREMENTS**

The bill requires each state agency that purchases prescription drugs to prepare and submit a report to OPM annually, beginning October 15, 2004. It requires the agencies to list total amounts of:

1. agency prescription drug expenditures for the preceding fiscal year and
2. rebates or credits the agency received from manufacturers, wholesalers, or group purchasing organizations of which the state is a participating member.

Any agency with multiple institutions that purchase drugs must list the required information for each institution. Under the bill, "state agency" means each state board, authority, commission, department,

office, institution, council, or other agency of the state, including each constituent unit of higher education and each public institution of higher education. The bill, for reporting purposes, excludes from the prescription drug definition products prescribed for cosmetic purposes, diet pills, smoking cessation gum, contraceptives, multivitamin combinations, cough preparations, and antihistamines.

## **BACKGROUND**

### ***Legislative History***

On March 24, the Senate referred the bill (File 82) to the Public Health Committee, which favorably reported out a substitute bill on March 31. The Public Health Committee's substitute bill (1) changes the starting date for the expanded PDL from July 1, 2004 to October 1, 2004, (2) adds the Public Health Committee to the list of legislative committees that must receive the DSS commissioner's monthly progress reports until the initial three-drug-class PDL is adopted, (3) adds the exception to prior authorization for drugs that are not on the list but that a patient was using for a chronic illness before the list was adopted, (4) allows rather than requires consolidation of HUSKY A and B pharmacy benefits administration at contract renewal time, and (5) adds procedures for legislative approval of consolidation proposals. It also lowers the ConnPACE copay for brand name drugs from \$16.25 to \$12 and makes related changes. Finally, it removes a duplicative provision in the bill concerning regulations for the state agency drug return program and makes other minor changes.

### ***Prior Authorization***

On July 16, 2003, DSS began implementing a prior authorization (PA) program for drugs dispensed under the Medicaid, ConnPACE, SAGA, and General Assistance pharmacy programs.

PA means that before a patient enrolled in any of these programs can get certain drugs, and before pharmacists can get reimbursed for them, DSS must approve the prescription. (DSS has contracted with a company, ACS Healthcare, to run this program.) PA is now required when DSS clients have prescriptions for:

1. with one exception, brand-name drugs when a chemically equivalent generic is available;

2. early refills; and
3. drugs costing more than \$500 for a 30-day supply.

Individuals who were already taking atypical antipsychotic drugs on July 16, 2003 and continue to need them can receive these drugs without PA. But patients who need these drugs for the first time after July 16, 2003 must get PA.

For brand-name drugs or for early refills of controlled drugs, the prescribing practitioner must request PA. For all others, the pharmacist requests PA.

### ***Nursing Home Drug Return Program***

Under this program, nursing homes must return certain unused prescriptions (individually packaged unit dose medications for about 50 of the most commonly used drugs) for their Medicaid residents to the pharmacies that dispense them. The pharmacies may return the drugs to stock (in new packages) and resell them before they expire. DSS must reimburse pharmacies for processing each returned medication (currently \$5).

Facilities that violate this requirement are currently subject to a \$30,000 fine for each incident of noncompliance. The DSS commissioner can deduct the fine from a facility's Medicaid reimbursement. Fines collected must be deposited in the General Fund and credited to the Medicaid account.

PA 03-116 required the DSS commissioner annually to update and expand the list of drugs included in the program beginning by June 30, 2003. It required the list to include the 50 drugs with the highest average wholesale price that meet the program's requirements.

### ***Related Bills***

sSB 352 (File 398), reported favorably by the Public Health Committee on March 16, also, among other provisions, (1) expands the PDL and the programs it applies to as of October 1, 2004 and (2) exempts drugs the patient was using for chronic illness before the PDL is adopted from prior authorization even though they are not on the PDL.

sHB 5041 (PA 04-6), passed by the House and Senate on March 24 and signed by the governor on March 30, updates the ConnPACE income limits in statute to 2004 levels (they are adjusted for inflation annually by regulation). It further deletes the language in statute concerning potential higher income limits and copays if federal approval is received for a Medicaid waiver to expand ConnPACE income limits, which this bill (sSB 295) modifies to reduce the copayment for the higher income groups in that event.

**COMMITTEE ACTION**

Program Review and Investigations Committee

Joint Favorable Report

Yea 11    Nay 0

Public Health Committee

Joint Favorable Substitute

Yea 21    Nay 1