



General Assembly

Substitute Bill No. 295

February Session, 2004

* SB00295HS 043004 *

**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3 83 of public act 03-3 of the June 30 special session, is repealed and the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	<i>July 1, 2004</i>
Sec. 2	<i>July 1, 2004</i>
Sec. 3	<i>July 1, 2004</i>
Sec. 4	<i>July 1, 2004</i>
Sec. 5	<i>July 1, 2004</i>
Sec. 6	<i>July 1, 2004</i>

PH *Joint Favorable Subst.*

APP *Joint Favorable*

HS *Joint Favorable*