



House of Representatives

General Assembly

File No. 441

January Session, 2005

Substitute House Bill No. 6970

House of Representatives, April 19, 2005

The Committee on Public Health reported through REP. SAYERS of the 60th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

**AN ACT ESTABLISHING A COLLABORATIVE DRUG THERAPY
MANAGEMENT AGREEMENT PILOT PROGRAM.**

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

1 Section 1. Subsection (a) of section 20-631 of the general statutes is
2 repealed and the following is substituted in lieu thereof (*Effective*
3 *October 1, 2005*):

4 (a) (1) One or more pharmacists licensed under this chapter who are
5 determined eligible in accordance with subsection (c) of this section,
6 and employed by a hospital may enter into a written protocol-based
7 collaborative drug therapy management agreement with one or more
8 physicians licensed under chapter 370 to manage the drug therapy of
9 individual patients receiving inpatient services in a hospital licensed
10 under chapter 368v, in accordance with subsections (b) to (d),
11 inclusive, of this section and subject to the approval of the hospital.
12 Each patient's collaborative drug therapy management shall be
13 governed by a written protocol specific to that patient established by

14 the treating physician in consultation with the pharmacist.

15 (2) One or more pharmacists licensed under this chapter who are
16 determined eligible in accordance with subsection (c) of this section
17 and employed by or under contract with a nursing home facility, as
18 defined in section 19a-521, may enter into a written protocol-based
19 collaborative drug therapy management agreement with one or more
20 physicians licensed under chapter 370 to manage the drug therapy of
21 individual patients receiving services in a nursing home facility, in
22 accordance with subsections (b) to (d), inclusive, of this section and
23 subject to the approval of the nursing home facility. Each patient's
24 collaborative drug therapy management shall be governed by a
25 written protocol specific to that patient established by the treating
26 physician in consultation with the pharmacist. Each such protocol shall
27 be reviewed and approved by the active organized medical staff of the
28 nursing home in accordance with the requirements of section 19-13-
29 D8t(i) of the Public Health Code.

30 (3) One or more pharmacists licensed under this chapter who are
31 determined eligible in accordance with subsection (c) of this section
32 and employed by or under contract with a hospital licensed under
33 chapter 368v may enter into a written protocol-based collaborative
34 drug therapy management agreement with one or more physicians
35 licensed under chapter 370 to manage the drug therapy of individual
36 patients receiving outpatient hospital care or services for diabetes,
37 asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart
38 failure or smoking cessation, including patients who qualify as
39 targeted beneficiaries under the provisions of Section 1860D-
40 4(c)(2)(A)(ii) of the federal Social Security Act, in accordance with
41 subsections (b) to (d), inclusive, of this section and subject to the
42 approval of the hospital. Each patient's collaborative drug therapy
43 management shall be governed by a written protocol specific to that
44 patient established by the treating physician in consultation with the
45 pharmacist.

46 Sec. 2. *(Effective from passage)* Not later than January 1, 2006, the

47 Commissioners of Public Health and Consumer Protection, in
48 consultation with the Commission of Pharmacy, shall establish and
49 operate a two-year pilot program to allow not more than ten
50 pharmacists licensed under chapter 400j of the general statutes who are
51 determined eligible in accordance with subsection (c) of this section
52 and employed by or under contract with a licensed community
53 pharmacy, to enter into a written protocol-based collaborative drug
54 therapy management agreement with one or more physicians licensed
55 under chapter 370 of the general statutes, to manage the drug therapy
56 of individual patients receiving drug therapy for diabetes, asthma,
57 hypertension, hyperlipidemia, osteoporosis, congestive heart failure or
58 smoking cessation, including patients who qualify as targeted
59 beneficiaries under the provisions of Section 1860D-4(c)(2)(A)(ii) of the
60 federal Social Security Act, in accordance with subsections (b) to (d),
61 inclusive, of this section and subject to the approval of the licensed
62 community pharmacy. Each patient's collaborative drug therapy
63 management shall be governed by a written protocol specific to that
64 patient established by the treating physician in consultation with the
65 pharmacist.

66 (b) A collaborative drug therapy management agreement may
67 authorize a pharmacist to implement, modify or discontinue a drug
68 therapy that has been prescribed for a patient, order associated
69 laboratory tests and administer drugs, all in accordance with a patient-
70 specific written protocol. Each protocol developed, pursuant to the
71 collaborative drug therapy management agreement, shall contain
72 detailed direction concerning the actions that the pharmacist may
73 perform for that patient. The protocol shall include, but need not be
74 limited to, (1) the specific drug or drugs to be managed by the
75 pharmacist, (2) the terms and conditions under which drug therapy
76 may be implemented, modified or discontinued, (3) the conditions and
77 events upon which the pharmacist is required to notify the physician,
78 and (4) the laboratory tests that may be ordered. All activities
79 performed by the pharmacist in conjunction with the protocol shall be
80 documented in the patient's medical record. The pharmacist shall
81 report to the physician through oral, written or electronic manner

82 regarding the implementation, administration, modification or
83 discontinuation of a drug therapy that has been prescribed for a
84 patient not later than twenty-four hours after such implementation,
85 administration, modification or discontinuation. The collaborative
86 drug therapy management agreement and protocols shall be available
87 for inspection by the Departments of Public Health and Consumer
88 Protection. A copy of the protocol shall be filed in the patient's medical
89 record.

90 (c) In order to be selected for participation in the program, a
91 pharmacist shall be responsible for demonstrating, in accordance with
92 this subsection, the competence necessary for participation in each
93 drug therapy management agreement into which such pharmacist may
94 enter. The pharmacist's competency shall be determined by the
95 Commission of Pharmacy using criteria based on the continuing
96 education requirements of sections 20-599 and 20-600 of the general
97 statutes.

98 (d) The Commissioner of Public Health, in consultation with the
99 Commissioner of Consumer Protection and the Commission of
100 Pharmacy, shall evaluate the pilot program established under this
101 section and shall submit a report of the commissioner's findings and
102 recommendations to the joint standing committees of the General
103 Assembly having cognizance of matters relating to public health,
104 human services and general law, not later than December 31, 2008, in
105 accordance with the provisions of section 11-4a of the general statutes.
106 Such report shall include an evaluation of the data collected with
107 respect to improved medication management and cost savings, based
108 on patient outcomes.

109 (e) Records or information collected or maintained pursuant to this
110 section shall not be disclosed pursuant to subsection (a) of section 1-
111 210 of the general statutes for a period of six months from the date
112 such records or information were created or collected and shall not be
113 subject to subpoena or discovery or introduced into evidence in any
114 judicial or administrative proceeding except as otherwise specifically

115 provided by law.

116 (f) For purposes of this section, "community pharmacy" means a
117 pharmacy licensed under section 20-594 of the general statutes that
118 stores and dispenses legend drugs, as defined by section 20-571 of the
119 general statutes, and legend devices, as defined by said section 20-571,
120 and from which related pharmaceutical care services are provided,
121 primarily to noninstitutionalized patients living in a community
122 setting.

| | | |
|---|------------------------|-------------|
| This act shall take effect as follows and shall amend the following sections: | | |
| Section 1 | <i>October 1, 2005</i> | 20-631(a) |
| Sec. 2 | <i>from passage</i> | New section |

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 06 \$ | FY 07 \$ |
|---|--------------|-----------------|-----------------|
| Public Health, Dept. | GF - Cost | 22,150 - 43,500 | 28,500 - 57,000 |
| Consumer Protection, Dept. | GF - None | None | None |
| Social Services, Dept. | GF - Savings | Potential | Potential |
| Comptroller Misc. Accounts (Fringe Benefits) | GF - Cost | 4,835 - 9,670 | 15,365 - 30,730 |

Note: GF=General Fund

Municipal Impact: None

Explanation

This bill makes changes concerning collaborative drug therapy management agreements between physicians and pharmacists. Fiscal impacts associated with each of the bill's sections are as follows:

Section 1 allows pharmacists employed by or under contract with a hospital to enter into collaborative agreements with physicians to manage drug therapy of individuals receiving outpatient hospital care or services for diabetes, asthma, hypertension, hyperlipidemia, osteoporosis, congestive heart failure or smoking cessation. No fiscal impact will result for either the Departments of Public Health (DPH) or Consumer Protection (DCP).

Savings may result for the Medicaid program under the Department of Social Services. If this program reduces adverse pharmaceutical reactions and improves the health outcomes of patients, utilization of more costly health care services by Medicaid clients may be reduced. The extent of these savings will be dependent upon the number of patients involved with these collaborative practices and the level of success in improving health outcomes, which cannot be determined in advance.

Section 2 establishes a two-year pilot program under which up to ten pharmacists employed by or under contract to a community pharmacy may enter into a collaborative drug therapy management agreement with physicians to manage drug therapy of patients being treated for the same seven conditions listed above. The Commission of Pharmacy must determine each participating pharmacist's competence. The pilot program shall be implemented not later than January 1, 2006, and the DPH must conduct an evaluation in consultation with the DCP and submit findings and recommendations by December 31, 2008.

The DPH will incur FY 06 costs of between \$22,150 to \$43,500 to support the three-quarter year salary of one-half to one (0.5 - 1) Health Program Associate and related one-time equipment costs. This position would be needed to review patient-specific drug management protocols and medical records with the purpose of determining whether the pilot program leads to improved medication management and cost savings. The lesser cost figure would be incurred if a small number of patients are involved in the pilot project. The greater cost would result if a larger number of patients are involved.

In FY 07 these costs would rise to \$28,500 - \$56,950 to reflect full year compensation for this position. Fringe benefit costs of \$4,835 - \$9,670 in FY 06 and \$15,365 - \$30,730 in FY 07 would also be incurred.¹

It is anticipated that the DCP will assist the DPH in evaluating the pilot project by devoting existing pharmaceutical staff resources to this endeavor.

¹ The fringe benefit costs for state employees are budgeted centrally in the Miscellaneous Accounts administered by the Comptroller. The estimated fringe benefit reimbursement rate as a percentage of payroll is 53.91%, effective July 1, 2004. However, first year fringe benefit costs for new positions do not include pension costs lowering the rate to 22.65%. The state's pension contribution is based upon the prior year's certification by the actuary for the State Employees Retirement System.

OLR Bill Analysis

sHB 6970

AN ACT ESTABLISHING A COLLABORATIVE DRUG THERAPY MANAGEMENT AGREEMENT PILOT PROGRAM**SUMMARY:**

This bill expands the settings in which pharmacists and physicians can enter into collaborative practice agreements to manage patients' drug therapy. Under current law, physicians and hospital pharmacists, as well as pharmacists working in nursing homes and physicians, can enter into such collaborative agreements. Hospital-based agreements are limited to inpatient drug therapies. These agreements must be based on patient-specific written protocols and must be approved by the hospital and nursing home, respectively. The protocols can authorize a pharmacist to implement, modify, or discontinue a drug therapy the physician describes, as well as order associated lab tests and administer drugs. The law requires the hospital or nursing home facility employing the pharmacist to determine his competency to participate in the collaborative agreement.

The bill allows hospital pharmacists to enter into written protocol-based collaborative drug therapy agreements to manage the drug therapy of patients receiving outpatient hospital care or services for (1) diabetes, (2) asthma, (3) hypertension, (4) hyperlipidemia, (5) osteoporosis, (6) congestive heart failure, or (7) smoking cessation. Patients can include those who qualify as targeted beneficiaries under the new Medicare Part D prescription drug benefit. The protocols must be patient-specific and established by the treating physician in consultation with the pharmacist. The hospital must determine the pharmacist's competency to participate.

The bill also establishes a pilot program for collaborative drug therapy arrangements between physicians and community pharmacies.

EFFECTIVE DATE: October 1, 2005, except that the pilot program provisions take effect upon passage

PILOT PROGRAM

Program Basics and Eligibility

The bill requires the public health and consumer protection commissioners, in consultation with the Commission of Pharmacy, to establish a two-year pilot program allowing collaborative drug therapy agreements between physicians and pharmacists employed by or under contract with community pharmacies. They must establish it by January 1, 2006. A "community pharmacy" is a licensed pharmacy storing and dispensing prescription drugs and devices and providing pharmaceutical care services primarily to noninstitutionalized patients living in a community setting.

The pilot program is for up to 10 pharmacists working in community pharmacies. As with the other collaborative drug therapy management agreements allowed by law, the program must be based on patient-specific written protocols established by the treating physician in consultation with the pharmacist.

The program permits drug therapy management of patients with any of the conditions listed above for the outpatient setting, including patients qualifying as targeted beneficiaries under the Medicare Part D prescription drug benefit.

The collaborative agreements entered into under the pilot program must meet the same standards and requirements covering existing agreements in the other settings discussed above. The commission must determine the competency of pharmacists seeking to participate in the program, based on existing continuing education requirements for pharmacists.

Report to Legislature

The public health and consumer protection commissioners and the Pharmacy Commission must evaluate the pilot program and report to the Public Health, Social Services, and General Law committees by December 31, 2008.

The report must evaluate the data collected on improved medication management and cost savings, based on patient outcomes. The bill prohibits disclosing, under a freedom of information request, records

or information collected or maintained for six months from the date they were created or collected. Also, this information is not subject to subpoena or discovery and cannot be introduced into evidence in any judicial or administrative proceeding except as allowed by law.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 25 Nay 1