Senate

General Assembly

File No. 213

February Session, 2022

Substitute Senate Bill No. 186

Senate, March 30, 2022

The Committee on General Law reported through SEN. MARONEY of the 14th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING COLLABORATIVE DRUG THERAPY MANAGEMENT AGREEMENTS AND POLICIES.

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

Section 1. Section 20-631 of the 2022 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(a) For the purposes of this section:

(1) "Care-giving institution" has the same meaning as provided in section 20-571;

(2) "Commissioner" means the Commissioner of Consumer Protection;

(3) "Collaborative drug therapy care plan" means a written document memorializing the outcome of the process through which a patient and one or more health care providers discuss, review and agree on an approach to achieve the patient's desired health outcome;

(4) "Collaborative drug therapy management agreement" means an agreement between one or more qualified pharmacists and one or more prescribing practitioners to manage the drug therapy of individual patients, or a patient population, based on a written protocol or a collaborative drug therapy care plan;

(5) "Collaborative drug therapy management policy" means a written policy adopted by a care-giving institution under which one or more qualified pharmacists manage the drug therapy of individual patients, or a patient population, based on a written protocol or a collaborative drug therapy care plan;

(6) "Pharmacist" has the same meaning as provided in section 20-571;

(7) "Prescribing practitioner" has the same meaning as provided in section 20-571;

(8) "Provider-patient relationship" means a relationship between a prescribing practitioner and a patient in which (A) the patient has made a medical complaint, (B) the patient has provided such patient's medical history, (C) the patient has received a physical examination, and (D) there exists a logical connection between such medical complaint, medical history and physical examination and any drug prescribed for such patient; and

(9) "Qualified pharmacist" means a pharmacist who (A) is deemed competent under regulations adopted by the commissioner pursuant to subsection (e) of this section, and (B) has reviewed the latest edition of the "Pharmacists' Patient Care Process" published by the Joint Commission of Pharmacy Practitioners.

[(a)**]** (b) Except as provided in section 20-631b, one or more qualified pharmacists **[**licensed under this chapter who are determined competent in accordance with regulations adopted pursuant to subsection (d) of this section**]** may enter into a **[**written protocol-based**]** collaborative drug therapy management agreement **[**with one or more physicians licensed under chapter 370 or advanced practice registered

nurses licensed under chapter 378 to**]** or manage the drug therapy of individual patients, or a patient population, under a collaborative drug therapy management policy. In order to enter into a **[**written protocol-based**]** collaborative drug therapy management agreement **[**, such physician or advanced practice registered nurse shall have established**]** or collaborative drug therapy care plan, or operate under a collaborative drug therapy management policy, a prescribing practitioner must first establish a provider-patient relationship with the patient or patients who will receive collaborative drug therapy. Each patient's collaborative drug therapy management shall be **[**governed by a written protocol which may include guideline-directed management established by the treating physician or advanced practice registered nurse in consultation with the pharmacist. For purposes of this subsection, a "provider-patient relationship" is a relationship based on (1) the patient making a medical complaint, (2) the patient providing a medical history, (3) the patient receiving a physical examination, and (4) a logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient**]** based on a diagnosis made by such patient's prescribing practitioner or a specific test set forth in a collaborative drug therapy management agreement or collaborative drug therapy management policy.

[(b)**]** (c) A collaborative drug therapy management agreement or collaborative drug therapy management policy may authorize a **[**pharmacist to implement**]** qualified pharmacist or qualified pharmacists to initiate, modify, continue, discontinue or deprescribe a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific or patient population-specific written protocol **[**. Such agreement**]** or collaborative drug therapy care plan, but may not authorize a qualified pharmacist or qualified pharmacists to establish a port to administer parenteral drugs. A collaborative drug therapy management agreement or collaborative drug therapy management policy may specifically address issues that may arise during a medication reconciliation and concerns related to polypharmacy that enable an authorized qualified pharmacist or qualified pharmacists to

[implement**]** initiate, modify, continue, discontinue or deprescribe drug therapy. In instances where drug therapy is discontinued or deprescribed, the qualified pharmacist or qualified pharmacists shall notify the **[**treating physician or advanced practice registered nurse**]** prescribing practitioner of such discontinuance or deprescribing **[**no**]** not later than twenty-four hours **[**from the time of such discontinuance or deprescribing**]** after such drug therapy is discontinued or deprescribed. Each written protocol or collaborative drug therapy care plan developed, pursuant to **[**the**]** a collaborative drug therapy management agreement or collaborative drug therapy management policy, shall contain detailed direction concerning the actions that the qualified pharmacist or qualified pharmacists may perform for **[**that**]** the patient **[**. The**]** or patient population. Such written protocol or collaborative drug therapy care plan shall include, but need not be limited to, (1) the specific drug or drugs, therapeutic class of drug or classes of drugs, or medical devices to be managed by the qualified pharmacist or qualified pharmacists, (2) the terms and conditions under which drug therapy may be **[**implemented**]** initiated, modified, continued, discontinued or deprescribed, (3) the conditions and events upon which the qualified pharmacist is, or qualified pharmacists are, required to notify the **[**physician or advanced practice registered nurse, and**]** prescribing practitioner, (4) the laboratory tests that may be ordered, and (5) a definition of the patient population included in such written protocol or collaborative drug therapy care plan. All activities performed by the qualified pharmacist or qualified pharmacists in conjunction with the protocol shall be documented in the patient's medical record **[**. The pharmacist shall report any encounters within the scope of the collaborative drug therapy management agreement within thirty days to the physician or advanced practice registered nurse regarding the patient's drug therapy management or document such information within a shared medical record. The**]** in accordance with all applicable care-giving institution policies. Each collaborative drug therapy management agreement, **[**and protocols**]** collaborative drug therapy management policy, written protocol and collaborative drug therapy care plan shall be available for inspection by the **[**Departments**]**

Department of Consumer Protection and the Department of Public Health. [and Consumer Protection.] A copy of the protocol shall be filed in the patient's medical record.

[(c)] (d) A pharmacist shall be responsible for demonstrating, in accordance with regulations adopted pursuant to subsection [(d)] (e) of this section, the competence necessary for [participation] the pharmacist to participate in each collaborative drug therapy management agreement, [into which such pharmacist enters] collaborative drug therapy management policy and collaborative drug therapy care plan in which such pharmacist seeks to participate by, among other things, demonstrating that such pharmacist has reviewed the latest edition of the "Pharmacists' Patient Care Process" published by the Joint Commission of Pharmacy Practitioners.

[(d)] (e) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, shall (1) adopt regulations, in accordance with chapter 54, concerning competency requirements for participation in a [written protocol-based] collaborative drug therapy management agreement, [described in subsection (a) of this section,] the minimum content of the collaborative drug therapy management agreement [and the written protocol] and such other matters said commissioners deem necessary to carry out the purpose of this section, and (2) on or after the effective date of this section, amend such regulations to include competency requirements for participation in a collaborative drug therapy management policy or collaborative drug therapy care plan and the minimum content of collaborative drug therapy management policies, collaborative drug therapy care plans and written protocols governing collaborative drug therapy management.

Sec. 2. Section 19a-521d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

A medical director of a nursing home facility, as defined in section 19a-521, may establish protocols for a prescription drug formulary system in accordance with guidelines established by the American

Society of Health-System Pharmacists and any applicable collaborative drug therapy management agreement or collaborative drug therapy management policy, as **[**described**]** defined in section 20-631, as amended by this act. The medical director of a nursing home facility that implements a prescription drug formulary system may make a substitution for a drug prescribed to a patient of the facility in accordance with the provisions of this section. Prior to making any substitution for a drug prescribed to a patient of the facility in accordance with the facility's protocols, the medical director, or the medical director's designee, shall notify the prescribing practitioner of the medical director's intention to make such substitution. If the prescribing practitioner does not authorize the medical director or the medical director's designee to make such substitution or objects to such substitution, the medical director, or the medical director's designee, shall not make the substitution. Notwithstanding the provisions of this section, a facility, when administering prescription drugs to a patient who receives benefits under a medical assistance program administered by the Department of Social Services, shall consider and administer prescription drugs to such patient in accordance with (1) the department's preferred drug list, developed in accordance with section 17b-274d, (2) prescription drug formularies under Medicare Part D, or (3) the patient's health insurance policy, as the medical director of the nursing home facility deems appropriate.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	20-631
Sec. 2	*from passage*	19a-521d

Statement of Legislative Commissioners:

In Section 1(b), "patients or a patient population" was changed to "patients, or a patient population," for clarity; in Section 1(c), "that" was bracketed and "the" was inserted after the closing bracket, and "caregiving institution" was changed to "care-giving institution", for consistency; and in Section 1(e)(2), "and" was inserted before "the minimum" for clarity.

GL *Joint Favorable Subst. -LCO*

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

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 23 $	FY 24 $
Consumer Protection, Dept.	GF - Cost	98,918	96,668
State Comptroller - Fringe Benefits[1]	GF - Cost	36,646	36,646

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill allows the creation of collaborative drug therapy management policies and agreements between prescribing practitioners and pharmacists resulting in a cost to the Department of Consumer Protection (DCP) and the Office of the State Comptroller. DCP will have to hire one drug control agent for a total cost[2] of $135,564 in FY 23 and $133,314 in FY 24 to review the collaborative drug therapy agreements and enforce the expanded scope of practice for pharmacists.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 40.53% of payroll in FY 23.

[2] Total cost includes salary, other expenses, and fringe benefits.

OLR Bill Analysis

sSB 186

AN ACT CONCERNING COLLABORATIVE DRUG THERAPY MANAGEMENT AGREEMENTS AND POLICIES.

SUMMARY

This bill makes various changes affecting collaborative drug therapy agreements between certain health care practitioners and pharmacists. Specifically, it:

1. expands the types of practitioners authorized to enter into these agreements to include any prescribing practitioner or caregiving institution ("providers"), instead of only state-licensed physicians and advanced practice registered nurses;

2. expands the types of authorized arrangements between pharmacists and providers to include collaborative drug therapy management policies between pharmacists and caregiving institutions, instead of only collaborative drug therapy agreements between pharmacists and prescribing practitioners;

3. expands pharmacists' authority under these arrangements to include (a) managing drug therapy for patient populations, instead of only individual patients and (b) managing a therapeutic class of drugs, instead of only specified drugs; and

4. requires the Department of Consumer Protection (DCP) commissioner to amend regulations on pharmacist qualifications and requirements for these arrangements to include competency requirements and requirements for the minimum content of these arrangements.

Under the bill, "prescribing practitioners" are practitioners licensed in Connecticut or another U.S. jurisdiction who have prescriptive

authority under their professional scope of practice. "Care-giving institutions" are institutions that provide medical services and are licensed, operated, certified, or approved by the commissioners of public health (DPH), developmental services, or mental health and addiction services (e.g., hospitals, nursing homes, or assisted living facilities).

Lastly, the bill makes technical and conforming changes, including specifying that a nursing home's medical director may enter into collaborative drug management policies.

EFFECTIVE DATE: Upon passage

PERMITTED ARRANGEMENTS

The bill authorizes two types of formal arrangements between providers and qualified pharmacists, which must be based on either written protocols or a collaborative drug therapy care plan. These arrangements include:

1. "collaborative drug therapy management agreements" similar to those under current law (i.e., agreements between one or more pharmacists and prescribing practitioners to manage individual patients', or a patient population's, drug therapy); and

2. "collaborative drug therapy management policies" (i.e., written policies adopted by care-giving institutions under which one or more pharmacists manage individual patients', or a patient population's, drug therapy).

Under the bill, a "qualified pharmacist" is a DCP-licensed pharmacist who (1) is deemed competent under department regulations and (2) has reviewed the latest edition of the "Pharmacists' Patient Care Process," published by the Joint Commission of Pharmacy Practitioners.

"Collaborative drug therapy care plans" are written documents memorializing an agreed-upon approach to achieve a patient's desired health outcome, as determined by the patient in collaboration with one

or more health care providers ("care plans").

CONDITIONS FOR ENTERING INTO ARRANGEMENTS

Provider-Patient Relationship

The bill extends current law's requirements for entering into collaborative drug therapy agreements to the new agreements, care plans, and policies the bill authorizes. So, before entering into an agreement or care plan, or operating under a management policy, a practitioner must establish a provider-patient relationship with the patient or patients who will receive collaborative drug therapy.

By law, this is a relationship in which (1) the patient has made a medical complaint, provided his or her medical history, and received a physical examination and (2) there exists a logical connection between the medical complaint and history, physical examination, and any drug prescribed.

Diagnosis or Test

The bill also requires that each patient's collaborative drug therapy management be based on (1) a diagnosis made by the patient's practitioner or (2) a specific test set out in an agreement or policy.

PHARMACISTS' AUTHORITY

Under the bill, pharmacists providing collaborative drug therapy management under an agreement or policy may, in keeping with the agreement or policy:

1. initiate, modify, continue, discontinue, or deprescribe a patient's prescribed drug therapy;

2. order associated laboratory tests; and

3. administer drugs.

This scope of authority is generally the same as currently allowed for collaborative drug therapy arrangements, except the bill (1) authorizes pharmacists to initiate, rather than implement, a prescribed drug

therapy and (2) does not require the specification of the drugs to be managed (see below).

As is currently required for collaborative drug therapy arrangements, agreements and policies may specifically address issues that come up during medication reconciliation (i.e., review of all of a patient's current and new medications) or related to polypharmacy (i.e., the simultaneous use of multiple drugs by a patient).

The bill specifies that agreements and policies cannot authorize a pharmacist to establish a port to administer parenteral drugs (e.g., IV infusions).

AGREEMENT OR POLICY'S CONTENTS

Under the bill, any written protocol or care plan developed under to a collaborative drug therapy agreement or policy must have detailed direction on the pharmacist's permitted actions, including the (1) specific drug or drugs, (2) therapeutic class or classes of drugs, and (3) medical devices that the pharmacist may manage. (The bill does not explicitly give pharmacists authority to manage medical devices.)

As under current law, the written protocol or care plan must also specify:

1. the terms and conditions under which drug therapy may be initiated, modified, continued, discontinued, or deprescribed;

2. when a pharmacist must notify the prescribing practitioner;

3. the laboratory tests that the pharmacist may order; and

4. the patient population it covers.

Under the bill, agreements, policies, protocols, and care plans must be made available to DCP and DPH for inspection, upon request, as current law requires for agreements and written protocols.

Notice to Practitioner and Medical Record Updates

Under the bill, if a pharmacist discontinues or deprescribes a drug, he or she must notify the prescribing practitioner within 24 hours. Any actions the pharmacist takes must be documented in the patient's medical record as specified by any applicable care-giving institution's policies. (The bill does not similarly require compliance with practitioners' policies if they are not associated with a care-giving institution.)

Additionally, any protocol (presumably, this includes agreements, policies, care plans, and other written protocols) must be filed in the patient's medical record.

Current law requires pharmacists to (1) report any encounters within the agreement's scope within 30 days or document them in a shared medical record and (2) file protocols in the patient's medical record.

COMMITTEE ACTION

General Law Committee

Joint Favorable
Yea 18 Nay 0 (03/15/2022)