The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	SB 1020
INTRODUCER:	Senator Bean
SUBJECT:	Institutional Formularies Established by Nursing Home Facilities
DATE:	January 27, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kibbey	Brown	HP	**Favorable**
2.	McKnight	Kidd	AHS	**Recommend: Favorable**
3.			AP	

I. Summary:

SB 1020 authorizes a nursing home facility to establish and implement an institutional formulary (a list of medicinal drugs) that a pharmacist may use as a therapeutic substitution to replace a resident's prescribed medicinal drug with a chemically different drug listed in the formulary that is expected to have the same clinical effect.

The bill:

- Provides definitions, requirements, and operational parameters for a nursing home facility's implementation of an institutional formulary and for participation by prescribers and pharmacists.
- Requires participating nursing home facilities to establish a committee to develop the institutional formulary and perform quarterly monitoring of clinical outcomes when a therapeutic substitution occurs.
- Requires each prescriber to annually approve, for his or her patients, the use of, and any subsequent changes made to, an institutional formulary and allows a prescriber to opt out of the institutional formulary with regard to a particular patient, medicinal drug, or class of medicinal drugs.
- Prohibits a nursing home facility from taking adverse action against a prescriber for not agreeing to use the facility's institutional formulary.

The bill does not have a fiscal impact on state revenues or expenditures.

The bill takes effect on July 1, 2020.

II. Present Situation:

Substitution of Drug Products

To contain drug costs, virtually every state has adopted laws and regulations that encourage the substitution of drug products.[1] These state laws generally require a substitution be limited to drugs on a specific list (the positive drug formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative drug formulary approach).[2] Florida law authorizes the negative drug formulary approach.

The negative drug formulary is composed of medicinal drugs that have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and that, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications.[3]

Florida law requires pharmacists to substitute a less expensive generic medication for a prescribed brand name medication, unless otherwise indicated by the purchaser.[4] Generic drugs are chemically very similar to their corresponding brand-name drugs. They contain the same active ingredient, have the same strength, use the same dosage form and route of administration, and meet the same quality standards as those of brand-name drugs.[5]

Florida law authorizes, but does not require, a pharmacist to substitute a biosimilar[6] for a prescribed biological product[7] if the biosimilar has been determined by the U.S. Food and Drug Administration to be interchangeable with the prescribed biological product and the prescriber does not express a preference against substitution in writing, orally, or electronically.[8]

For generic and biosimilar substitutions, the pharmacist must notify the patient and advise the patient of the right to reject the substitution and request the prescribed brand name medication or biologic.[9]

Without the express authorization of the prescriber, Florida law does not provide for the substitution of a medicinal drug that is therapeutically equivalent to, but chemically different from, the originally prescribed drug and that is expected to produce a similar patient outcome as

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[1] U.S. Food and Drug Administration, *Orange Book Preface* (Feb. 5, 2018), *available at* https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last visited Jan. 8, 2020).
[2] *Id*.
[3] Section 465.025(6), F.S.; see also Rule 64B-16.27.500, F.A.C.
[4] Section 465.025(2), F.S.
[5] U.S. Food and Drug Administration, *Understanding Generic Drugs* (Sept. 13, 2017), *available at* https://www.fda.gov/drugs/generic-drugs/overview-basics (last visited Jan. 8, 2020).
[6] 42 U.S.C. s. 262 (i)(2) defines a "biosimilar" is a biological product that is highly similar to the licensed biological product or reference product, that has no clinically meaningful differences in terms of safety, purity, and potency of the product.
[7] 42 U.S.C. s. 262 (i)(1) defines "biological product" as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine, applicable to the prevention, treatment, or cure of a disease or condition of human beings.
[8] Section 465.0252(2), F.S.
[9] Sections 465.025(3)(a) and 465.0252(2)(c), F.S., respectively.

the reference drug or treatment. Possible consequences of such therapeutic substitution may include different adverse effects and under- or over-treatment.[10]

Therapeutic Substitution in Other States

There is little research available on the approaches to, and outcomes of, therapeutic substitution laws and regulations in other states. However, research that is available pertains to three states that authorize therapeutic substitution in community pharmacies.[11]

In 2003, Kentucky was the first state to pass a law authorizing therapeutic substitution in community pharmacies. Arkansas followed suit in 2015, and Idaho's legislation took effect on July 1, 2018.[12] In all three states, a prescriber must opt in to allow the therapeutic substitution and the pharmacist must notify the prescriber if any therapeutic substitution is made to ensure a complete and accurate medical record.[13, 14, 15] Arkansas and Kentucky require a pharmacist to notify the prescriber in the first 24 business hours after a therapeutic substitution.[16] Idaho requires such notification within five days.[17] In Idaho and Arkansas, but not in Kentucky, the patient is notified and has a right to refuse the therapeutic substitution.[18]

Idaho and Kentucky require that the substitution be in compliance with the patient's health plan formulary, such as changing from a nonpreferred drug to a preferred drug.[19] Arkansas states that the substitution must be to a drug "that is at a lower cost to the patient."[20] Idaho adopts this lower cost language for patients who do not have health plan coverage.[21]

Several states, including Idaho, have authorized therapeutic substitution in institutional settings.[22] Additionally, Connecticut authorizes a medical director of a nursing home facility to make a substitution for a drug prescribed to a patient of the facility after obtaining authorization from the prescriber.[23] Wisconsin authorizes a pharmacist to make therapeutic substitutions for a

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[10] Robert L. Talbert., *Therapeutic Substitution*, National Conference of State Legislatures, *available at* http://www.ncsl.org/documents/statetribe/RTalbert61010.pdf (last visited Jan. 8, 2020).
[11] Section 465.003(11)(a)1., F.S., defines a community pharmacy as a location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
[12] Thomas Vanderholm, Donald Klepser, Alex J. Adams, *State Approaches to Therapeutic Interchange in Community Pharmacy Settings: Legislative and Regulatory Authority*, Journal of Managed Care & Specialty Pharmacy, Dec. 2018, 24(12): 1260-1263, https://www.jmcp.org/doi/10.18553/jmcp.2018.24.12.1260 (last visited Jan. 8, 2020).
[13] 201 K.A.R. 2:280, https://apps.legislature.ky.gov/law/kar/201/002/280.pdf (last visited Jan 9, 2020).
[14] Section 54-1768, Idaho Code, https://legislature.idaho.gov/statutesrules/idstat/Title54/T54CH17/SECT54-1768/ (last visited Jan 8, 2020).
[15] Arkansas Register, Regulation 7—drug products/prescriptions. 07-00-0010: Therapeutic substitution, https://www.sos.arkansas.gov/uploads/rulesRegs/Arkansas%20Register/2014/dec2014/070.00.14-006.pdf (last visited Jan. 9, 2020).
[16] *Supra* notes 13 and 15.
[17] *Supra* note 14.
[18] *Supra* notes 14 and 15.
[19] *Supra* note 12.
[20] *Id.*
[21] *Id.*
[22] *Supra* note 14.
[23] Conn. Gen. Stat. Ch. 368v 19a-521d., https://www.cga.ct.gov/current/pub/chap_368v.htm#sec_19a-521d (last visited Jan. 9, 2020).

nursing home patient if approved by the patient's attending physician for the patient's period of stay within the facility.[24]

Institutional Formulary Systems in Florida

Section 465.019, F.S., authorizes a Class II[25] or Class III[26] institutional pharmacy to adopt an institutional formulary system for use with approval of the medical staff for the purpose of identifying those medicinal drugs, proprietary preparations, biologics, biosimilars, and biosimilar interchangeables that may be dispensed by the pharmacists employed in such institution. The term "institutional formulary system" means "a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy."[27]

A facility that adopts an institutional formulary system under section 465.019, F.S., must establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and the American Society of Hospital Pharmacists (now known as the American Society of Health-System Pharmacists[28]) for the utilization of a hospital formulary system, which must be approved by the medical staff.

Nursing Homes and Residents' Rights

Federal law requires nursing home facilities to provide routine and emergency drugs to residents, or to obtain them under an agreement.[29] A nursing home facility must employ or obtain the services of a licensed pharmacist and provide pharmaceutical services to meet the needs of each resident.[30] Florida law requires the Agency for Health Care Administration to license and regulate nursing homes pursuant to part II of chapter 408 and part II of chapter 400, F.S., respectively.

Section 400.022, F.S., requires a nursing home facility to adopt a statement of residents' rights and to provide a copy of the statement to each resident or the resident's legal representative at or before the resident's admission to the facility. The statement must assure each resident the right to:

- Civil and religious liberties, including knowledge of available choices and the right to independent personal decision, which will not be infringed upon, and the right to

[24] Wis. Stat. s. 450.01(16)(hm) https://docs.legis.wisconsin.gov/statutes/statutes/450/13 (last visited Jan. 8, 2020).
[25] Section 465.019(2)(b), F.S. defines "class II institutional pharmacies" as those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution.
[26] Section 465.019(2)(d)1., F.S., defines "class III institutional pharmacies" as those institutional pharmacies, including central distribution facilities, affiliated with a hospital that provide the same services that are authorized by a Class II institutional pharmacy permit that may also dispense, distribute, compound, and fill prescriptions for medicinal drugs and prepare prepackaged drug products.
[27] Section 465.003, F.S.
[28] American Society of Health-System Pharmacists, *ASHP History*¸ https://www.ashp.org/About-ASHP/Our-History/ASHP-History (last visited Jan. 9, 2020).
[29] 42 CFR § 483.45.
[30] *Id.*

encouragement and assistance from the staff of the facility in the fullest possible exercise of these rights.

- Be adequately informed of his or her medical condition and proposed treatment, unless the resident is determined to be unable to provide informed consent under Florida law, or the right to be fully informed in advance of any nonemergency changes in care or treatment that may affect the resident's well-being; and, except with respect to a resident adjudged incompetent, the right to participate in the planning of all medical treatment, including the right to refuse medication and treatment, unless otherwise indicated by the resident's physician; and to know the consequences of such actions.
- Receive adequate and appropriate health care and protective and support services.
- Obtain pharmaceutical supplies and services from a pharmacy of the resident's choice, at the resident's own expense or through Medicaid.

A nursing home that violates the statement of resident's rights set forth in s. 400.022, F.S., may be subject to administrative fines, emergency moratorium on admissions, or denial, suspension, or revocation of license if it violates a resident's rights, depending on the nature of the violation and the gravity of its probable effect on clients.[31]

III. Effect of Proposed Changes:

Section 1 creates s. 400.143, F.S., to

- Add definitions for "institutional formulary," "medicinal drug," "prescriber," and "therapeutic substitution."
- Authorize a nursing home facility to establish and implement an institutional formulary that a pharmacist may use as a therapeutic substitution for a medicinal drug prescribed to a resident of the facility.
- Require a nursing home facility that implements an institutional formulary to:
    - Establish a committee to develop the institutional formulary, as well as written guidelines or procedures. The committee must consist of, at a minimum, the facility's medical director and director of nursing, and a consultant pharmacist licensed by the Department of Health.
    - Establish methods and criteria for selecting and objectively evaluating all available pharmaceutical products that may be used as therapeutic substitutes.
    - Establish policies and procedures for developing and maintaining the formulary and for approving and notifying prescribers of the formulary.
    - Perform quarterly monitoring to ensure compliance of policies and procedures and monitor clinical outcomes when a therapeutic substitution occurs.
- Require the nursing home facility to maintain and make available all written policies and procedures for the institutional formulary.
- Require a prescriber to annually authorize, for his or her patients, the institutional formulary and opt into any subsequent changes made to the facility's institutional formulary. The prescriber may opt out of the institutional formulary with regard to a specific patient, a particular drug, or a class of drugs. A prescriber may prevent a therapeutic substitution for a specific medication order by indicating verbally or electronically on the prescription "NO THERAPEUTIC SUBSTITUTION."

[31] Sections 400.022 and 408.813, F.S.

- Prohibit a nursing home facility from taking adverse action against a prescriber for not agreeing to use the facility's institutional formulary.

Section 2 amends s. 465.025, F.S., to authorize, but not require, a pharmacist to therapeutically substitute medicinal drugs for a resident of a nursing home in accordance with the nursing home's institutional formulary if the prescriber has agreed to the use of the institutional formulary and has not indicated "NO THERAPEUTIC SUBSTITUTION."

Section 3 establishes an effective date of July 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 400.143 of the Florida Statutes.

This bill substantially amends section 465.025 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.