

HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/HB 559 Institutional Formularies Established by Nursing Home Facilities

SPONSOR(S): Health & Human Services Committee, Byrd and others

TIED BILLS: **IDEN./SIM. BILLS:** SB 1020

FINAL HOUSE FLOOR ACTION: 116 Y's 2 N's **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 559 passed the House on March 9, 2020, and subsequently passed the Senate on March 11, 2020.

Nursing homes provide 24-hour a day care, case management, health monitoring, personal care, nutritional meals and special diets, physical, occupational, and speech therapy, social activities, and respite care for those who are ill or physically infirm. In providing such care, nursing homes acquire, dispense, or administer prescription medications to residents.

Therapeutic substitution is the practice of dispensing a drug that is chemically distinct from the prescribed drug, but therapeutically similar in terms of efficacy, safety, and tolerability profile. Therapeutic substitution is designed to achieve an improved or neutral outcome with a different drug, while reducing overall treatment costs. Currently, a pharmacist must dispense a prescription for a nursing home resident as written, unless substituting a generic or biosimilar drug. Otherwise, a pharmacist must contact the prescribing physician and request a new prescription.

The bill authorizes a nursing home to establish an institutional formulary by which a pharmacist may use therapeutic substitution, without obtaining a new prescription, to replace a resident's prescribed drug with a chemically different drug listed in the formulary that is expected to have the same clinical effect.

The bill requires a nursing home to obtain a prescriber's authorization to use an institutional formulary for each of the prescriber's patients in the nursing home and allows a prescriber to opt out of the institutional formulary for a specific drug or a class of drugs. The nursing home must notify the prescriber prior to each therapeutic substitution and document the resident's medical record when a substitution occurs. The bill requires a nursing home to obtain informed consent from a resident or a resident's representative to use the institutional formulary for the resident.

The bill prohibits a nursing home from taking adverse action against a prescriber or resident who refuses to use the institutional formulary.

The bill has an insignificant, negative fiscal impact on the Agency for Health Care Administration, which can be absorbed within existing resources. The bill has no fiscal impact on local governments.

The bill was approved by the Governor on June 27, 2020, ch. 2020-103, L.O.F., and the effective date is July 1, 2020.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Nursing Homes

Nursing homes provide 24 hour a day care, case management, health monitoring, personal care, nutritional meals and special diets, physical, occupational, and speech therapy, social activities, and respite care for those who are ill or physically infirm.¹ Nursing homes are regulated by the Agency for Health Care Administration (AHCA) under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S., which provides licensure requirements for all provider types regulated by AHCA, and part II of chapter 400, F.S., which includes unique provisions for nursing home licensure beyond the uniform criteria in the Act.

Resident Rights

Florida law requires nursing homes to adopt the residents' bill of rights², which provides the rights and responsibilities of residents, and requires nursing homes to treat such residents in accordance with its provisions.³ Nursing homes must provide a copy of the resident's bill of rights to each resident or the resident's legal representative at or before the resident's admission to the facility.⁴ The residents' bill of rights include, among other things, the right to:⁵

- 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 encouragement and assistance from staff to exercise 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; and
- Receive adequate and appropriate health care and protective and support services.

The staff of the nursing home must receive training on resident rights and also be provided a copy of the resident's rights.⁶ A nursing home may be subject to administrative fines, emergency moratorium on admissions, or denial, suspension, or revocation of license if it violates a resident's rights.⁷

Nursing Home Pharmacy Services

Nursing homes must adopt procedures to assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals, to meet the needs of each resident.⁸ Nursing homes must also employ the services of a state licensed consultant pharmacist to provide consultation on all

¹ Agency for Health Care Administration, *Nursing Homes*, available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Long_Term_Care/Nursing_Homes.shtml (last visited December 6, 2019).

² Rule 59A-4.106(1)(a)1., F.A.C.

³ Section 400.022(1), F.S.

⁴ Section 400.022(2), F.S.

⁵ *Supra* note 3.

⁶ *Id.*

⁷ Section 400.022(3), F.S. The action imposed by AHCA will be dependent on the scope of the violation and the gravity of its probably effect on the residents. See part II of ch. 408, F.S.

⁸ Rule 59A-4.112(1), F.A.C.

aspects of the provision of pharmacy services in the facility. Other duties of the consultant pharmacist include:⁹

- Establishing a system to accurately record the receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and
- Ensuring that all drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

Prescription drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles.¹⁰ Nursing homes must also maintain an emergency medication kit containing a limited supply of medications in the facility for use during emergency or after-hours situations. The contents of the kit is determined by the residents' needs, in consultation with the medical director, director of nursing, and pharmacist and must be in accordance with facility policies and procedures.¹¹

Pharmacies

The Florida Pharmacy Act regulates the practice of pharmacy and contains the minimum requirements for safe practice.¹² The Board of Pharmacy (board) is tasked with adopting rules to implement the provisions of the chapter and setting standards of practice within the state.¹³ Any person who operates a pharmacy in Florida must have a permit from the Department of Health (DOH).

DOH issues several types of pharmacy permits, including those for community pharmacies and institutional pharmacies. A community pharmacy is a location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis;¹⁴ generally, retail pharmacies such as CVS or Walgreens. An institutional pharmacy is a location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.¹⁵

DOH issues four classes of permits for institutional pharmacies.¹⁶ A Class I institutional pharmacy is a pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises.¹⁷ No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit fills and dispense individual patient prescriptions.

A Class II institutional pharmacy is a pharmacy which employs the services of a registered pharmacist who, in practicing institutional pharmacy, provides dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution.¹⁸ A consultant pharmacist of record is responsible for establishing a written policy and procedure manual for the implementation of the drug delivery system and the requirement of Board rules.¹⁹

A modified Class II institutional pharmacy is a pharmacy in a short-term, primary care treatment center that meet all the requirements for a Class II permit, except space and equipment requirements.²⁰

⁹ Rule 59A-4.112(2)(3)(4), F.A.C.

¹⁰ Rule 59A-4.112(5), F.A.C.

¹¹ Rule 59A-4.112(10), F.A.C.

¹² Chapter 465, F.S.

¹³ Sections 465.005, 465.0155, and 465.022, F.S.

¹⁴ Sections 465.003(11)(a)1., and 465.018, F.S.

¹⁵ Sections 465.003(11)(a)2., and 465.019, F.S.

¹⁶ Section 465.019, F.S.

¹⁷ Section 465.019(2)(a), F.S.

¹⁸ Section 465.019(2)(b), F.S.

¹⁹ Rule 64B16-28.702, F.A.C.

²⁰ Section 465.019(c)(c), F.S.

Modified Class II Institutional pharmacies are further classified according to the type of specialized pharmaceutical delivery system utilized.²¹

A Class III institutional pharmacy is a pharmacy, including central distribution facilities affiliated with a hospital that provides the same services as a Class II institutional pharmacy, but may also dispense, distribute, compound, and fill prescriptions for medicinal drugs and prepare prepackaged drug products.²²

Institutional Formularies

A drug formulary is a continually updated list of medications supported by the clinical judgment of physicians, pharmacists, and other experts in the diagnosis, prophylaxis, or treatment of disease and promotion of health.²³ The purpose of a formulary is to encourage the use of safe, effective, and most affordable medication.²⁴ Formularies are primarily used by health care payers, such as employers and insurers, to reduce costs.

An institutional formulary system is a method by which the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations, which, in the medical staff's clinical judgment, are the most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II or Class III institutional pharmacy.²⁵ Under current law, a facility with a Class I or Class II institutional pharmacy that operates under a formulary system must establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospitals Pharmacists for the utilization of a hospital formulary system, which must be approved by medical staff.²⁶ Such standards include the following requirements.²⁷

- An organized and representative pharmacy and therapeutics (P&T) committee or equivalent body, composed of actively participating physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication use process.
- Policies formulated by the P&T committee regarding evaluation, selection, diagnostic and therapeutic use, and monitoring of medications.
- Mechanisms to communicate to health care professionals, patients, and payers about all aspects of the formulary system, including changes to the formulary or policies and formulary decisions are made.

According to the joint standards of the American Hospital Association and American Society of Hospitals Pharmacists, a formulary system must also:²⁸

- Evaluate the clinical use of medications (outcomes);
- Establish and implement policies and quality assurance activities for medication use and administration;
- Evaluate and monitor adverse drug reactions and medication errors;
- Be endorsed by medical staff based on recommendations of the P&T committee; and

²¹ *Supra* note 19.

²² Section 465.019(2)(d), F.S.

²³ American Society of Health System Pharmacists, *ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System*, AM J HEALTH SYST PHARM, 2008, 65:2384-6, available at <https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx> (last visited December 5, 2019).

²⁴ Academy of Managed Care Pharmacy, *Formulary Management*, (Nov. 2009), available at <https://amcp.org/sites/default/files/2019-03/Formulary%20Management.pdf> (last visited December 5, 2019).

²⁵ Section 465.003(7), F.S.

²⁶ Section 465.019(6), F.S.

²⁷ *Supra* note 23.

²⁸ *Id.*

- Ensure that all personnel involved in patient care are informed about the existence of the formulary system, how to access the formulary system, the procedures governing operation, any changes in those procedures, and other necessary information.

Under these standard, an evidence-based institutional formulary, the P&T committee must:²⁹

- Timely revise and maintain the formulary;
- Promote the rational, clinically appropriate, safe, and cost-effective use of medications via guidelines, protocols, and other mechanisms;
- Objectively appraise, evaluate, and select medications for addition to or deletion from the formulary, on an ongoing basis;
- Select formulary items based on their relative economic, clinical, and humanistic outcomes and not solely on economic factors;
- Identify potential safety concerns for each medication considered for inclusion and ensure those concerns are addressed if the medication is added to the formulary;
- Clearly define terminology related to the formulary; and
- Evaluate coordination issues with local health care plans and other organizations' formularies.

The formulary should be published and updated regularly.³⁰ It should also be readily available and accessible at all times to all personnel involved in patient care and the use of medications.³¹ The P&T committee should also recommend or assist in the formulation of educational programs for professional staff, patients, families, and caregivers related to medications and medication use.

Similarly, the American Medical Association (AMA), recommends that institutional formularies meet the following standards:³²

- Have the concurrence of the organized medical staff;
- Openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;
- Have policies for the development, maintenance, approval, and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;
- Provide for protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drugs;
- Have enough qualified medical staff, pharmacists, and other professionals to carry out required activities;
- Include policies that state practitioners will not be penalized for prescribing non-formulary drugs that are medically necessary; and
- Be in compliance with applicable state and federal rules and statutes.

Therapeutic Substitution of Prescription Drugs

For most medicines, there exist several similar or alternative products which can be either generic or therapeutically equivalent brand-name drugs.³³ Therapeutic substitution is the practice of switching or dispensing drugs that are chemically distinct but therapeutically similar in terms of their efficacy, safety,

²⁹ Id.

³⁰ Id.

³¹ Id.

³² Id.

³³ Rachel Chu, et al, *Patient Safety and Comfort - The Challenges of Switching Medicines* (2010), p. 8, available at http://www.patients-rights.org/uploadimages/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf (last visited December 5, 2019).

and tolerability profiles.³⁴ Therapeutic substitution is designed to achieve an improved or neutral outcome by using the new drug, while reducing overall treatment costs.³⁵

Substitution of brand name drugs may include substituting a brand-name drug for its generic equivalent. Generic drugs are copies of brand-name drugs with the same dosage form, safety, strength, route of administration, quality, and performance characteristics.³⁶ Therapeutic substitution may also involve brand name products that have been deemed to have therapeutic equivalence with an originally prescribed medicine or therapy.³⁷ These drugs will have a different chemical composition and use a different active ingredient than the originally prescribed drug.³⁸

The AMA recommends therapeutic interchange, as long as it is authorized by the prescriber and occurs in accordance with previously established and approved written guidelines or protocols within a formulary system.³⁹ The AMA further states that facilities that perform therapeutic interchanges must inform the prescriber in a timely manner of any substitutions and allow the prescriber to override the system when necessary, without in appropriate burden. Such facilities must also provide active surveillance mechanisms to regularly monitor both compliance with standards and clinical outcomes where substitution has occurred, and intercede when indicated.

Three states authorize therapeutic substitution in community pharmacies: Arkansas, Idaho, and Kentucky.⁴⁰ In general, the prescriber must opt-in to allow the therapeutic substitution and the pharmacist must notify the prescriber of any interchanges made.⁴¹ Arkansas and Idaho also require patient notification and allow patients to refuse the substitution.⁴²

Some states authorize therapeutic substitution in institutional pharmacies. For example, Idaho, authorizes therapeutic substitution in a nursing home based on a formulary developed by the Board of Pharmacy.⁴³ Connecticut allows a medical director of a nursing home to substitute a prescribed drug for a resident of the facility, but requires approval from the prescriber before making the substitution.⁴⁴ Wisconsin authorizes a pharmacist to make therapeutic substitutions for a nursing home patient if approved by the patient's attending physician for the patient's period of stay within the nursing facility.⁴⁵

Pharmacist Substitution in Florida

Florida law requires pharmacists to substitute a less expensive generic medication for a prescribed brand name medication.⁴⁶ The presenter of the prescription may specifically request the brand name medication to override this requirement.⁴⁷ The prescriber may also prevent substitution by indicating the brand name medication is "medically necessary" in writing, orally, or, in the case of an electronic

³⁴ Flood, J., Mihalik, C., Fleming, R., Strober, B., Zucker, D., & Burgoyne, D., "The Use of Therapeutic Interchange for Biologic Therapies," *Managed Care Magazine*, January 2007, p. 51. http://www.managedcaremag.com/archives/0701/0701_peer_switch.html (last visited December 5, 2019).

³⁵ *Id.*

³⁶ U.S. Food and Drug Administration, *Generic Drug Facts*, (last rev. June 1, 2018), available at <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm> (last visited December 5, 2019).

³⁷ *Id.*

³⁸ *Supra* note 33.

³⁹ American Medical Association, "Drug Formularies and Therapeutic Interchange H-125.991," (last rev. 2010), available at <https://policysearch.ama-assn.org/policyfinder/detail/Drug%20Formularies%20and%20Therapeutic%20Interchange%20H-125.991?uri=%2FAMADoc%2FHOD.xml-0-227.xml> (last visited December 5, 2019),

⁴⁰ Vanderholm, T. Klepser, D., & Adams, A., "State Approaches to Therapeutic Interchange in Community Pharmacy Settings: Legislative and Regulatory Authority," *J MANAG CARE SPEC PHARM*, Dec. 2018, 24(12): 1260-1263, available at <https://www.jmcp.org/doi/10.18553/jmcp.2018.24.12.1260> (last visited December 6, 2019).

⁴¹ *Id.*

⁴² *Id.*

⁴³ Rule 27.01.03, ID Admin. Code.

⁴⁴ See CT Public Act No. 12-30.

⁴⁵ Wis. Stat. s. 450.01.

⁴⁶ Section 465.025(2), F.S.

⁴⁷ *Id.*

transmission of the prescription, by making an overt act to indicate the brand name medication is “medically necessary.”⁴⁸ The Board of Pharmacy and the Board of Medicine establish a formulary which lists brand name medications and generic medications they determine to be so clinically different as to be biologically and therapeutically inequivalent, which cannot be substituted.⁴⁹

Florida law allows a pharmacist to substitute a biosimilar⁵⁰ for a prescribed biological product⁵¹ 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.⁵² The ability of a pharmacist to substitute a biosimilar for a prescription biological product is permissive unlike the substitution of brand name drugs with generic drugs, which is mandatory.

For generic and biosimilar substitution, 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.⁵³

Florida law does not specifically authorize a pharmacist to substitute a therapeutically equivalent, but chemically different, drug for a prescribed drug without the express authorization of the prescriber.

Effect of Proposed Changes

The bill authorizes a nursing home to establish an institutional formulary through which a pharmacist may use therapeutic substitution. This would allow a pharmacist to replace a resident’s prescribed drug with a chemically different drug listed in the formulary that is expected to have the same clinical effect.

To implement an institutional formulary, a nursing home must:

- Establish a committee, which consists of the medical director, director of nursing, and a consultant pharmacist, to develop the institutional formulary, as well as written guidelines or procedures for the formulary;
- Establish methods and criteria for selecting and objectively evaluating available drugs that may be used as therapeutic substitutes;
- Establish and maintain policies and procedures for developing and maintaining an institutional formulary and for approving, disseminating, and notifying prescribers of the formulary and make such policies and procedures available to AHCA, upon request; and
- Quarterly monitor compliance with the established policies and procedures and the clinical outcomes of therapeutic substitutions.

The nursing home must obtain authorization from a prescriber for the use of the institutional formulary for each of the prescriber’s patients. The prescriber must also approve any subsequent changes to the formulary. The nursing home must notify the prescriber prior to each therapeutic substitution in the prescriber’s preferred manner and document the therapeutic substitution in the president’s medical record. The bill prohibits the nursing home from taking adverse action against a prescriber who refuses to use the institutional formulary.

⁴⁸ Id.

⁴⁹ Section 465.025(6), F.S.; see also Rule 64B-16.27.500, F.A.C.

⁵⁰ 42 U.S.C. s. 262 (h) defines a “biosimilar” as a biological product that is highly similar to the licensed biological product or reference product, that notwithstanding minor differences in clinically inactive components, has no clinically meaningful differences in terms of safety, purity, and potency of the product.

⁵¹ 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.

⁵² Section 465.0252(2), F.S.

⁵³ Sections 465.025(3)(a) and 465.0252(2)(c), respectively.

The bill also requires a nursing home to obtain informed consent from the resident or resident's representative to use the institutional formulary for the resident. The bill prohibits a nursing home from taking adverse action against a prescriber who refuses to agree to use the institutional formulary.

A prescriber who has authorized the use of the institutional formulary for his or her patients may opt out of the formulary with respect to a specific drug or class of drugs. If a prescriber does not want a therapeutic substitution for a particular prescription, the bill requires the prescriber to indicate "NO THERAPEUTIC SUBSTITUTION" on the prescription or make an overt action to indicate that a substitution is not authorized when the prescription is provided orally.

The bill authorizes a pharmacist to perform a therapeutic substitution in accordance with a nursing home's institutional formulary if the prescriber has agreed to its use. The pharmacist may not therapeutically substitute a drug if the prescriber indicates "NO THERAPEUTIC SUBSTITUTION" on the prescription or overtly indicates that therapeutic substitution is not authorized if the prescription is provided orally. A pharmacist must dispense the drug or drugs as prescribed if the prescriber or the resident has not authorized the use of the institutional formulary.

The bill provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

AHCA may experience an insignificant, nonrecurring, negative fiscal impact to amend rules and survey materials to ensure nursing homes that adopt institutional formularies comply with the bill's requirements.

The bill has no impact on the Medicaid program, which uses a preferred drug list and prior authorization protocol; the institutional formularies authorized by the bill would not apply to Medicaid patients.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Patients and nursing homes who receive a bundled payment for Medicare Part A patients may experience cost savings if a less expensive drug is therapeutically substituted for a prescribed drug, in instances where patients and nursing homes incur drug costs. It is unclear whether private insurers using their own formularies would experience an economic impact.

D. FISCAL COMMENTS:

None.