

CHAPTER 2020-103

Committee Substitute for House Bill No. 559

An act relating to institutional formularies established by nursing home facilities; creating s. 400.143, F.S.; providing definitions; authorizing a nursing home facility to establish and implement an institutional formulary; requiring a nursing home facility to establish a committee to develop an institutional formulary; providing for committee membership; providing requirements for the development and implementation of the institutional formulary; requiring a nursing home facility to maintain the written policies and procedures for the institutional formulary; requiring a nursing home facility to make available such policies and procedures to the Agency for Health Care Administration, upon request; requiring a prescriber to authorize the use of the institutional formulary for each patient; requiring a nursing home facility to obtain the prescriber's approval for any changes made to the institutional formulary; authorizing a prescriber to opt out of using the institutional formulary; prohibiting a nursing home facility from taking adverse action against a prescriber for declining to use the institutional formulary; requiring a nursing home facility to notify the prescriber of therapeutic substitutions using a certain method of communication; requiring the nursing home facility to document such substitutions in a resident's medical records; authorizing a prescriber to prevent a therapeutic substitution for a specific prescription; requiring the nursing home facility to obtain informed consent for the use of the institutional formulary; requiring such facility to inform a resident or the resident's legal representative, or his or her designee, of the right to refuse to participate in the use of the institutional formulary; prohibiting a nursing home facility from taking adverse action against a resident for refusing to participate in the use of the institutional formulary; amending s. 465.025, F.S.; authorizing a pharmacist to therapeutically substitute medicinal drugs under an institutional formulary established by a nursing home facility under certain circumstances; prohibiting a pharmacist from therapeutically substituting a medicinal drug under certain circumstances; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 400.143, Florida Statutes, is created to read:

400.143 Institutional formularies established by nursing home facilities.

(1) For purposes of this section, the term:

(a) "Institutional formulary" means a list of medicinal drugs established by a nursing home facility under this section for which a pharmacist may use a therapeutic substitution for a medicinal drug prescribed to a resident of the facility.

(b) “Medicinal drug” has the same meaning as provided in s. 465.003(8).

(c) “Prescriber” has the same meaning as provided in s. 465.025(1).

(d) “Therapeutic substitution” means the practice of replacing a nursing home facility resident’s prescribed medicinal drug with another chemically different medicinal drug that is expected to have the same clinical effect.

(2) A nursing home facility may establish and implement an institutional formulary in accordance with the requirements of this section.

(3) A nursing home facility that implements an institutional formulary under this section must:

(a) Establish a committee to develop the institutional formulary and written guidelines or procedures for such institutional formulary. The committee must consist of, at a minimum:

1. The facility’s medical director.

2. The facility’s director of nursing services.

3. A consultant pharmacist licensed by the Department of Health and certified under s. 465.0125.

(b) Establish methods and criteria for selecting and objectively evaluating all available pharmaceutical products that may be used as therapeutic substitutes.

(c) Establish policies and procedures for developing and maintaining the institutional formulary and for approving, disseminating, and notifying prescribers of the institutional formulary.

(d) Perform quarterly monitoring to ensure compliance with the policies and procedures established under paragraph (c) and monitor the clinical outcomes in circumstances in which a therapeutic substitution has occurred.

(4) The nursing home facility shall maintain all written policies and procedures for the institutional formulary established under this section. Each nursing home facility shall make available such policies and procedures to the agency, upon request.

(5)(a) A prescriber who uses the institutional formulary must authorize such use for each patient. A nursing home facility must obtain the prescriber’s approval for any subsequent change made to a nursing home facility’s institutional formulary. A prescriber may opt out of the nursing home facility’s institutional formulary with respect to a medicinal drug or class of medicinal drugs for any resident. A nursing home facility may not take adverse action against a prescriber for declining to use the facility’s institutional formulary.

(b) A nursing home facility must notify the prescriber before each therapeutic substitution using a method of communication designated by the prescriber. A nursing home facility must document the therapeutic substitution in the resident’s medical records.

(c) A prescriber may prevent a therapeutic substitution for a specific prescription by indicating “NO THERAPEUTIC SUBSTITUTION” on the prescription. If the prescription is provided orally, the prescriber must make an overt action to opt out of the therapeutic substitution.

(6) The nursing home facility must obtain informed consent from a resident or a resident’s legal representative, or his or her designee, to the use of the institutional formulary for the resident. The nursing home facility must clearly inform the resident or the resident’s legal representative, or his or her designee, of the right to refuse to participate in the use of the institutional formulary and may not take any adverse action against the resident who refuses to participate in the use of the institutional formulary.

Section 2. Subsection (9) is added to section 465.025, Florida Statutes, to read:

465.025 Substitution of drugs.—

(9) A pharmacist may therapeutically substitute medicinal drugs in accordance with an institutional formulary established under s. 400.143 for the resident of a nursing home facility if the prescriber has agreed to the use of such institutional formulary for the patient. The pharmacist may not therapeutically substitute a medicinal drug pursuant to the facility’s institutional formulary if the prescriber indicates on the prescription “NO THERAPEUTIC SUBSTITUTION” or overtly indicates that therapeutic substitution is prohibited as authorized under s. 400.143(5)(c).

Section 3. This act shall take effect July 1, 2020.

Approved by the Governor June 27, 2020.

Filed in Office Secretary of State June 27, 2020.