

400.143 Institutional formularies established by nursing home facilities.

For purposes of this section, the term: "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. "Medicinal drug" has the same meaning as provided in s. 465.003. "Prescriber" has the same meaning as provided in s. 465.025(1). "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. A nursing home facility may establish and implement an institutional formulary in accordance with the requirements of this section. A nursing home facility that implements an institutional formulary under this section must: 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: The facility's medical director. The facility's director of nursing services. A consultant pharmacist licensed by the Department of Health and certified under s. 465.0125. 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 institutional formulary and for approving, disseminating, and notifying prescribers of the institutional formulary. 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. 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. 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. 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. 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. 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.