

1                   A bill to be entitled  
2           An act relating to institutional formularies  
3           established by nursing home facilities; creating s.  
4           400.143, F.S.; providing definitions; authorizing a  
5           nursing home facility to establish and implement an  
6           institutional formulary; requiring a nursing home  
7           facility to establish a committee to develop an  
8           institutional formulary; providing for committee  
9           membership; providing requirements for the development  
10          and implementation of the institutional formulary;  
11          requiring a nursing home facility to maintain the  
12          written policies and procedures for the institutional  
13          formulary; requiring a nursing home facility to make  
14          available such policies and procedures to the Agency  
15          for Health Care Administration, upon request;  
16          requiring a prescriber to annually authorize the use  
17          of the institutional formulary for certain patients;  
18          requiring the prescriber to opt into any changes made  
19          to the institutional formulary; authorizing a  
20          prescriber to opt out of using the institutional  
21          formulary or to prevent a therapeutic substitution  
22          under certain circumstances; prohibiting a nursing  
23          home facility from taking adverse action against a  
24          prescriber for refusing to agree to the use of the  
25          institutional formulary; amending s. 465.025, F.S.;

26 | authorizing a pharmacist to therapeutically substitute  
 27 | medicinal drugs under an institutional formulary  
 28 | established by a nursing home facility under certain  
 29 | circumstances; prohibiting a pharmacist from  
 30 | therapeutically substituting a medicinal drug under  
 31 | certain circumstances; providing an effective date.

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

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

37 | 400.143 Institutional formularies established by nursing  
 38 | home facilities.-

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

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

44 | (b) "Medicinal drug" has the same meaning as provided in  
 45 | s. 465.003(8).

46 | (c) "Prescriber" has the same meaning as provided in s.  
 47 | 465.025(1).

48 | (d) "Therapeutic substitution" means the practice of  
 49 | replacing a nursing home facility resident's prescribed  
 50 | medicinal drug with another chemically different medicinal drug

51 that is expected to have the same clinical effect.

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

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

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

- 61 1. The facility's medical director.
- 62 2. The facility's director of nursing services.
- 63 3. A consultant pharmacist licensed by the Department of  
64 Health and certified under s. 465.0125.

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

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

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

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

81       (5) (a) A prescriber must annually authorize the  
82 institutional formulary for his or her patients. A prescriber  
83 must opt into any subsequent changes made to a nursing home  
84 facility's institutional formulary.

85       (b) A prescriber may opt out of the nursing home  
86 facility's institutional formulary with respect to a particular  
87 patient, medicinal drug, or class of medicinal drugs.

88       (c) A prescriber may prevent a therapeutic substitution  
89 for a specific medication order if such order is provided  
90 verbally or generated and transmitted electronically by  
91 indicating "NO THERAPEUTIC SUBSTITUTION" on the prescription.

92       (d) A nursing home facility may not take adverse action  
93 against a prescriber for refusing to agree to the use of the  
94 facility's institutional formulary.

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

97       465.025 Substitution of drugs.—

98       (9) A pharmacist may therapeutically substitute medicinal  
99 drugs in accordance with an institutional formulary established  
100 under s. 400.143 for the resident of a nursing home facility if

101 the prescriber has agreed to the use of such institutional  
102 formulary. The pharmacist may not therapeutically substitute a  
103 medicinal drug pursuant to the facility's institutional  
104 formulary if the prescriber indicates verbally or electronically  
105 on the prescription "NO THERAPEUTIC SUBSTITUTION" as authorized  
106 under s. 400.143(5)(c).

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