

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 authorize the use of the  
17          institutional formulary for each patient; requiring a  
18          nursing home facility to obtain the prescriber's  
19          approval for any changes made to the institutional  
20          formulary; authorizing a prescriber to opt out of  
21          using the institutional formulary; prohibiting a  
22          nursing home facility from taking adverse action  
23          against a prescriber for declining to use the  
24          institutional formulary; requiring a nursing home  
25          facility to notify the prescriber of therapeutic

26 | substitutions using a certain method of communication;  
27 | requiring the nursing home facility to document such  
28 | substitutions in a resident's medical records;  
29 | authorizing a prescriber to prevent a therapeutic  
30 | substitution for a specific prescription; requiring  
31 | the nursing home facility to obtain informed consent  
32 | for the use of the institutional formulary; requiring  
33 | such facility to inform a resident or the resident's  
34 | legal representative, or his or her designee, of the  
35 | right to refuse to participate in the use of the  
36 | institutional formulary; prohibiting a nursing home  
37 | facility from taking adverse action against a resident  
38 | for refusing to participate in the use of the  
39 | institutional formulary; amending s. 465.025, F.S.;  
40 | authorizing a pharmacist to therapeutically substitute  
41 | medicinal drugs under an institutional formulary  
42 | established by a nursing home facility under certain  
43 | circumstances; prohibiting a pharmacist from  
44 | therapeutically substituting a medicinal drug under  
45 | certain circumstances; providing an effective date.

46 |  
47 | Be It Enacted by the Legislature of the State of Florida:

48 |  
49 | Section 1. Section 400.143, Florida Statutes, is created  
50 | to read:

51 400.143 Institutional formularies established by nursing  
 52 home facilities.-

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

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

58 (b) "Medicinal drug" has the same meaning as provided in  
 59 s. 465.003(8).

60 (c) "Prescriber" has the same meaning as provided in s.  
 61 465.025(1).

62 (d) "Therapeutic substitution" means the practice of  
 63 replacing a nursing home facility resident's prescribed  
 64 medicinal drug with another chemically different medicinal drug  
 65 that is expected to have the same clinical effect.

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

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

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

75 1. The facility's medical director.

76        2. The facility's director of nursing services.

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

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

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

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

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

95        (5) (a) A prescriber who uses the institutional formulary  
 96 must authorize such use for each patient. A nursing home  
 97 facility must obtain the prescriber's approval for any  
 98 subsequent change made to a nursing home facility's  
 99 institutional formulary. A prescriber may opt out of the nursing  
 100 home facility's institutional formulary with respect to a

101 medicinal drug or class of medicinal drugs for any resident. A  
102 nursing home facility may not take adverse action against a  
103 prescriber for declining to use the facility's institutional  
104 formulary.

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

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

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

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

126           465.025 Substitution of drugs.—  
127           (9) A pharmacist may therapeutically substitute medicinal  
128 drugs in accordance with an institutional formulary established  
129 under s. 400.143 for the resident of a nursing home facility if  
130 the prescriber has agreed to the use of such institutional  
131 formulary for the patient. The pharmacist may not  
132 therapeutically substitute a medicinal drug pursuant to the  
133 facility's institutional formulary if the prescriber indicates  
134 on the prescription "NO THERAPEUTIC SUBSTITUTION" or overtly  
135 indicates that therapeutic substitution is prohibited as  
136 authorized under s. 400.143(5)(c).

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