

ENROLLED

CS/HB 559

2020 Legislature

1
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

ENROLLED

CS/HB 559

2020 Legislature

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:

ENROLLED

CS/HB 559

2020 Legislature

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.

ENROLLED

CS/HB 559

2020 Legislature

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

ENROLLED

CS/HB 559

2020 Legislature

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:

ENROLLED

CS/HB 559

2020 Legislature

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.