



26 Section 2. Subsection (6) of section 465.019, Florida  
 27 Statutes, is amended, subsection (7) is added to that section,  
 28 and paragraph (a) of subsection (2) of that section is  
 29 republished, to read:

30 465.019 Institutional pharmacies; permits.—

31 (2) The following classes of institutional pharmacies are  
 32 established:

33 (a) "Class I institutional pharmacies" are those  
 34 institutional pharmacies in which all medicinal drugs are  
 35 administered from individual prescription containers to the  
 36 individual patient and in which medicinal drugs are not  
 37 dispensed on the premises, except that nursing homes licensed  
 38 under part II of chapter 400 may purchase medical oxygen for  
 39 administration to residents. No medicinal drugs may be dispensed  
 40 in a Class I institutional pharmacy.

41 (6) In a Class I institutional pharmacy, a Class II  
 42 institutional pharmacy, or a Class III institutional pharmacy,  
 43 an institutional formulary system may be adopted with approval  
 44 of the medical staff for the purpose of identifying those  
 45 medicinal drugs, proprietary preparations, biologics,  
 46 biosimilars, and biosimilar interchangeables that may be  
 47 dispensed by a practicing pharmacist for a Class I institutional  
 48 pharmacy, or dispensed by a practicing pharmacist in a Class II  
 49 institutional pharmacy or a Class III institutional pharmacy,  
 50 who is employed by the institutional pharmacy ~~the pharmacists~~

51 ~~employed in such institution.~~ A facility that has with a Class I  
52 institutional pharmacy permit, a Class II institutional pharmacy  
53 permit, or a Class III institutional pharmacy permit which is  
54 operating under the formulary system shall establish policies  
55 and procedures for the development of the system, in accordance  
56 with the joint standards of the American Hospital Association  
57 and American Society of Hospital Pharmacists, for the use  
58 ~~utilization of an institutional a hospital~~ formulary system,  
59 which must ~~formulary shall~~ be approved by the medical staff.

60 (7) The policies and procedures for an institutional  
61 formulary system in a Class I institutional pharmacy must:

62 (a) Be approved by the medical staff.

63 (b) Openly provide detailed methods and criteria for the  
64 selection and objective evaluation of all available  
65 pharmaceuticals.

66 (c) Include policies for the development, maintenance,  
67 approval, dissemination, and notification to prescribers of the  
68 drug formulary and for continuous and comprehensive review of  
69 formulary drugs.

70 (d) Provide for regular monitoring of compliance with the  
71 policies and procedures and of clinical outcomes in  
72 circumstances in which a substitution of drugs has occurred.

73 (e) Provide a mechanism to inform the prescriber prior to  
74 any substitution of drugs by using a method of communication  
75 designated by the prescriber for such purpose. The method of

76 communication designated by the prescriber must be noted in the  
77 patient's chart.

78 (f) Establish a process that allows any individual  
79 prescriber to opt out of the formulary system.

80 (g) Establish a process that allows any individual  
81 prescriber to opt out of the formulary system only with respect  
82 to a particular patient.

83 (h) Include policies stating that practitioners will not  
84 be penalized for prescribing nonformulary drug products that are  
85 medically necessary.

86 (i) Be consistent with applicable state and federal laws  
87 and with rules of the department and board.

88 Section 3. This act shall take effect July 1, 2019.