1	A bill to be entitled
2	An act relating to institutional pharmacies; amending
3	s. 465.003, F.S.; revising the definition of the term
4	"institutional formulary system"; amending s. 465.019,
5	F.S.; authorizing the use of an institutional
6	formulary system in a Class I institutional pharmacy;
7	specifying requirements for the policies and
8	procedures of an institutional formulary system in a
9	Class I institutional pharmacy; providing an effective
10	date.
11	
12	Be It Enacted by the Legislature of the State of Florida:
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14	Section 1. Subsection (7) of section 465.003, Florida
15	Statutes, is amended to read:
16	465.003 Definitions.—As used in this chapter, the term:
17	(7) "Institutional formulary system" means a method
18	whereby the medical staff evaluates, appraises, and selects
19	those medicinal drugs or proprietary preparations that, which in
20	the <u>clinical judgment of the</u> medical <u>staff,</u> staff's clinical
21	$rac{judgment}{are}$ are most useful in patient care, and $rac{which}{hich}$ are
22	available for dispensing by a practicing pharmacist for a Class
23	I institutional pharmacy, or a practicing pharmacist in a Class
24	II <u>institutional pharmacy</u> or <u>a</u> Class III institutional pharmacy <u>,</u>
25	as those terms are defined in s. 465.019(2).

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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 The following classes of institutional pharmacies are (2)32 established: 33 "Class I institutional pharmacies" are those (a) institutional pharmacies in which all medicinal drugs are 34 35 administered from individual prescription containers to the individual patient and in which medicinal drugs are not 36 37 dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for 38 39 administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy. 40 (6) In a Class I institutional pharmacy, a Class II 41 institutional pharmacy, or a Class III institutional pharmacy, 42 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 dispensed by a practicing pharmacist for a Class I institutional 47 pharmacy, or dispensed by a practicing pharmacist in a Class II 48 institutional pharmacy or a Class III institutional pharmacy, 49 50 who is employed by the institutional pharmacy the pharmacists

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employed in such institution. A facility that has with a Class I institutional pharmacy permit, a Class II institutional pharmacy permit, or a Class III institutional pharmacy permit which is operating under the formulary system shall establish policies and procedures for the development of the system, in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists, for the use utilization of an institutional a hospital formulary system, which must formulary shall be approved by the medical staff. The policies and procedures for an institutional (7) formulary system in a Class I institutional pharmacy must: (a) Be approved by the medical staff. (b) Openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals. (c) Include policies for the development, maintenance, approval, dissemination, and notification to prescribers of the drug formulary and for continuous and comprehensive review of formulary drugs. (d) Provide for regular monitoring of compliance with the policies and procedures and of clinical outcomes in circumstances in which a substitution of drugs has occurred. (e) Provide a mechanism to inform the prescriber prior to any substitution of drugs by using a method of communication designated by the prescriber for such purpose. The method of

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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.					
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