

By Senator McClain

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A bill to be entitled

An act relating to outsourcing facilities; creating s. 465.0199, F.S.; providing legislative findings and intent; requiring outsourcing facilities to apply to the Department of Health, using a form prescribed by the Board of Pharmacy, to obtain a permit before engaging in specified activities; requiring the department to issue outsourcing facility permits to applicants the board certifies as meeting certain criteria; requiring that the initial application for the permit include specified documentation; requiring the board to review such documentation and consider certain actions of the applicant outsourcing facility; prohibiting the department from issuing a permit to an outsourcing facility under certain circumstances; providing that certain outsourcing facilities are only required to obtain an outsourcing facility permit; requiring outsourcing facilities to obtain additional applicable permits if they engage in certain activities; providing applicability; providing that outsourcing facilities holding a valid outsourcing permit issued before a specified date are deemed to be in compliance with certain permitting requirements; authorizing such facilities to continue operating under such permit until a certain condition occurs; requiring the board and the department to rely on and recognize certain federal inspection reports as satisfying state inspection requirements for purposes of initial permitting and subsequent renewals;

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authorizing the department to conduct inspections under certain circumstances; providing that the board is the sole state regulatory authority responsible for the permitting, oversight, and discipline of outsourcing facilities; exempting permitted outsourcing facilities from separate licensure or permitting requirements under the Florida Drug and Cosmetic Act for engaging in specified activities; requiring the board to adopt rules; amending s. 499.002, F.S.; exempting permitted outsourcing facilities from the applicability of the Florida Drug and Cosmetic Act under certain circumstances; providing an effective date.

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

Section 1. Section 465.0199, Florida Statutes, is created to read:

465.0199 Outsourcing facility permit; inspection; board authority.—

(1) LEGISLATIVE INTENT.—The Legislature finds that outsourcing facilities registered under 21 U.S.C. s. 353b are subject to comprehensive federal inspection and oversight by the United States Food and Drug Administration to ensure the quality, safety, and integrity of compounded drug products. The Legislature further finds that duplicative state and federal inspection regimes, overlapping regulatory requirements, and inconsistent standards among jurisdictions create unnecessary administrative burdens and confusion, thereby diminishing the

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effectiveness of regulatory oversight. It is the intent of the Legislature to recognize the primacy of federal oversight under 21 U.S.C. s. 353b, ensure coordination between federal and state regulatory authorities, and promote efficient regulation of outsourcing facilities while maintaining the protection of the public's health, welfare, and safety.

(2) PERMIT REQUIRED.—

(a) An outsourcing facility as defined in s. 465.003 which is located within this state must apply to the department, using a form prescribed by the board, and obtain an outsourcing facility permit before engaging in the compounding, dispensing, distributing, or other furnishing of compounded drug products within this state or in any jurisdiction outside this state.

(b) The department shall issue an outsourcing facility permit to an outsourcing facility that the board certifies as meeting the requirements of this chapter and applicable federal law.

(c) An initial application for an outsourcing facility permit under this section must include documentation of an inspection conducted by the United States Food and Drug Administration demonstrating compliance with all current federal good manufacturing practices. In reviewing such documentation, the board shall also consider any corrective actions taken by the outsourcing facility in response to observations noted by the United States Food and Drug Administration. The department may not issue an initial permit to an outsourcing facility that has not been inspected by the United States Food and Drug Administration.

(d) An outsourcing facility that does not engage in

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88 patient-specific sterile compounding and dispensing pursuant to  
89 a prescription is only required to obtain an outsourcing  
90 facility permit. However, if the outsourcing facility engages in  
91 patient-specific sterile compounding, it must also obtain the  
92 appropriate pharmacy permit corresponding to the type of  
93 dispensing conducted, such as a community pharmacy permit or an  
94 institutional pharmacy permit.

95 (e) This subsection applies only to an outsourcing facility  
96 that submits an initial application for an outsourcing facility  
97 permit on or after July 1, 2026. An outsourcing facility that  
98 holds a valid outsourcing facility permit issued by the  
99 department before July 1, 2026, is deemed to be in compliance  
100 with the permitting requirements of this subsection and may  
101 continue to operate under such permit until its expiration,  
102 renewal, suspension, or revocation in accordance with this  
103 chapter.

104 (3) INSPECTION.—

105 (a) For both initial permitting and renewal, the board and  
106 the department shall rely upon and recognize the outsourcing  
107 facility's most recent inspection report issued by the United  
108 States Food and Drug Administration as satisfying any state  
109 inspection requirement. For initial licensure, a preoperational  
110 inspection by the United States Food and Drug Administration  
111 demonstrating compliance with current good manufacturing  
112 practices, together with any corrective actions taken by the  
113 facility in response to observations by the United States Food  
114 and Drug Administration, satisfies the state inspection  
115 requirement.

116 (b) The department may conduct an inspection for cause upon

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117 receipt of credible evidence of noncompliance or to verify the  
118 implementation of corrective actions related to federal  
119 findings.

120 (4) BOARD AUTHORITY.—

121 (a) The board is the sole state regulatory authority  
122 responsible for the permitting, oversight, and discipline of  
123 outsourcing facilities under this section.

124 (b) An outsourcing facility permitted under this section is  
125 exempt from separate licensure or permitting required under part  
126 I of chapter 499 for those activities that fall within the scope  
127 of an outsourcing facility pursuant to 21 U.S.C. s. 353b and the  
128 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.

129 (5) RULEMAKING.—The board shall adopt rules to implement  
130 this section, including, but not limited to, procedures for  
131 application, renewal, and recognition of federal inspection  
132 documentation.

133 Section 2. Subsection (8) is added to section 499.002,  
134 Florida Statutes, to read:

135 499.002 Purpose, administration, and enforcement of and  
136 exemption from this part.—

137 (8) This part does not apply to an outsourcing facility  
138 that holds a valid outsourcing facility permit issued under s.  
139 465.0199 for activities conducted within the scope of such  
140 permit pursuant to 21 U.S.C. s. 353b and the Federal Food, Drug,  
141 and Cosmetic Act, 21 U.S.C. ss. 301 et seq.

142 Section 3. This act shall take effect July 1, 2026.