

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;

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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; 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

51 outsourcing facilities registered under 21 U.S.C. s. 353b are
52 subject to comprehensive federal inspection and oversight by the
53 United States Food and Drug Administration to ensure the
54 quality, safety, and integrity of compounded drug products. The
55 Legislature further finds that duplicative state and federal
56 inspection regimes, overlapping regulatory requirements, and
57 inconsistent standards among jurisdictions create unnecessary
58 administrative burdens and confusion, thereby diminishing the
59 effectiveness of regulatory oversight. It is the intent of the
60 Legislature to recognize the primacy of federal oversight under
61 21 U.S.C. s. 353b, ensure coordination between federal and state
62 regulatory authorities, and promote efficient regulation of
63 outsourcing facilities while maintaining the protection of the
64 public's health, welfare, and safety.

65 (2) PERMIT REQUIRED.—

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

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

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

87 (d) An outsourcing facility that does not engage in
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
96 facility that submits an initial application for an outsourcing
97 facility permit on or after July 1, 2026. An outsourcing
98 facility that holds a valid outsourcing facility permit issued
99 by the department before July 1, 2026, is deemed to be in
100 compliance with the permitting requirements of this subsection

101 and may continue to operate under such permit until its
102 expiration, renewal, suspension, or revocation in accordance
103 with this 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
117 upon receipt of credible evidence of noncompliance or to verify
118 the 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
125 is exempt from separate licensure or permitting required under

126 part I of chapter 499 for those activities that fall within the
127 scope of an outsourcing facility pursuant to 21 U.S.C. s. 353b
128 and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301
129 et seq.

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

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

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

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

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