

Senate File 240 - Introduced

SENATE FILE 240
BY CAMPBELL

A BILL FOR

- 1 An Act relating to the inspection of compounding pharmacies, and
- 2 making penalties applicable.
- 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

unofficial

1 Section 1. Section 22.7, Code 2025, is amended by adding the
2 following new subsection:

3 NEW SUBSECTION. 76. Records relating to the investigation
4 and remediation of an infraction at a compounding facility
5 engaging in the compounding of nonsterile preparations as
6 provided in section 155A.15A.

7 Sec. 2. NEW SECTION. **155A.15A Compounding facilities —**
8 **inspections — penalties.**

9 1. a. If an inspector employed by the board discovers
10 during the course of an inspection that a compounding facility
11 engaging in the compounding of nonsterile preparations is out of
12 compliance with the requirements of United States pharmacopeia
13 general chapter 795, the inspector shall notify the pharmacist
14 in charge of the compounding facility of the infraction that the
15 pharmacist in charge must correct.

16 b. If an inspector employed by the board discovers during the
17 course of an inspection conducted not less than thirty days, or
18 more than ninety days, after the date of an inspection described
19 in paragraph "a" that the infraction identified pursuant to
20 paragraph "a" has not been corrected, the inspector shall
21 provide comprehensive instruction regarding the infraction and
22 the correction of the infraction to the pharmacist in charge.

23 c. If an inspector employed by the board discovers during the
24 course of an inspection conducted not less than thirty days, or
25 more than ninety days, after an inspection described in paragraph
26 "b" that the infraction identified pursuant to paragraph "a"
27 has not been corrected, the inspector shall prescribe mandatory
28 education for the pharmacist in charge for the correction of the
29 infraction.

30 2. If a compounding facility engaging in the compounding
31 of nonsterile preparations does not correct an infraction as
32 provided in subsection 1, the board may impose a single fine
33 not to exceed five hundred dollars, which shall be adjusted for
34 inflation, as defined in section 668.15A, by the board by rule on
35 January 1 of each even-numbered year. The board shall not impose

1 any other fine or remedy for a violation of this section. This
2 subsection shall not affect damages available in tort, contract,
3 or otherwise for a violation of this section.

4 EXPLANATION

5 The inclusion of this explanation does not constitute agreement with
6 the explanation's substance by the members of the general assembly.

7 This bill relates to the investigation and remediation of
8 infractions at compounding facilities (facility) engaging in the
9 compounding of nonsterile preparations. The bill requires an
10 inspector employed by the board of pharmacy (board) who discovers
11 during the course of an inspection that a facility engaging in
12 the compounding of nonsterile preparations is out of compliance
13 with the United States pharmacopeia general chapter 795 to notify
14 the pharmacist in charge of the infraction. If an inspector
15 discovers at a subsequent inspection that the infraction has
16 not been corrected, the bill requires the inspector to provide
17 comprehensive instruction regarding the infraction and the
18 correction of the infraction to the pharmacist in charge. If an
19 inspector discovers at a third inspection that an infraction has
20 not been corrected, the bill requires the inspector to prescribe
21 mandatory education for the correction of the infraction to the
22 pharmacist in charge.

23 The bill allows the board to impose a single fee of not
24 more than \$500, adjusted for inflation, on a facility that fails
25 to correct an infraction as provided in the bill. The bill
26 makes records relating to the investigation and remediation of
27 infractions pursuant to the bill confidential records that are
28 not subject to examination by the public.