

HB79 INTRODUCED



1 3PL7EV-1
2 By Representative Rigsby
3 RFD: Boards, Agencies and Commissions
4 First Read: 07-Mar-23
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SYNOPSIS:

Under existing law, each manufacturer, bottler, packager, wholesale drug distributor, or other entity in the supply chain for pharmaceutical products is required to obtain an annual permit from the Board of Pharmacy and pay an annual permit fee.

This bill would require each holder of a permit to designate a representative of the permit holder and would require the representative to register with the board and pay an additional annual registration fee.

A BILL
TO BE ENACTED
AN ACT

Relating to the Board of Pharmacy; to amend Section 34-23-32 of the Code of Alabama 1975, requiring a manufacturer, bottler, packager, wholesale drug distributor, and other entities in the supply chain for pharmaceutical products to obtain an annual permit from the board; to require each permit holder to designate a representative of the permit holder who would be required to register with the board; and to provide for an additional annual registration fee.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Section 34-23-32 of the Code of Alabama



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29 1975, is amended to read as follows:

30 "§34-23-32

31 (a) Commencing on August 1, 2017, every manufacturer,
32 bottler, packager, repackager, third party logistic provider,
33 wholesale drug distributor, private label distributor,
34 outsourcing facility, or pharmacy business identified in the
35 supply chain of drugs, medicines, chemicals, or poisons for
36 medicinal purposes shall register annually with the board by
37 application for a permit on a form furnished by the board and
38 accompanied by a fee to be determined by the board as follows:

39 (1) The fee shall not be less than five hundred dollars
40 (\$500) nor more than two thousand dollars (\$2,000) for a new
41 establishment.

42 (2) The fee shall not be less than two hundred fifty
43 dollars (\$250) nor more than one thousand dollars (\$1,000) for
44 a renewal permit.

45 (3) The fee shall not be less than five hundred dollars
46 (\$500) nor more than two thousand dollars (\$2,000) for a
47 permit due to transfer of ownership.

48 (b) A holder of a permit shall employ a full-time
49 licensed pharmacist whose principal duty shall be confined to
50 on-premise pharmaceutical operations. Wholesale drug
51 distributors who strictly limit their operation to
52 distribution of drugs, medicines, chemicals, or poisons for
53 medicinal purposes are exempt from the requirement to employ a
54 full-time licensed pharmacist.

55 (c) The professional practice of any physician licensed
56 to practice medicine is exempt from the requirements of this



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57 section.

58 (d) All permits issued under this section shall become
59 due on October 31 and shall become null and void if not paid
60 by December 31. Each application for the renewal of the permit
61 shall be made annually on or before December 31. A penalty of
62 one hundred dollars (\$100) for each overdue month shall be
63 assessed in addition to the permit fee for renewal of
64 delinquent permits. ~~For each application for a permit made and
65 found to be satisfactory by the board, the secretary of the
66 board shall issue to the applicant a permit for such
67 appropriate function, which permit shall be displayed in a
68 conspicuous place.~~

69 (e) (1) Commencing on January 1, 2024, each holder of a
70 permit issued under this section, with the exception of an
71 outsourcing facility, shall designate a current representative
72 of the permit holder and shall register the designated
73 representative with the board. The designated representative
74 shall possess the qualifications, requirements, and background
75 as set out by the board.

76 (2) The holder of the permit shall pay an initial
77 registration fee to register the designated representative of
78 not less than one hundred dollars (\$100), as set by rule of
79 the board. The registration of a designated representative
80 shall expire on December 31. The renewal of the registration
81 shall be due on October 31 of each year and shall be
82 delinquent after December 31. The annual fee for the renewal
83 of a designated representative shall not be less than one
84 hundred dollars (\$100), as set by rule of the board. If the



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85 renewal is not timely received by the board, the applicant for
86 renewal of the registration shall pay a penalty of not more
87 than fifty dollars (\$50) for each month the renewal is late,
88 as set by rule of the board.

89 ~~(e)~~ (f) All holders of a permit shall, before shipping
90 any drug bearing the legend, "caution, federal law prohibits
91 dispensing without prescription" or similar wording causing
92 these drugs to be known as legend drugs to new customers,
93 assure themselves that the recipient is either a duly licensed
94 doctor of medicine, dentistry, or veterinary medicine or holds
95 a registered pharmacy permit from the board by contacting the
96 office of the board.

97 ~~(f)~~ (g) No manufacturer, manufacturer affiliate,
98 bottler, packager, repackager, third party logistic provider,
99 wholesale drug distributor, private label distributor,
100 outsourcing facility, or pharmacy business identified in the
101 supply chain of any legend drug or device shall ship, or cause
102 to be shipped, into the state any legend drug or device
103 without a valid permit issued by the board. The civil penalty
104 for a violation of this subsection shall be four thousand
105 dollars (\$4,000) for each violation.

106 ~~(g)~~ (h) The holder of a permit to ship any legend drug
107 or device into the state shall provide to the board a list of
108 all trading partners, upon request of the board.

109 ~~(h)~~ (i) No holder of a permit shall ship any legend drug
110 to any person or firm after receiving written notice from the
111 board that the person or firm no longer holds a registered
112 pharmacy permit. Any person violating this section shall be



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113 guilty of a misdemeanor.

114 (j) For each application for a permit found to be
115 satisfactory by the board, the secretary of the board shall
116 issue to the applicant a permit for the appropriate function,
117 which permit shall be displayed in a conspicuous place."

118 Section 2. This act shall become effective on the first
119 day of the third month following its passage and approval by
120 the Governor, or its otherwise becoming law.