

- 1 3PL7EV-2
- 2 By Representative Rigsby
- 3 RFD: Boards, Agencies and Commissions
- 4 First Read: 07-Mar-23
- 5
- 6 2023 Regular Session



1	Enrolled, An Act,		
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4	A BILL		
5	TO BE ENACTED		
6	AN ACT		
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8	Relating to the Board of Pharmacy; to amend Section		
9	34-23-32 of the Code of Alabama 1975, requiring a		
10	manufacturer, bottler, packager, wholesale drug distributor,		
11	and other entities in the supply chain for pharmaceutical		
12	products to obtain an annual permit from the board; to require		
13	each permit holder to designate a representative of the permi		
14	holder who would be required to register with the board; and		
15	to provide for an additional annual registration fee.		
16	BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:		
17	Section 1. Section 34-23-32 of the Code of Alabama		
18	1975, is amended to read as follows:		
19	"§34-23-32		
20	(a) Commencing on August 1, 2017, every manufacturer,		
21	bottler, packager, repackager, third party logistic provider,		
22	wholesale drug distributor, private label distributor,		
23	outsourcing facility, or pharmacy business identified in the		
24	supply chain of drugs, medicines, chemicals, or poisons for		
25	medicinal purposes shall register annually with the board by		
26	application for a permit on a form furnished by the board and		
27	accompanied by a fee to be determined by the board as follows:		
28	(1) The fee shall not be less than five hundred dollars		

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29 (\$500) nor more than two thousand dollars (\$2,000) for a new 30 establishment.

31 (2) The fee shall not be less than two hundred fifty 32 dollars (\$250) nor more than one thousand dollars (\$1,000) for 33 a renewal permit.

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

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

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

47 (d) All permits issued under this section shall become 48 due on October 31 and shall become null and void if not paid 49 by December 31. Each application for the renewal of the permit 50 shall be made annually on or before December 31. A penalty of 51 one hundred dollars (\$100) for each overdue month shall be 52 assessed in addition to the permit fee for renewal of 53 delinquent permits. For each application for a permit made and found to be satisfactory by the board, the secretary of the 54 board shall issue to the applicant a permit for such 55 56 appropriate function, which permit shall be displayed in a



57	conspicuous place.			
58	(e)(1) Commencing on January 1, 2024, each holder of a			
59	permit issued under this section, with the exception of an			
60	outsourcing facility, shall designate a current representative			
61	of the permit holder and shall register the designated			
62	representative with the board. The designated representative			
63	shall possess the qualifications, requirements, and background			
64	as set out by the board.			
65	(2) The holder of the permit shall pay an initial			
66	registration fee to register the designated representative of			
67	not less than one hundred dollars (\$100), as set by rule of			
68	the board. The registration of a designated representative			
69	shall expire on December 31. The renewal of the registration			
70	shall be due on October 31 of each year and shall be			
71	delinquent after December 31. The annual fee for the renewal			
72	of a designated representative shall not be less than one			
73	hundred dollars (\$100), as set by rule of the board. If the			
74	renewal is not timely received by the board, the applicant for			
75	renewal of the registration shall pay a penalty of not more			
76	than fifty dollars (\$50) for each month the renewal is late,			
77	as set by rule of the board.			

78 (c) (f) All holders of a permit shall, before shipping 79 any drug bearing the legend, "caution, federal law prohibits 80 dispensing without prescription" or similar wording causing 81 these drugs to be known as legend drugs to new customers, 82 assure themselves that the recipient is either a duly licensed 83 doctor of medicine, dentistry, or veterinary medicine or holds 84 a registered pharmacy permit from the board by contacting the



85 office of the board.

86 (f) (g) No manufacturer, manufacturer affiliate, 87 bottler, packager, repackager, third party logistic provider, 88 wholesale drug distributor, private label distributor, 89 outsourcing facility, or pharmacy business identified in the 90 supply chain of any legend drug or device shall ship, or cause 91 to be shipped, into the state any legend drug or device 92 without a valid permit issued by the board. The civil penalty 93 for a violation of this subsection shall be four thousand dollars (\$4,000) for each violation. 94

95 (g) (h) The holder of a permit to ship any legend drug 96 or device into the state shall provide to the board a list of 97 all trading partners, upon request of the board.

98 (h)(i) No holder of a permit shall ship any legend drug 99 to any person or firm after receiving written notice from the 100 board that the person or firm no longer holds a registered 101 pharmacy permit. Any person violating this section shall be 102 guilty of a misdemeanor.

103 (j) For each application for a permit found to be 104 satisfactory by the board, the secretary of the board shall 105 issue to the applicant a permit for the appropriate function, 106 which permit shall be displayed in a conspicuous place."

107 Section 2. This act shall become effective on the first 108 day of the third month following its passage and approval by 109 the Governor, or its otherwise becoming law.

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113		Speaker of the House of Re	presentatives			
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118		President and Presiding Offic	er of the Senate			
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121	House of Representatives					
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123	I hereby certify that the within Act originated in and					
124	was pas	was passed by the House 11-Apr-23.				
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126	John Treadwell					
127	Clerk					
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135	Senate	25-Apr-23	Passed			