

House Bill 1361

By: Representatives Kelley of the 16<sup>th</sup>, Hawkins of the 27<sup>th</sup>, and Dempsey of the 13<sup>th</sup>

A BILL TO BE ENTITLED  
AN ACT

1 To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to  
2 pharmacists and pharmacies, so as to provide for the compounding of certain active  
3 pharmaceutical ingredients; to provide for definitions; to prohibit the sale, transfer, or  
4 distribution of certain compounded drugs under certain conditions; to require manufacturers  
5 and wholesalers to provide certain documentation; to provide for record maintenance; to  
6 provide for the timely furnishing of records to the State Board of Pharmacy; to authorize  
7 inspections by the State Board of Pharmacy; to provide for penalties and enforcement; to  
8 provide for rules and regulations; to provide for related matters; to repeal conflicting laws;  
9 and for other purposes.

10 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

11 **SECTION 1.**

12 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and  
13 pharmacies, is amended in Article 5, relating to prescription drugs, by adding a new Code  
14 section to read as follows:

15 "26-4-91.

16 (a) As used in this Code section, the term:

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17 (1) 'Active pharmaceutical ingredient' means any substance that is intended for  
18 incorporation into a finished drug product and is intended to furnish pharmacological  
19 activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention  
20 of disease, or to affect the structure or any function of the body. Such term shall include  
21 bulk drug substances, but shall not include inactive ingredients, such as flavoring agents,  
22 or intermediates used in the synthesis of the substance.

23 (2) 'Human drug establishment' means a place of business that manufactures, prepares,  
24 propagates, compounds, or processes drugs intended for human use and subject to  
25 inspections under 21 U.S.C. Section 374. Such term shall not include a wholesaler,  
26 relabeler, repacker, or similar entity.

27 (3) 'Pharmaceutical grade product' means any active or inactive drug, biologic, or reagent  
28 that is manufactured under good manufacturing practices and approved by the federal  
29 Food and Drug Administration for use in humans and for which a chemical purity  
30 standard has been written or established by a recognized compendia. Such term shall not  
31 include chemical grade, research grade, animal grade, or food grade substances.

32 (b) It shall be unlawful for any person or entity to engage in the sale, transfer, or  
33 distribution of a drug compounded under Section 503A of the federal act using an active  
34 pharmaceutical ingredient that is a glucose-dependent insulintropic polypeptide receptor  
35 or a glucagon-like peptide-1 receptor agonist used for obesity or weight management or  
36 that is a component of a similar drug approved by the federal Food and Drug  
37 Administration for obesity or weight management unless the compounder of the drug:

38 (1) Uses active pharmaceutical ingredients that:

39 (A) Comply with the standards of an applicable United States Pharmacopeia or  
40 National Formulary monograph, if a monograph exists, and the United States  
41 Pharmacopeia chapter on pharmacy compounding;

42 (B) If such a monograph does not exist, are pharmaceutical ingredients that are  
43 components of drugs approved by the federal Food and Drug Administration; or

44 (C) If such a monograph does not exist and the drug substance is not a component of  
45 a drug approved by the federal Food and Drug Administration, appear on the list  
46 developed by the federal Food and Drug Administration pursuant to Section  
47 503A(b)(1)(A)(i)(III) of the federal act;

48 (2) Confirms that any active pharmaceutical ingredient used under subparagraph (B) of  
49 paragraph (1) of this subsection was reviewed as part of a new drug application approved  
50 by the federal Food and Drug Administration under Section 505 of the federal act;

51 (3) Ensures that the active pharmaceutical ingredient is a pharmaceutical grade product;

52 (4) Verifies that the active pharmaceutical ingredient is accompanied by a valid  
53 certificate of analysis;

54 (5) Conducts and documents quality control testing of any active pharmaceutical  
55 ingredient prior to its use in a compounded drug to confirm:

56 (A) The identity and content of the active pharmaceutical ingredient; and

57 (B) The name and quantity of each impurity present in the active pharmaceutical  
58 ingredient;

59 (6) Conducts and documents quality control testing of the finished compounded drug  
60 product in batches before release and at expiry for any impurities derived from the use  
61 of an active pharmaceutical ingredient, including identifying the chemical name and  
62 quantifies of any such impurities;

63 (7) Obtains proof that the manufacture of the active pharmaceutical ingredient took place  
64 in an establishment that:

65 (A) Is duly registered with the federal Food and Drug Administration under Section  
66 510 of the federal act;

67 (B) Has undergone an inspection by the federal Food and Drug Administration as a  
68 human drug establishment; and

69 (C) Is not subject to an import alert by the federal Food and Drug Administration; and

70 (8) Complies with the provisions of the federal act, including, but not limited to, the  
71 provisions in Section 503A.

72 (c) It shall be unlawful for any manufacturer or wholesaler to sell, transfer, or distribute  
73 any active pharmaceutical ingredient in this state for use in compounding without  
74 providing to the purchaser written documentation that such ingredient is a pharmaceutical  
75 grade product, a valid certificate of analysis of such ingredient, any quality control testing  
76 of such ingredient, and the sourcing requirements for such ingredient as provided for under  
77 paragraphs (3) through (7) of subsection (b) of this Code section.

78 (d) Any person or entity engaging in the sale, transfer, or distribution of compounded  
79 drugs shall maintain all records related to the acquisition, examination, and testing of the  
80 active pharmaceutical ingredient for not less than two years after the expiration date of the  
81 last lot of drug containing the active pharmaceutical ingredient and, upon a request by the  
82 board of pharmacy, shall furnish such records within one business day of receiving the  
83 request, or within a reasonable time as determined by the board based on the circumstances  
84 of the request.

85 (e) The board of pharmacy, its duly authorized agent, or a duly authorized agent of a third  
86 party approved by the board shall have the authority to inspect any person or entity that  
87 engages in compounding drugs, as well as any domestic supplier, wholesaler, repackager,  
88 or other provider of the active pharmaceutical ingredient for compounding, for compliance  
89 with the requirements in subsection (b) of this Code section. Refusal to permit the board  
90 or its duly authorized agent or third party access to conduct an inspection shall constitute  
91 a violation of this Code section.

92 (f) A violation of this Code section shall result in:

93 (1) A fine of \$1,000.00 per dose of the illegally compounded drug sold, transferred, or  
94 distributed; and

95 (2) Revocation of the pharmacy or business license, as applicable.

96 (g) The board is authorized to promulgate rules and regulations as necessary to implement  
97 the provisions of this Code section."

98 **SECTION 2.**

99 All laws and parts of laws in conflict with this Act are repealed.