Stricken language would be deleted from and underlined language would be added to present law. Act 961 of the Regular Session

| 1 | State of Arkansas | As Engrossed: S4/9/25 | |
|----|--|--------------------------------------|-----------------------|
| 2 | 95th General Assembly | A Bill | |
| 3 | Regular Session, 2025 | | HOUSE BILL 1801 |
| 4 | | | |
| 5 | By: Representative K. Moore | е | |
| 6 | By: Senator B. Davis | | |
| 7 | | | |
| 8 | For An Act To Be Entitled | | |
| 9 | AN ACT TO AUTHORIZE AN OUTSOURCING FACILITY OF LEGEND | | |
| 10 | DRUGS AND CONTROLLED SUBSTANCES THAT COMPOUNDS A | | |
| 11 | PRODUCT TO SELL THE COMPOUNDED PRODUCT TO CERTAIN | | |
| 12 | ENTITIES; | AND FOR OTHER PURPOSES. | |
| 13 | | | |
| 14 | | | |
| 15 | | Subtitle | |
| 16 | TO A | AUTHORIZE AN OUTSOURCING FACILITY OF | |
| 17 | LEGEND DRUGS AND CONTROLLED SUBSTANCES | | |
| 18 | THAT | COMPOUNDS A PRODUCT TO SELL THE | |
| 19 | COMP | POUNDED PRODUCT TO CERTAIN ENTITIES. | |
| 20 | | | |
| 21 | BE IT ENACTED BY THE | GENERAL ASSEMBLY OF THE STATE OF ARK | CANSAS: |
| 22 | | | |
| 23 | SECTION 1. Ark | ansas Code Title 17, Chapter 92, Sub | ochapter l, is |
| 24 | amended to add an additional section to read as follows: | | |
| 25 | <u>17-92-121.</u> Out | sourcing facility of legend drugs an | <u>nd controlled</u> |
| 26 | substances. | | |
| 27 | <u>(a) As used in</u> | this section, "outsourcing facility | v of legend drugs and |
| 28 | controlled substances" means an entity that is registered as a 503B | | |
| 29 | outsourcing facility with the United States Food and Drug Administration and | | |
| 30 | has a permit with the Arkansas State Board of Pharmacy. | | |
| 31 | (b)(1) An outsourcing facility of legend drugs and controlled | | |
| 32 | substances that compounds a product may sell a compounded product to: | | |
| 33 | <u>(A)</u> | An Arkansas-licensed retail pharma | acy for dispensing to |
| 34 | <u>a patient;</u> | | |
| 35 | <u>(B)</u> | An Arkansas-licensed healthcare fa | acility for |
| 36 | administration to a p | atient; or | |



HB1801

| 1 | (C) An Arkansas-licensed healthcare provider, such as a | | |
|----|---|--|--|
| 2 | physician or nurse practitioner, for administration to a patient in a medical | | |
| 3 | <u>clinic.</u> | | |
| 4 | (2) With the exception of the entities listed in subdivision | | |
| 5 | (b)(1) of this section, an outsourcing facility of legend drugs and | | |
| 6 | controlled substances shall not sell a compounded drug to a wholesale | | |
| 7 | distributor, pharmaceutical repackager, pharmaceutical relabeler, marketing | | |
| 8 | firm, or any other entity. | | |
| 9 | (c) An outsourcing facility of legend drugs and controlled substances | | |
| 10 | shall comply with the Current Good Manufacturing Practices regulations in 21 | | |
| 11 | C.F.R. Part 210, 21 C.F.R. Part 211, and 21 C.F.R. Part 212, as existing on | | |
| 12 | January 1, 2025. | | |
| 13 | (d) The board shall adopt rules pertaining to an Arkansas-licensed | | |
| 14 | retail pharmacy dispensing a compound obtained from an outsourcing facility | | |
| 15 | of legend drugs and controlled substances to a patient, including without | | |
| 16 | limitation requiring: | | |
| 17 | (1) Patient education on the compound; | | |
| 18 | (2) The name of the outsourcing facility of legend drugs and | | |
| 19 | controlled substances preparing the compound; and | | |
| 20 | (3) Any other item related to the dispensing of a compound by an | | |
| 21 | outsourcing facility of legend drugs and controlled substances deemed | | |
| 22 | necessary by the board. | | |
| 23 | | | |
| 24 | /s/K. Moore | | |
| 25 | | | |
| 26 | | | |
| 27 | APPROVED: 4/21/25 | | |
| 28 | | | |
| 29 | | | |
| 30 | | | |
| 31 | | | |
| 32 | | | |
| 33 | | | |
| 34 | | | |
| 35 | | | |
| 36 | | | |

2