

1 State of Arkansas  
2 93rd General Assembly  
3 Regular Session, 2021  
4

As Engrossed: S2/4/21

# A Bill

SENATE BILL 143

5 By: Senators Irvin, Bledsoe  
6 By: Representatives M. Gray, Vaught  
7

## For An Act To Be Entitled

9 AN ACT TO ENSURE THAT BENEFICIARIES OF THE ARKANSAS  
10 MEDICAID PROGRAM HAVE ACCESS TO NEW PRODUCTS AND  
11 LABEL EXPANSIONS APPROVED BY THE UNITED STATES FOOD  
12 AND DRUG ADMINISTRATION; TO CREATE THE RARE DISEASE  
13 ADVISORY COUNCIL; AND FOR OTHER PURPOSES.  
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## Subtitle

16 TO ENSURE THAT BENEFICIARIES OF THE  
17 ARKANSAS MEDICAID PROGRAM HAVE ACCESS TO  
18 NEW PRODUCTS AND LABEL EXPANSIONS  
19 APPROVED BY THE UNITED STATES FOOD AND  
20 DRUG ADMINISTRATION; AND TO CREATE THE  
21 RARE DISEASE ADVISORY COUNCIL.  
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25 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:  
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27 SECTION 1. Arkansas Code Title 20, Chapter 77, Subchapter 1, is  
28 amended to add an additional section to read as follows:

29 20-77-140. Products and label expansions approved by the United States  
30 Food and Drug Administration.

31 (a) The General Assembly finds that:

32 (1) The Arkansas Medicaid Program has historically delayed or  
33 denied access to new products and label expansions approved by the United  
34 States Food and Drug Administration during the time period after the products  
35 or label expansions have been approved by the United States Food and Drug  
36 Administration but before the Arkansas Medicaid Drug Utilization Review Board



1 has conducted a formal clinical review;

2 (2) This practice:

3 (A) Unnecessarily delays patient access to innovative  
4 products which can be particularly harmful for citizens of Arkansas who are  
5 living with life-shortening or life-threatening conditions; and

6 (B) May result in irreversible harm to the health of  
7 citizens of Arkansas;

8 (3) Other state Medicaid programs provide immediate access to  
9 new products and label expansions approved by the United States Food and Drug  
10 Administration prior to a formal clinical review; and

11 (4) It is in the best interest of the citizens of this state to  
12 provide immediate access to new products and label expansions approved by the  
13 United States Food and Drug Administration prior to a formal clinical review.

14 (b) Consistent with federal laws and regulations, the Arkansas  
15 Medicaid Program shall:

16 (1) Provide immediate access to and reimbursement for new  
17 products and label expansions approved by the United States Food and Drug  
18 Administration, or outpatient drugs with a federal rebate agreement in place,  
19 if the product is prescribed according to approved indications or medically  
20 accepted indications; and

21 (2) Not deny or delay coverage or reimbursement for new products  
22 and label expansions for an existing covered product approved by the United  
23 States Food and Drug Administration for an existing covered product,  
24 including denying or delaying access to a product solely because the Arkansas  
25 Medicaid Drug Utilization Review Board or any other advisory body has not  
26 conducted a formal clinical review of the product or label expansion.

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28 SECTION 2. Arkansas Code Title 25, Chapter 10, Subchapter 1, is  
29 amended to add an additional section to read as follows:

30 25-10-145. Rare Disease Advisory Council – Creation.

31 (a) As used in this section, "rare disease or condition" means any  
32 disease or condition that affects:

33 (1) Less than two hundred thousand (200,000) persons in the  
34 United States; or

35 (2) More than two hundred thousand (200,000) persons in the  
36 United States and for which there is no reasonable expectation that the cost

1 of developing and making available in the United States a drug for the  
2 disease or condition will be recovered from sales in the United States of the  
3 drug.

4 (b) There is established the Rare Disease Advisory Council within the  
5 Department of Human Services.

6 (c) The purposes of the council are to:

7 (1)(A) Provide expert, clinical advice and input in writing to  
8 the Arkansas Medicaid Drug Utilization Review Board when the board reviews a  
9 drug or treatment for a rare disease or condition.

10 (B) The board shall:

11 (i) Seek advice and feedback on drafts of clinical  
12 criteria from the council before reviewing any treatment or drug that treats  
13 a rare disease or condition;

14 (ii) Distribute the advice of the council to the  
15 members of the board; and

16 (iii) Publish the advice of the council in the  
17 meeting minutes of the board;

18 (2) Provide input and feedback in writing to the department, the  
19 Arkansas Medicaid Program, and other state agencies on matters that affect  
20 people who have been diagnosed with rare diseases or conditions, including  
21 without limitation:

22 (A) Access to care, insurance, specialists, and other  
23 needed services for patients who have been diagnosed with rare diseases or  
24 conditions;

25 (B) The impact on coverage, cost-sharing, tiering or other  
26 utilization management procedures on providing treatment and services to  
27 patients who have been diagnosed with rare diseases or conditions; and

28 (C) Pandemic preparedness and response; and

29 (3) Provide publicly accessible resources on research,  
30 diagnosis, treatment, and education relating to rare diseases or conditions  
31 in Arkansas.

32 (d)(1) The council shall consist of twelve (12) voting members to be  
33 appointed as follows:

34 (A)(i) Four (4) members appointed by the Governor.

35 (ii) One (1) member appointed by the Governor shall  
36 be a representative from the department.

1 (iii) One (1) member appointed by the Governor shall  
2 be a representative of an organization that operates in the state and  
3 represents people who have been diagnosed with a rare *disease or condition*.

4 (iv) Two (2) members appointed by the Governor shall  
5 be residents of the state who are either:

6 (a) Eighteen (18) years of age or older and  
7 have been diagnosed with a rare *disease or condition*; or

8 (b) A parent or caregiver for a child under  
9 eighteen (18) years of age who has been diagnosed with a rare *disease or*  
10 *condition*;

11 (B)(i) Three (3) members appointed by the President Pro  
12 Tempore of the Senate.

13 (ii) One (1) member appointed by the President Pro  
14 Tempore of the Senate shall be a representative from an academic research  
15 institution in the state that receives grant funding for rare *disease or*  
16 *condition* research.

17 (iii) One (1) member appointed by the President Pro  
18 Tempore of the Senate shall be a physician who is licensed and practicing in  
19 the state and has experience in researching, diagnosing, or treating rare  
20 *diseases or conditions*.

21 (iv) One (1) member appointed by the President Pro  
22 Tempore of the Senate shall be a geneticist who is licensed and practicing in  
23 the state;

24 (C)(i) Three (3) members appointed by the Speaker of the  
25 House of Representatives.

26 (ii) One (1) member appointed by the Speaker of the  
27 House of Representatives shall be a representative from an academic research  
28 institution in the state that receives grant funding for rare *disease or*  
29 *condition* research.

30 (iii) One (1) member appointed by the Speaker of the  
31 House of Representatives shall be a physician who is licensed and practicing  
32 in the state and has experience in researching, diagnosing, or treating rare  
33 *diseases or conditions*.

34 (iv) One (1) member appointed by the Speaker of the  
35 House of Representatives shall be a registered nurse or advanced practice  
36 registered nurse who is licensed and practicing in the state and has

1 experience treating rare diseases or conditions;

2 (D) One (1) member appointed by the Chair of the Senate  
3 Committee on Public Health, Welfare, and Labor; and

4 (E) One (1) member appointed by the Chair of the House  
5 Committee on Public Health, Welfare, and Labor.

6 (2) A member of the council shall not be a current member of the  
7 board or any other drug utilization advisory group to the Arkansas Medicaid  
8 Program.

9 (e)(1)(A) At the first meeting of the council, the length of the terms  
10 of the initial appointees shall be determined by lot.

11 (B) A member subsequently appointed to the council shall  
12 serve a term of two (2) years.

13 (2)(A) A vacancy on the council shall be filled in the same  
14 manner as the initial appointment.

15 (B) A member appointed to fill a vacancy shall serve for  
16 the remainder of the vacated term.

17 (3) Members may be removed by the appointing official for cause.

18 (f) The department shall provide offices and staff for the council.

19 (g) The council shall annually elect a chair and vice-chair from its  
20 membership.

21 (h)(1) A majority of the membership of the council constitutes a  
22 quorum.

23 (2) A majority vote of the members present is required for any  
24 action of the council.

25 (3) Members may participate in meetings electronically via  
26 teleconference and be considered present.

27 (i) The council may appoint subcommittees to study, research, and  
28 advise the council.

29 (j) With the exception of members who are employed by the state,  
30 members may receive expense reimbursement and stipends under § 25-16-901 et  
31 seq.

32 (k) The council shall submit an annual report to the Governor, the  
33 General Assembly, the department, and other relevant agencies that:

34 (1) Describes the findings, activities, and progress of the  
35 council; and

36 (2) Provides feedback on ways to address the needs of people

1 living with a rare disease or condition in the state.

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*/s/ Irvin*

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