

117TH CONGRESS  
2D SESSION

# S. 4043

To instruct the Secretary of Health and Human Services to issue regulations regarding over-the-counter hearing aids.

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## IN THE SENATE OF THE UNITED STATES

APRIL 7, 2022

Ms. WARREN (for herself, Mr. GRASSLEY, Ms. HASSAN, and Mrs. BLACKBURN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To instruct the Secretary of Health and Human Services to issue regulations regarding over-the-counter hearing aids.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Delivering Over-the-  
5 Counter Hearing Aids Now Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) More than 38,000,000 individuals in the  
9 United States experience some degree of hearing  
10 loss.

1           (2) Difficulty hearing is reported by half of in-  
2           dividuals 75 years and older, and nearly 1 in 3 indi-  
3           viduals between the ages of 65 and 75.

4           (3) Individuals with hearing loss are at a great-  
5           er risk of developing Alzheimer’s disease and Alz-  
6           heimer’s disease related dementia.

7           (4) Individuals in the United States with hear-  
8           ing loss are more likely to experience feelings of  
9           loneliness and isolation, which have been exacerbated  
10          by the COVID–19 pandemic.

11          (5) Despite the prevalence of hearing loss, only  
12          1 in 5 individuals who could benefit from a hearing  
13          aid use one.

14          (6) The high cost of hearing aids, which are not  
15          generally covered by private health insurance plans  
16          or under traditional Medicare, makes them prohibi-  
17          tively expensive for many individuals in the United  
18          States and limits access.

19          (7) The provisions addressing the regulation of  
20          over-the-counter hearing aids were enacted in 2017  
21          as part of the FDA Reauthorization Act of 2017  
22          (Public Law 115–52), which removes outdated regu-  
23          lations blocking consumer access to affordable hear-  
24          ing aids and allows certain types of hearing aids to  
25          be made available over-the-counter to individuals in

1 the United States with mild to moderate hearing  
2 loss.

3 (8) The law required the Food and Drug Ad-  
4 ministration to issue implementing regulations not  
5 later than 3 years following the date of enactment  
6 of the FDA Reauthorization Act of 2017 (Public  
7 Law 115–52), but the Food and Drug Administra-  
8 tion did not issue a proposed rulemaking for more  
9 than 4 years.

10 (9) The law further required the Food and  
11 Drug Administration to issue a final rule not later  
12 than 180 days following the end of the public com-  
13 ment period for the proposed rule. The public com-  
14 ment period closed on January 18, 2022.

15 **SEC. 3. INSTRUCTION TO ISSUE FINAL RULE.**

16 Not later than 30 days after the date of enactment  
17 of this Act, the Secretary of Health and Human Services  
18 shall issue a final rule to establish a category of over-the-  
19 counter hearing aids, as defined in subsection (q) of sec-  
20 tion 520 of the Federal Food, Drug, and Cosmetic Act  
21 (21 U.S.C. 360j), as described in section 709(b) of the  
22 FDA Reauthorization Act of 2017 (Public Law 115–52).

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