117TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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 _____

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Delivering Over-the-Counter Hearing Aids Now Act''.

SEC. 2. FINDINGS.

Congress finds the following:

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

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

(3) Individuals with hearing loss are at a greater risk of developing Alzheimer's disease and Alzheimer's disease related dementia.

(4) Individuals in the United States with hearing loss are more likely to experience feelings of loneliness and isolation, which have been exacerbated by the COVID–19 pandemic.

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

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

(7) The provisions addressing the regulation of over-the-counter hearing aids were enacted in 2017 as part of the FDA Reauthorization Act of 2017 (Public Law 115–52), which removes outdated regulations blocking consumer access to affordable hearing aids and allows certain types of hearing aids to be made available over-the-counter to individuals in

the United States with mild to moderate hearing loss.

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

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

SEC. 3. INSTRUCTION TO ISSUE FINAL RULE.

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