

115TH CONGRESS
1ST SESSION

S. 670

To provide for the regulation of over-the-counter hearing aids.

IN THE SENATE OF THE UNITED STATES

MARCH 21, 2017

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

A BILL

To provide for the regulation of 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 “Over-the-Counter
5 Hearing Aid Act of 2017”.

6 **SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING**
7 **AIDS.**

8 (a) IN GENERAL.—Section 520 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by
10 adding at the end the following:

1 “(p) REGULATION OF OVER-THE-COUNTER HEARING
2 AIDS.—

3 “(1) DEFINITION.—In this subsection, the term
4 ‘over-the-counter hearing aid’ means a device—

5 “(A) that uses the same fundamental sci-
6 entific technology as air conduction hearing
7 aids (as defined in section 874.3300 of title 21,
8 Code of Federal Regulations) (or any successor
9 regulation) or wireless air conduction hearing
10 aids (as defined in section 874.3305 of title 21,
11 Code of Federal Regulations) (or any successor
12 regulation);

13 “(B) that is intended to be used by adults
14 over the age of 18 to compensate for perceived
15 mild to moderate hearing impairment;

16 “(C) that, through tools, tests, or software,
17 allows the user to control the over-the-counter
18 hearing aid and customize it to the user’s hear-
19 ing needs;

20 “(D) that may—

21 “(i) use wireless technology; or

22 “(ii) include tests for self-assessment
23 of hearing loss; and

24 “(E) that is available over-the-counter,
25 without the supervision, prescription, or other

1 order, involvement, or intervention of a licensed
2 person, to consumers through in-person trans-
3 actions, by mail, or online.

4 “(2) REGULATION.—An over-the-counter hear-
5 ing aid shall be subject to the regulations promul-
6 gated in accordance with section 2(b) of the Over-
7 the-Counter Hearing Aid Act of 2017 and shall be
8 exempt from sections 801.420 and 801.421 of title
9 21, Code of Federal Regulations (or any successor
10 regulations).”.

11 (b) REGULATIONS TO ESTABLISH CATEGORY.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services (referred to in this section as the
14 “Secretary”), not later than 3 years after the date
15 of enactment of this Act, shall promulgate proposed
16 regulations to establish a category of over-the-
17 counter hearing aids, as defined in subsection (p) of
18 section 520 of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 360j) as amended by sub-
20 section (a), and, not later than 180 days after the
21 date on which the public comment period on the pro-
22 posed regulations closes, shall issue such final regu-
23 lations.

24 (2) REQUIREMENTS.—In promulgating the reg-
25 ulations under paragraph (1), the Secretary shall—

1 (A) include requirements that provide rea-
2 sonable assurances of the safety and efficacy of
3 over-the-counter hearing aids;

4 (B) include requirements that establish or
5 adopt output limits appropriate for over-the-
6 counter hearing aids;

7 (C) include requirements for appropriate
8 labeling of the over-the-counter hearing aid, in-
9 cluding how consumers may report adverse
10 events, any conditions or contraindications, and
11 any advisements to consult promptly with a li-
12 censed physician; and

13 (D) describe the requirements under which
14 the sale of over-the-counter hearing aids is per-
15 mitted, without the supervision, prescription, or
16 other order, involvement, or intervention of a li-
17 censed person, to consumers through in-person
18 transactions, by mail, or online.

19 (3) PREMARKET NOTIFICATION.—The Sec-
20 retary shall make findings under section 510(m) of
21 the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 360(m)) to determine whether over-the-
23 counter hearing aids (as defined in section 520(p) of
24 the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 360j), as amended by subsection (a)) require

1 a report under section 510(k) to provide reasonable
2 assurance of safety and effectiveness.

3 (4) EFFECT ON STATE LAW.—No State or local
4 government shall establish or continue in effect any
5 law, regulation, order, or other requirement specifi-
6 cally applicable to hearing products that would re-
7 strict or interfere with the servicing, marketing, sale,
8 dispensing, use, customer support, or distribution of
9 over-the-counter hearing aids (as defined in section
10 520(p) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360j), as amended by subsection (a))
12 through in-person transactions, by mail, or online,
13 that is different from, in addition to, or otherwise
14 not identical to, the regulations promulgated under
15 this subsection, including any State or local require-
16 ment for the supervision, prescription, or other
17 order, involvement, or intervention of a licensed per-
18 son for consumers to access over-the-counter hearing
19 aids.

20 (c) NEW GUIDANCE ISSUED.—Not later than the
21 date on which final regulations are issued under sub-
22 section (b), the Secretary shall update and finalize the
23 draft guidance of the Department of Health and Human
24 Services entitled, “Regulatory Requirements for Hearing
25 Aid Devices and Personal Sound Amplification Products”,

1 issued on November 7, 2013. Such updated and finalized
2 guidance shall clarify which products, on the basis of
3 claims or other marketing, advertising, or labeling mate-
4 rial, meet the definition of a device in section 201 of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)
6 and which products meet the definition of a personal
7 sound amplification product, as set forth in such guidance.

○