Essential Health Benefits Benchmark plan Comment Letters

April 15 – April 29, 2024

From: Christine Seitz
To: Bailey, Sarah S (CED)
Cc: Christine Seitz; Sean Drake
Subject: Alaska Benchmark Plan

Date: Thursday, April 25, 2024 6:29:44 AM

Attachments: Outlook-fdy1qzfx.pnq

Dear State Official (Re OTC Hearing Aids) (FDA Guidance 10.13.22).pdf

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Dear Sarah Bailey,

Thank you for the opportunity to provide input/ ask questions on the Essential Health Benefits in Alaska. Is there an opportunity to discuss the Alaska Benchmark Plan (plan) to include hearing aids provided by a licensed hearing aid dealer, who is licensed under AK Stat § 08.55? Currently, the plan covers hearing aids provided by "an audiologist, otologist, otologist, or a physician."

I would also like to take this opportunity to address the United States Food and Drug Administration (FDA) August 2022 federal regulatory changes related to hearing aids (21 C.F.R. § 801.109(a)(1)). These changes necessitate states to make corresponding statutory and regulatory technical amendments to ensure continued access to essential hearing health care services. The International Hearing Society- the only membership organization in the United States that represents hearing aid dealers- writes to provide more information and request that the appropriate technical amendments be made to Alaska's hearing aid laws and regulations.

Specifically, we recommend that AAK Stat § 08.55 should be amended to include explicit state authorization for licensed hearing aid dealers, and licensed audiologists, to "order the use of" non-over-the-counter hearing aids (non-OTC) to ensure that your hearing aid laws are aligned with the FDA's regulatory changes that:

- 1. Created the new "Over-The-Counter (OTC) hearing aid" category and
- 2. Reclassified any non-OTC hearing aids as "prescription" hearing aids that now require a "prescription or other order from a state-licensed practitioner."

The reason this is important is because the phrase "order the use of" can be interpreted differently from the words "selection" and "sale" (currently included in § 08.55.200). An example amendment:

Alaska Statutes Title 8. Business and Professions Chapter 55. Hearing Aid Dealers Sec. 08.55.200. Definitions. (AK Stat § 08.55.200)

(2) "dealing in hearing aids" means the <u>ordering the use of</u>, sale, or lease, or attempted sale or lease of hearing aids, and the recommendation, selection, fitting, or adaptation of hearing aids; ***

Furthermore, due to the new federal OTC rule and the FDA's reclassification of "traditional hearing aids," which have been dispensed by licensed hearing aid dealers and audiologists for decades, as "prescription medical devices," (now commonly referred to as non-over-the-

counter hearing aids) must be "prescribed or ordered the use of" by a "state-licensed practitioner." Since licensure is under the jurisdiction of the state, states must authorize licensed hearing aid dispensers and licensed audiologists to "prescribe or order the use of" these devices for their hearing-impaired patients. This is the phrase the FDA uses, which is why the IHS recommends adding "order the use of" to state statute as a technical amendment.

To alleviate confusion, the FDA affirmed its intention, in an October 2022 letter to the States, that the reclassification of non-OTC hearing aids should not change who is authorized to prescribe or order the use of these hearing aids. The FDA reiterated that "the final rule defining non-OTC hearing aids as prescription devices is not intended to create barriers to accessing hearing aids, including prescription devices. It does not require the involvement of different or additional health care providers or examinations upon the effective date." I've attached the letter to this email.

I am happy to schedule a call to discuss this further.

Sincerely,

Christine Seitz

Christine Seitz
Manager of Government Affairs
(734) 522-7200, ext. 122 office / (734) 522-0200 fax

cseitz@ihsinfo.org

International Hearing Society

33900 W. 8 Mile Road, Suite 101, Farmington, MI 48335

#IHSHear4U www.ihsinfo.org





April 23, 2024

Lori Wing-Heier, Director Alaska Division of Insurance PO Box 110805 Juneau, AK 99811

Dear Director Wing-Heier,

I am writing today on behalf of the National Association of Benefits and Insurance Professionals Alaska Chapter – a member organization representing consultants, licensed agents and brokers who are engaged in the sale and service of health insurance and other ancillary products and serving employers and consumers in all fifty states – to provide additional perspective on the Department's selection of new essential health benefits.

NABIP Alaska Chapter is in favor of most of the Department's proposal, including the addition of coverage for hearing aids, additional chiropractic visits, massage therapy visits, and treatment for temporomandibular joint disorders. These proposals will have minimal impact on insurance premiums and will help individuals access critical services that will improve their health and quality of life.

NABIP Alaska Chapter is concerned about the Department's decision to include anti-obesity GLP-1 and GIP drugs to the proposed essential health benefits. Including these drugs, which cost around \$1,000 per month per utilizing member will significantly raise healthcare costs for employers and individuals throughout Alaska. This has been seen in states like North Carolina, where administers of the North Carolina State Health Plan were forced to vote to remove GLP-1 and GIP medications from their State Health Plan because the additional cost of covering GLP-1 and GIP medications totaled \$102 million in 2023. Further, according to Willis Towers Watson in a scenario in which GLP-1 and GIP drugs are required to be covered, if even half of an employer's workforce who are eligible to take such drugs were to take it, an employer's spending on healthcare could increase by more than 50 percent. These costs will be too much for many employers in Alaska and will harm the already struggling commercial insurance market.

In addition to the cost concerns, NABIP Alaska Chapter is concerned about the lack of research into the long term effects of taking GLP-1 and GIP drugs for weight loss, with some who take these drugs experiencing malnutrition, pancreatitis, and gallbladder disease. It is important to



understand the potential public health impacts of the widespread use of these drugs before taking measures that will guarantee an increase in the use of these drugs.

On behalf of NABIP Alaska Chapter, I would like to thank you for your attention and consideration on this matter. We applaud the Department's commitment to Alaskans and support much of what the Department proposes, however we sincerely hope the Department reconsiders including GLP-1 and GIP drugs in the state's essential health benefit.

Sincerely,

Albert Fogle

Albert Fogle

President, NABIP Alaska Chapter albert.fogle@modahealth.com

Work: 907-278-2628 Cell: 907-575-5625