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January 31, 2023

The Honorable Xavier Becerra Secretary of Health and Human Services
U.S. Department of Health and Human Services 200 Independence Ave., SW
Washington DC, 20201

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Essential Health Benefits Request for Information—Docket Number 2022-26282.

Dear Secretary Becerra and Administrator Brooks-LaSure:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) and the Department of Health and Human Services' (HHS) *Request for Information on Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act* (ACA). As explained in further detail below, **Aimed Alliance strongly urges CMS and HHS to clarify that specialty medications are part of the definition of prescription drugs as an EHB.**

I. HHS and CMS Must Clarify that as a Minimum Requirement Specialty Drugs are Included in the Definition of Prescription Drugs as an EHB.

Health plans are limiting coverage for prescription drugs as an EHB in a manner that is inconsistent with federal Law and HHS guidance by manipulating the definition of EHBs. As such, the definition of EHBs requires clearer minimum coverage requirements to prevent this practice.

In 2011, HHS issued a bulletin providing information on the agency's regulatory approach for defining EHBs.[1] This clarification provided that under the ACA, large group health plans and self-insured health plans are not required to offer EHBs.[2] However, if they choose to offer EHBs, then the ACA's limits on cost-sharing shall apply.[3] At the same time, HHS also stated that such plans could impose certain limits on benefits "that do not fall within the definition of EHB."[4] However, the guidance stated that large group health plans and self-insured plans may only modify the definition of EHB in a manner "that is ***authorized by the Secretary of HHS***."[5]

In 2014, HHS offered additional clarification as to how large group health plans and self-insured health plans could address prescription drug coverage through the EHB definition.[6] The

[1] Center for Consumer Information and Insurance Oversight, *Essential Health Benefits Bulletin,* https://perma.cc/38RW-GVE3 at p. 3.
[2] CMS, *Frequently Asked Questions on Essential Health Benefits Bulletin*, https://perma.cc/HCH7-6AYA at p. 4.
[3] *Id.* (stating that self-insured and large group plans "are permitted to impose non-dollar limits, consistent with other guidance, on EHB as long as they ***comply with other applicable statutory provisions***." (emphasis added)).
[4] *Id.* at p. 4.
[5] *Id*. (emphasis added).
[6] CMS, *FAQs About Affordable Care Act Implementation (Part XIX),* https://perma.cc/CX9B-RUZ6.

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clarification noted that a plan could exclude the cost of name brand prescriptions towards the out-of-pocket maximum "in circumstances in which a generic [is] available and medically appropriate (as determined by the individual's personal physician)". [7]

A. Health Plans Have Adopted EHB Definitions That Are Inconsistent with HHS Guidance.

Despite this clear explanation, many large group and self-insured health plans have taken liberties in defining EHBs. HHS has narrowly authorized medications used for abortion and brand name medications with a generic alternative to be excluded from the definition of a prescription drug as an EHB.[8] Despite this narrow exception, health plans claim that they may exclude all "specialty drugs" from the definition of prescription drugs as a category of EHBs.[9] This modification of the definition of prescription drugs has not been authorized by HHS. Further, health plans have adopted this definition irrespective of the fact that many specialty medications have no generic alternatives available, thus, not even attempting to narrow their carveout to an HHS-approved exception.

When a health plan defines EHBs to exclude specialty medications from the category of prescriptions drugs, they often use a third-party company to manage their specialty medication programs and coerce patients into enrolling in a manufacturer copay assistance program – even if doing so is not financially necessary for a patient. Specifically, patients are contacted by the third-party company that the health plan has partnered with. The company then informs the patient that they may enroll in a "specialty drug program" whereby their out-of-pocket costs for their specialty medication will be minimal; alternatively, they can elect not to enroll. If they do not enroll in the program, however, then the consumer will be responsible for a 30 percent to 100 percent coinsurance that will not count towards their deductible or annual out-of-pocket limit. [10] These programs justify this practice by claiming that they can carve out "specialty drugs" from the definition of EHBs and, therefore, these medications are not subject to the ACA's annual limits on cost-sharing.

This practice is not only inconsistent with HHS guidance, but it is also inconsistent with federal law. While self-insured and large group plans are not required to cover EHBs, when they choose to do so they are bound by the ACA and its implementing regulations. As such, when large group and self-insured plans adopt modified EHB definitions that are not approved by the Secretary and inconsistent with HHS guidance, they may be in violation of federal law.

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[7] *Id.*
[8] HHS, FAQ About Affordable Care Act, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19#ftn8.
[9] SaveoOnSP, https://perma.cc/X4LQ-RWNP:
[10] *See* Aimed Alliance & Center for Health Law and Policy Innovation at Harvard Law School, 2022 Letter to CCIIO, https://aimedalliance.org/wp-content/uploads/2023/01/Aimed-Alliance-and-CHLPI-2022-Non-EHB-Analysis-.pdf).

Furthermore, permitting plans to define EHBs in this way harms consumers with chronic conditions. When plans treat specialty medications as non-EHBs, individuals with chronic conditions are forced to enroll in specialty drug programs and, as a result, they must jump through several administrative hoops, leading to delays in accessing their medications. This not only jeopardizes their health stability but also interferes with their work and personal lives if they have to repeatedly engage with their health plan to access their medication.

Defining EHBs in this way also opens the door to health plans eroding other EHBs. For example, under this same approach health plans could adopt a benchmark plan with the least amount of services under the EHB category of "maternal and newborn care," and deem all additional services as non-EHBs. As a non-EHB, the consumer's costs for these services would not contribute towards their deductibles and annual out-of-pocket limits. This type of erosion is dangerous for many women who experience high-risk pregnancies and need more visits, tests, or ultrasounds than those provided in the benchmark plan.

Therefore, Aimed Alliance strongly urges CMS and HHS to clarify that specialty drugs are considered EHBs under the definition of prescription drugs.

B. Non-EHB Definitions are Used to Justify International Importation and Exploitation of Non-Profit Assistance.

The failure of CMS and HHS to take action to address how health plans are defining specialty medications as non-EHBs has led to plans using this definition to justify programs that import medications from outside the United States and exploit charitable assistance programs.

Specifically, health plans have continued to remove specialty drugs from the definition of a prescription drugs as an EHB to require consumers to enroll in a specialty drug program that not only attempts to enroll consumers in copay assistance programs, but also enrolls consumers in international importation schemes, and charitable assistance programs.[11] These programs operate identically to the above discussed programs, except that if a consumer is ineligible for copay assistance, the program will then determine if the consumer is eligible for non-profit charitable assistance or importation from outside the United States.[12] Even if a consumer did not want to receive their medication from outside the United States, realistically they would not have the option to refuse, because if they did the consumer would be responsible for 100 percent of the cost of the medication, and it would not count towards their cost-sharing limits due to the use of the non-EHB definition.[13]

[11] Aimed Alliance, *Essential Health Benefits, Importation, and More – Do You Know the Risks?*, https://aimedalliance.org/available-online-now-cannabis-cbd-and-cannabinoids-what-employers-and-consumers/.
[12] *Id.*
[13] *Id.*

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Therefore, to ensure these schemes are stopped, Aimed Alliance strongly encourages CMS and HHS to clarify that specialty medications are part of the definition of an EHB as a prescription drug.

C. Limited Reporting Through State and Federal Complaint Mechanisms Does Not Establish That Narrow Definitions of EHBs are Not Harming Consumers.

HHS and CMS should not rely solely on state and federal appeals mechanisms to assess the impact of narrow EHB definitions on consumers as consumers often lack a thorough knowledge about health insurance and appeals processes. Rather, the agencies should also consider feedback from patient advocacy organizations and non-profits that are working directly with impacted communities.

In the request for information, CMS stated that while it is aware of ambiguities in EHB-benchmark plans and covered benefits, it does not believe this is resulting in overt harm. Specifically, CMS stated:

> To be clear, we do not necessarily believe that this ambiguity in the covered benefits and limitations in the EHB-benchmark plans has resulted in overt consumer harm. For example, based on our discussions with States and a lack of consumer complaints about exclusions or claim denials, plans subject to EHB requirements do not appear to be excluding services that are generally understood to be covered regardless of their specific inclusion in the relevant EHB-benchmark plan document.

This position fails to recognize consumers' limited knowledge about health insurance and appeals processes. For instance, one survey from 2019 found that more than 50 percent of individuals did not know what a copay or deductible is, and 25 percent avoided health care because, even with health insurance, they were not clear as to what was covered by their health plan.[14] Thus, if a consumer is unaware of what a copay or deductible is, they are even less likely to be aware of state and federal laws that entitle them to an internal and external appeal. As such, when an individual receives a claim denial or is told a certain medication is not considered an EHB, the individual may unknowingly accept this conclusion as fact.

Moreover, CMS itself has reported that consumers file a limited number of complaints, with one report finding that in the 2021 plan year, less than 1 percent of claim denials were appealed.[15] Furthermore, it is essential that the agencies recognize that many individuals may be afraid or unwilling to file a consumer complaint with a state or federal agency when they are receiving

[14] Joshua Cohen, *Healthcare Consumers Lack Knowledge of Basic Health Insurance Terms*, (Dec. 3, 2019), https://www.forbes.com/sites/joshuacohen/2019/12/03/healthcare-consumers-lack-knowledge-of-basic-health-insurance-terms/?sh=1e5574b4e225.

[15] Karen Pollitiz, Matthew Rae, and Salem Manigistu, *Claim Denials and Appeals in ACA Marketplace Plans in 2020*, Kaiser Family Foundation (July 5, 2022), https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/.

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health insurance from their employer, as they could fear retaliation or other adverse employment consequences.

Therefore, Aimed Alliance strongly urges CMS and HHS to look beyond conversations with states and complaint or appeals data, and consider valuable input from patient advocacy organizations, consumer protection groups, provider associations, and other non-profits that work directly with individuals within these communities who are experiencing these barriers.

II. Conclusion

Aimed Alliance sincerely appreciates the opportunity to share feedback with CMS and HHS regarding EHBs and the current barriers consumers are experiencing in accessing their treatments.

Sincerely,

Ashira Vantrees
Counsel

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