AIMEDALLIANCE

July 25, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates under the Medicaid Drug Rebate Program – Docket ID CMS-2434-P

Dear 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 provide feedback on the Centers for Medicare and Medicaid Services (CMS) proposed rule on the Medicaid Drug Rebate Program, Docket ID CMS-2434-P.

As stated in our comments below, Aimed Alliance **supports CMS's decision to exclude copay assistance from the Best Price Rule. In addition, we are extremely concerned by, and oppose, CMS's proposal to mandate a consumer's diagnosis be included on their prescription in order for the drug to be covered by Medicaid.**

I. Best Price Rule

The Medicaid Rebate Statute requires drug manufacturers to provide prescription drugs to state Medicaid plans at a price that is as favorable as the price provided to commercial health plans. Under the rule, the amount that the drug manufacturer can charge state Medicaid programs is based on the manufacturers' "Best Price." 42 CFR §44.505 defines the "Best Price" as the lowest price paid for a drug by a Best Price eligible entity. Eligible entities include any wholesaler, provider, retailer, HMO, government entity, nonprofit, or other health care purchaser.[1] Under the statute, this price includes all applicable discounts, rebates or other transactions that adjust prices either directly or indirectly *to the eligible entities*.[2] CMS had previously proposed that copay assistance count towards determining the best price of a prescription drug. However, copay assistance is third-party financial assistance provided to consumers to help them afford the copays for their prescription drugs and meet their annual cost-sharing requirements.[3]

Pharmaceutical companies sued HHS, alleging counting copay assistance towards the "Best Price" violated the Best Price Statute. In response, the United States District Court for the District of Columbia held that the previous rule was invalid because copay assistance was provided directly to patients, *not a Best Price eligible entity*.[4] The current proposed rule would withdraw the previous requirement that copay assistance be counted towards determining the Best Price.

[1] 42 C.F.R. § 447.505, Determination of best price.
[2] 42 C.F.R. § 447.505, Determination of best price.
[3] Aimed Alliance, *Copay Accumulator 101,* https://aimedalliance.org/copay-accumulator-101/.
[4] *Pharmaceutical Research and Manufacturers of America vs. Becerra*, Civil Action No. 1:21-cv-1395 (CJN) (D.D.C. May 17, 2022).

Aimed Alliance supports CMS's proposal to rescind the previous copay assistance requirement, as it is not only consistent with the District Court's decision, but it will also ensure that drug manufacturers can continue to supply this necessary financial support to consumers. Without this financial assistance, many consumers would be unable to afford their medications resulting in consumers facing difficulties in adhering to their prescribed treatments which can result in disease progression, relapse in symptoms, and other negative and costly health consequences.[5]

II. Mandated Disclosure of Diagnosis on Prescriptions

Under the Medicaid Drug Rebate Program (MDRP), Medicaid only reimburses for treatments that are Food and Drug Administration (FDA) approved to treat a particular indication or condition.[6] However, as explained in the proposed rule, CMS does not currently have a manner to identify if a prescription is being prescribed for an FDA-approved indication.[7] Therefore, CMS is proposing a requirement that all prescriptions include a consumer's diagnosis on the prescription to permit CMS to more easily track if FDA-approved treatments and being prescribed for FDA-approved indications.[8]

Aimed Alliance opposes requiring health care providers to include a diagnosis on a prescription, as this violates consumers' privacy by mandating an unnecessary disclosure of their health condition. Furthermore, the requirement would exacerbate barriers experienced by individuals with rare and chronic conditions in accessing their medications.

First, all people have a right to have their privacy respected and protected, especially as it relates to health conditions that may also be considered a disability. While many individuals may feel comfortable speaking openly about their chronic condition or disability, others may not be comfortable speaking about it openly for a variety of reasons.[9] Therefore, requiring a prescription to state an individual's condition creates the risk that a consumer's condition will be disclosed without their consent. While prescriptions do provide information about a medication that may be indicative of a particular diagnosis, most people do not know which prescription drugs, name brand or generic, treat a particular condition. However, if a prescription stated a brand or generic drug name and the condition such as "depression" or "anxiety," any person looking at that prescription would know intimate details about the individual's health status.

Second, Medicaid plays a significant role in covering the cost of care and treatments for individuals with rare disorders.[10] Requiring prescriptions to include a diagnosis can create unnecessary confusion within the pharmacies and result in delays in accessing treatments for consumers with rare disorders.

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[5] Beena Jimmy & Jimmy Jose, *Patient Medication Adherence: Measures in Daily Practice,* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191684/#:~:text=The%20consequence%20of%20non%20adherence,hospital%20visits%20and%20hospital%20admissions.

[6] *Request for Information – Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment,* https://www.federalregister.gov/documents/2023/05/26/2023-10934/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates.

[7] *Request for Information – Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment,* https://www.federalregister.gov/documents/2023/05/26/2023-10934/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates.

[8] *Request for Information – Comments on Issues Relating to Requiring a Diagnosis on Medicaid Prescriptions as a Condition for Claims Payment,* https://www.federalregister.gov/documents/2023/05/26/2023-10934/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates.

[9] Katie Willard, *The Dilemma of Disclosing Chronic Illness,* https://www.psychologytoday.com/us/blog/chronically-me/202203/the-dilemma-disclosing-chronic-illness#:~:text=The%20benefits%20of%20chronic%20illness,succeed%20at%20work%20or%20school..

[10] NORD, https://rarediseases.org/policy-issues/medicaid-eligibility/.

For instance, individuals with KIF1A, a rare neurological degenerative disorder, can experience a variety of symptoms as a result of KIF1A, such as epilepsy.[11] Thus, many individuals with KIF1A who have epilepsy are prescribed anticonvulsants to manage their epilepsy symptoms.[12] Under the current proposed rule, a health care provider treating a consumer diagnosed with KIF1A, and experiencing epilepsy as a symptom of KIF1A, would prescribe an anticonvulsant and list the diagnosis on the prescription as KIF1A. However, there are no FDA-approved treatments for KIF1A.

As such, under the rule limiting Medicaid coverage of prescription drugs only to FDA-approved indications, this prescription could be denied coverage because the prescriber was requesting an FDA treatment for a non-FDA-approved indication (KIF1A). While the treatment may be FDA-approved to treat epilepsy as an approved indication, epilepsy is the symptom of KIF1A, not the diagnosed condition. Thus, under the currently proposed rule, Medicaid consumers with rare disorders, like KIF1A, would be more likely to experience unnecessary delays or the outright inability to access the treatments for their rare disease symptoms. This new requirement could exacerbate inequitable outcomes in which rare disease patients with epilepsy may not receive their necessary treatments, but non-rare disease patients with epilepsy could access their treatments without delay.

While providers could list the symptoms of rare disorders as the "diagnosis" rather than the rare disorder itself, this work-around approach could place prescribers in jeopardy of allegations of health care fraud. The "work-around" would also result in CMS receiving inaccurate data on the conditions being treated within Medicaid populations. Thus, for the aforementioned reasons, Aimed Alliance strongly urges CMS to remove the mandated diagnosis disclosures on prescriptions to ensure consumers can access their necessary medications without delays.

III. Conclusion

Thank you for providing us with the opportunity to comment on CMS-2434-P. Please contact us at policy@aimedalliance.org if you have any questions regarding this comment.

Sincerely,

Ashira Vantrees
Counsel

[11] KIF1A, *Symptoms of KAND,* https://www.kif1a.org/kand/signs-symptoms/.
[12] *Id.*