

# UNDERSTANDING THE EXTENT OF THE 2021 NBPP WIN\*

## What is the HIV + Hepatitis Policy Institute, et al. lawsuit about?

On August 30, 2022, the HIV + Hepatitis Policy Institute, Diabetes Patient Advocacy Coalition, and the Diabetes Leadership Council filed a lawsuit against the United States Department of Health and Human Services (HHS), in the United States District Court for the District of Columbia.<sup>1</sup> The lawsuit alleged that HHS's Notice of Benefit and Payment Parameters for 2021 (2021 NBPP) improperly permitted health plans to adopt their own definition of "cost-sharing,"<sup>2</sup> thereby permitting plans to implement copay accumulator programs. Copay accumulators accept copay assistance from drug manufacturers<sup>3</sup> but do not count this assistance towards the consumer's annual limit on cost-sharing.

This lawsuit alleged that the 2021 NBPP was unlawful because it was:

1. contrary to the statutory text of the Affordable Care Act;
2. conflicted with the regulations of HHS and Centers for Medicare and Medicaid Services (CMS);
3. arbitrary and capricious; and
4. improperly relied on the IRS's non-binding 2004 notice.<sup>4</sup>

Ultimately, the complaint asked the Court to invalidate the 2021 NBPP.<sup>5</sup>

Aimed Alliance and 28 other advocacy organizations filed an amicus brief in this case explaining to the Court the impact of copay accumulators on patients, caregivers, and providers; and addressing the national health policy implications of the 2021 NBPP interpretation.<sup>6</sup>

Read Aimed Alliance's detailed HIV and Hepatitis Policy Institute, et al. v. HHS, et al. case summary [here](#).

*\* This document is provided for informational purposes **only** and does not constitute legal advice. Aimed Alliance encourages all individuals and organizations to consult with their own legal counsel to determine your organization's interpretation of this decision.*



## What did the Court decide?

On September 29, 2023, the United States District Court for the District of Columbia held that the 2021 NBPP would be set aside because it was arbitrary and capricious.<sup>7</sup> In reaching this decision, the Court accepted the amicus brief filed by Aimed Alliance and fellow health policy and patient advocacy organizations explaining the impact of copay accumulators on patients, providers, and caregivers.<sup>8</sup>

In vacating the cost-sharing interpretation in the 2021 NBPP, the Court reasoned that the rule was arbitrary and capricious because HHS permitted two distinct interpretations of the same statutory text. The Court further explained that, while HHS may interpret a text with some ambiguity, it may not interpret the same piece of text to have contradictory meanings.<sup>9</sup>

Continuing its analysis, the Court assessed whether the statutory definition of cost-sharing included manufacturer copay assistance. The Court used the traditional canons of statutory interpretation, which include interpreting the text in light of its “plain meaning at the time of enactment.”<sup>10</sup> The Court reasoned that the statutory text does not include any definition of cost-sharing as it relates to manufacturer copay assistance.<sup>11</sup> However, the Court recognized it lacked the authority to pick a definition of “cost-sharing.”<sup>12</sup> As such, the Court remanded the matter to HHS to decide whether manufacturer copay assistance is part of the statutory definition of “cost-sharing.”<sup>13</sup>

## What is the current law in light of the Court's decision?

The rule established in the 2020 NBPP for copay assistance is the governing law.

When a court vacates an agency decision or rule, the court's judgment has the "effect of reinstating the rule [ ] previously in force."<sup>14</sup> In the case of the 2021 NBPP, vacating the "cost-sharing" rule will result in the law reverting to the 2020 NBPP.

Under the 2020 NBPP, health plans are required to count manufacturer assistance towards the annual limit on cost-sharing unless the medication has a medically appropriate generic drug available.<sup>15</sup>

Under this rule, if a generic is available but not medically appropriate (requiring the patient take the brand name drug), then the plan is required to count copay assistance for the brand name drug towards the annual limit, despite the availability of a generic on the market.<sup>16</sup> In the 2020 NBPP, HHS explicitly states this portion of the rule **is intended to apply to non-grandfathered group health plans and ERISA plans.**<sup>17</sup>

## Does the 2020 NBPP require plans to count copay assistance for biosimilars towards annual out-of-pocket limits?


Yes. Under the 2020 NBPP, all copay assistance must count towards the annual limit on cost-sharing *unless* a medically appropriate **generic** is available. Generic drugs are medications that are created to be the same in dosage form, safety, strength, route of administration, quality, performance, and intended use, as the brand name drug.<sup>18</sup>

Like generics, biosimilars are lower-cost versions of brand-name biologics.<sup>19</sup> However, unlike generics which are essentially replicas of brand-name small molecule drugs, biosimilars are made with living ingredients, and as such, cannot be copied exactly as the biologic brand-name product and may be chemically different from the referenced product.<sup>20</sup>

As such, the FDA has explicitly recognized that generics and biosimilars **are not the same.**<sup>21</sup> Therefore, because biosimilars are not generics, copay assistance for a biosimilar product is required to count towards the consumer's annual limit on cost-sharing.

## Does this ruling apply to copay maximizers?

No. Copay maximizers use the non-EHB definition to exclude all cost-sharing for prescription drugs from counting towards a consumer's annual limits. To learn more about the non-EHB definition, read Aimed Alliance's Fact Sheet [here](#).



## When does the revocation become effective and the 2020 NBPP apply?

September 29, 2023.<sup>22</sup>

### Does this law apply retroactively?

Yes, unless the Court states otherwise.

When an agency action is revoked, the revocation should “restore the status quo before the invalid rule took effect”— to restore the status quo, the revocation must be applied retroactively.<sup>23</sup> The D.C. Circuit has also previously confirmed that, when an agency rule is revoked, the presumption is that the rule's revocation is applied retroactively, unless “the most compelling circumstances” justify otherwise.<sup>24</sup>

Insurers will likely argue that there are compelling circumstances because they were acting consistently with the law at the time, and therefore, it would be inequitable to reimburse consumers for overpaying to reach their annual cost-sharing requirements.<sup>25</sup> This argument should fail because, if the Court had found compelling circumstances to limit the retroactive application of its order, it would have done so.

It is not uncommon for Courts to limit retroactivity through either explicitly stating the vacatur does not apply retroactively, or by stating the rule will be left in place until the agency develops a new appropriate rule.<sup>26</sup> In this case, the Court did neither. Therefore, the decision should be considered to apply retroactively.

Aimed Alliance nevertheless expects retroactivity to be a matter addressed in future litigation.<sup>27</sup>





## Who can benefit from this ruling?

Consumers enrolled in individual, small group, large group, or ERISA plans can benefit from this ruling.\* This decision does not apply to individuals enrolled in Medicare and Medicaid.<sup>28</sup>

Typically, the outcome of a lawsuit only impacts those who are party to the litigation (i.e., the plaintiffs or the defendants). However, because this case vacated a federal agency rule, anyone who was subject to the previous rule is able to benefit from the rule being vacated.

***\*Consumers that have received or will receive manufacturer copay assistance after September 29, 2023, should ask their health plan to count this assistance towards their annual limit on cost-sharing. Health plans may be unfamiliar with this decision, and therefore, many not automatically apply this amount to consumer's annual limits on cost-sharing. Reach out to [policy@aimedalliance.org](mailto:policy@aimedalliance.org) if you have additional questions about speaking with your health plan.***



## What are the long-term implications of this decision?

HHS and CMS have 60 days to appeal the decision.

If the decision is not appealed, or upheld on appeal, HHS and CMS will review and update the definition of “cost-sharing” under the Affordable Care Act (ACA) and determine whether copay assistance from drug manufacturers will count towards the consumer’s annual limits on cost-sharing as defined under the ACA. This new definition can either state:

1. copay assistance must be counted towards the consumer’s annual out-of-pocket limit; or
2. that copay assistance is excluded from the definition of cost-sharing under the ACA, thereby permitting copay accumulators to be used.

The Court did not impose a timeline for HHS and CMS to issue their clarification. Therefore, a proposed rule clarifying the definition of “cost-sharing” is expected to be released in 2024.



## REFERENCES

1. HIV & Hepatitis Policy Institute, et al., *Compliance*, [https://hivhep.org/wp-content/uploads/2022/08/CMS-Accumulator-Rule-HIV-\\_-Hep-Policy-Inst.-Complaint-8\\_25-clean.pdf](https://hivhep.org/wp-content/uploads/2022/08/CMS-Accumulator-Rule-HIV-_-Hep-Policy-Inst.-Complaint-8_25-clean.pdf)
2. *Id.*
3. When privately insured patients cannot afford their medications, they may rely on financial assistance from pharmaceutical manufacturers and other third parties to meet their health plans' cost-sharing requirements and fill their prescriptions. Typically, the value of this assistance can count towards a patient's deductible and annual out-of-pocket limit. However, health plans that adopt a copay accumulator program accept this third-party assistance but do not count it towards satisfying the patient's deductible or annual out of pocket limit. The 2021 NBPP permitted plans to implement copay accumulators, unless a state law prohibited accumulators.
4. *Id.*
5. *Id.*
6. HHS, *Reply in Support of Defendant's Cross-Motion for Summary Judgment*, <https://aimedalliance.org/wp-content/uploads/2023/08/HHS-Reply-Brief-July-2023.pdf>.
7. *Memorandum Opinion*, <https://aimedalliance.org/wp-content/uploads/2023/10/final-decision.pdf>; The Court did not address the other arguments raised by HIV + Hepatitis Policy Institute, et al., because it invalidated the rule based on the arbitrary and capricious argument.
8. *Id.*
9. *Id.*
10. *Id.*
11. *Id.*
12. *Id.*
13. *Id.*
14. *Action on Smoking & Health v. Civil Aeronautic Bd*, 713 F.2d 795, 797 (D.C. Cir. 1983); *Vacating a rule restores the status quo. Virgin Islands Tel. Corp. v. FCC*, 444 F.3d 666, 672 (D.C. Cir. 2008).
15. CMS, *2020 NBPP*, <https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020>.
16. *Id.*
17. *Id.*
18. FDA, *Generic Drugs: Questions & Answers*, <https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#:~:text=A%20generic%20drug%20is%20a,performance%20characteristics%2C%20and%20intended%20use>.
19. ExpressScripts, *Generics vs. Biosimilars: What are they and how are they different?*, <https://www.express-scripts.com/pharmacy/blog/generics-vs-biosimilars-what-are-they-and-how-are-they-different>.
20. *Id.*
21. FDA, *Biological Product Definitions*, <https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf>.
22. The Court issued its opinion and order on September 29, 2023, therefore, the 2021 NBPP is considered revoked as of September 29, 2023.
23. Daniel H. Conrad, *Filling the Gap: The Retroactive Effect of Vacating Agency Regulations*, *Pace Envir. L. R.* (2011) <https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1682&context=pehr>.
24. *Id.* at p. 18; See p. 19 stating the D.C. Circuit Court has stated previous retroactively consideration factors established by the Supreme Court in *Chevron Oil Co. v. Hudson*, 404 U.S. 97 (1971) does not apply.
25. Daniel H. Conrad, *Filling the Gap: The Retroactive Effect of Vacating Agency Regulations*, *Pace Envir. L. R.* (2011) <https://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1682&context=pehr>.
26. *See generally*, Stephanie J. Tatham, *The Unusual Remedy of Remand with Vacatur*, <https://www.acus.gov/sites/default/files/documents/Remand%20Without%20Vacatur%20Final%20Report.pdf>.
27. In a final footnote, the Court stated "[ ]Should the agencies need further clarification as to what rule is in effect while they consider the matter on remand, they may seek guidance from the Court." *Memorandum Opinion*, at fn. 5 <https://aimedalliance.org/wp-content/uploads/2023/10/final-decision.pdf>.
28. Individuals enrolled in Medicare and Medicaid are not eligible for manufacturer copay assistance as these programs are not eligible for manufacturer copay assistance program because use of these programs violates the federal Anti-Kickback Statute. Lisa Rapaport, *Drug assistance programs offer little charity to uninsured*, *Reuters*, <https://www.reuters.com/article/us-health-pharma-charities-idUKKCN1UW2EL>.



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