AIMEDALLIANCE

May 30, 2025

Hon. Lori Chavez-DeRemer
Secretary of Labor
Department of Labor
200 Constitution Ave NW
Washington, DC 20210

Re: Request for Information 2025-07395 (90 FR 17982)

Dear Secretary Chavez-DeRemer:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing in response to the request for information relating to the Affordable Care Act's (ACA) internal and external appeals procedures. Specifically, we urge the Department of Labor to continue requiring health plans to utilize transparent internal and external appeals processes and data collection procedures.

I. Background

Federal regulation 45 C.F.R. § 147.136 requires all health plans subject to the ACA to provide both internal and external appeals processes, allowing consumers to challenge adverse benefit determinations. These appeals are essential to ensuring consumers can access the items and services they are entitled to in exchange for their premiums. Importantly, Aimed Alliance's forthcoming June 2025 report on appeals oversight found that over 40 percent of internal appeals and 30 percent of external appeals are reversed in favor of the consumer. These findings underscore the value of internal and external appeals processes as tools to ensure health plans provide benefits in accordance with their contractual obligations.

Despite their importance, appeals processes remain underutilized by patients and providers. For example, in 2023, Pennsylvania reported 2,135,041 denied claims, yet only 3,156 internal appeals were filed, which is **less than 1% of all denials**. However, on appeal, nearly 50 percent were reversed in favor of the consumer,[1] raising serious concerns about how many of the original 2 million denials should have been approved.

Thus, Aimed Alliance urges the Department of Labor to maintain the current requirements for health plans to collect and report information on the internal and external appeals processes, as this is essential to guaranteeing that consumers receive their covered benefits.

[1] Pennsylvania Insurance Department, *Transparency in Coverage Report* (Oct. 2024), transparency-coverage-report-aca-health-plans-2024.pdf.

II. Requirements for External Review Process

Federal law requires that the external review process, *at minimum,*[2] provide (1) an external review for adverse determinations based on medical necessity, health care setting, level of care, effectiveness of covered benefit, surprise billing, and cost-sharing; and (2) a written notice to the claimant of their right to an external review. Additionally, the external review process must: (1) allow consumers to file an appeal up to four months after the internal appeal denial; (2) be accessible with no cost-sharing or with a nominal fee of no more than $25, which can be refunded if the claimant prevails; and (3) be accessible irrespective of the claim's monetary value.[3]

To ensure independence and impartiality, external review cases must be randomly assigned to an external reviewer. The external reviewer must consider all timely received information and review all materials *de novo*, giving no deference to the decision of the plan or internal appeals process.[4] The decision of the external reviewer must be provided within 45 days.

For claims involving services deemed "experimental or investigational," external reviewers must maintain a process that is substantially similar to Section 10 of the NAIC Uniform Model Act. While adherence to the exact terms of the Uniform Model Act is not required, the review process must be *substantially similar* to Section 10. These requirements apply to all IROs and external reviewers, including HHS's external review contractor MAXIMUS.[5]

A. Swift Decisions in Complex Cases

Federal regulation 45 C.F.R. § 147.136(b)(5) requires exernal reviewers to consider ***all timely received information and documents*** *de novo*, providing no deference to the decisions or conclusions reached during the internal claims and appeals processes.

This provision is crucial to ensuring that independent reviewers are not influenced by previous coverage decisions, analyses, and rationales that may have been inaccurate or incorrect. It also helps ensure that each review is assessed on a case-by-case basis, allowing reviewers to consider each individual's unique medical history and needs. While the prompt review of appeals is important, it must not come at the expense of a thorough reconsideration of the coverage request.

Aimed Alliance is particularly concerned about instances where certain external reviewers issue decisions to external review requests within unusually short time frames, despite receiving large volumes of documentation for a single claim. These swift reviews, coupled with cursory explanations in denial letters, can leave consumers without access to necessary treatments and without a clear understanding of why their plan is refusing to provide coverage. Therefore, it is essential for DOL to continue to require health plans to collect and report data on internal and external appeals.

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[2] 45 C.F.R. §147.136 (c)(2).
[3] *Id.*
[4] 45 C.F.R. §147.136 (b)(5).
[5] The Ctrs. for Medicare and Medicaid Servs., *supra* note 2.

B. Failure to Provide Adequate Justifications

Federal Regulation 45 C.F.R. § 147.136(b)(5)(iv) requires that a decision on an external appeal include:

- A general description of the request for review;
- Principal reason or reasons for its decision, including what applicable, if any, evidence-based standards were used as a basis for the decision;
- Rational for the decision; and
- References to the evidence or documentation used in rendering the decision.

This information is critically important for consumers and health care providers. For consumers, it explains why a requested medical treatment is not being covered and identifies any medically appropriate alternatives that are covered by the plan. For health care providers, it clarifies the plan's coverage standards and outlines the documentation needed to cover a particular treatment in the future.

However, based on information received by Aimed Alliance, external reviewers often do not comply with these requirements. Specifically, some external reviewers are issuing expedited denials that cite vague or generic reasons, such as asserting that a treatment is not covered by plan terms or is not supported by sufficient evidence, without clearly specifying how the consumer failed to meet plan's criteria. These cursory decisions fail to demonstrate that the reviewer meaningfully considered the submitted materials and reconciled them with the plan's coverage requirements. This lack of transparency is compounded by troubling data indicating that some external reviewers are denying nearly 100 percent of secondary appeals, a rate which stands in stark contrast to CMS data showing that nearly 45 percent of external reviews are typically overturned in favor of the consumer.[6]

C. Failure to Properly Weigh Medical Guidelines

When a health plan denies coverage on the grounds that a treatment is "experimental or investigational," it constitutes an adverse benefit determination. As such, consumers have the right to challenge the decision through both internal and external appeals.[7] The NAIC Uniform Model Act recognizes that, given potential novelty of treatments, these types of denials require distinct considerations within the external review process, as established under Section 10 of the Uniform Model Act. [8]

To determine if an "experimental or investigational" treatment should be covered, the reviewer must assess whether the treatment could be considered a covered benefit, despite the experimental or investigational designation, and whether it is an excluded benefit in the plan's terms.[9] Additionally, the reviewer must also consider whether the beneficiary's treating physician has certified that: (1) standard health care services or treatments have not been effective in improving the condition of the beneficiary;

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[6] The Ctrs. for Medicare and Medicaid Servs, *Appealing Health Plan Decisions*, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/appealing-health-plan-decisions#:~:text=External%20appeals%20have%20helped%20consumers%20get%20the%20care,against%20the%20insurance%20company%2045%25%20of%20the%20time.

[7] The National Association of Insurance Commissioners, *Health Carrier External Review Model Act* (2004), https://content.naic.org/sites/default/files/model-law-075.pdf.

[8] *Id.*

[9] *Id.*

(2) standard health care services or treatments are not medically appropriate; ***or*** (3) there is no available alternative that is more beneficial than the requested treatment or service.[10]

The treating physician must also certify that the recommended treatment or service is likely to be more beneficial than any available alternative or that scientifically valid studies using accepted protocols demonstrate the requested service or treatment is more beneficial than any available standard health care treatment or service.[11]

Once an adverse benefit is eligible for review, the external review organization must assign at least one independent physician with expertise in treating the covered person's condition and familiarity with the requested treatment or service.[12] After considering *all* submitted materials, each reviewer must provide a written opinion stating whether the requested health care service or treatment should be covered.[13]

Unique to the "experimental or investigational" review process, the reviewer must explain the criteria used to determine whether sufficient evidence exists to demonstrate that the treatment ***is more likely than not*** to be beneficial to the patient, compared to standard treatments and services, ***and*** that the associated risks are not substantially greater than alternative treatments and services. As in traditional reviews, the reviewer must also provide a description and analysis of the medical or scientific evidence relied upon to reach the decision.

Based on information received by Aimed Alliance, many reviewers are not providing this required justification when reviewing treatments classified as "experimental or investigational." Failing to include this critical reasoning leaves consumers without a clear understanding of why their coverage was denied, and leaves health care providers without sufficient guidance on how to demonstrate medical necessity for future requests.

III. Ways to Enhance the Utility and Clarity of the Information Collection

While internal and external appeals processes are valuable tools to correct improper benefit decisions, these mechanisms are significantly underutilized by consumers. Moreover, as explained above, when appeals processes are utilized, appeal outcome letters can fail to provide new and adequate consideration as required under federal law.

As such, Aimed Alliance urges DOL to collect additional data on internal and external appeals outcomes to better understand why claims are denied, reversed, or upheld. This will ensure the agency has adequate data to implement future reforms that protect access for consumers and are not unduly burdensome on plans.

- **Mandate Annual Reporting on Claims and Appeals:** Require health plans to report annually on the number of claim denials, internal appeals, external appeals, and appeal outcomes.

[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*, at Section 10 (d)(5).

- **Require Detailed, Anonymized Claims and Appeals Data:** Require health plans to include anonymized data on claims and appeals, such as diagnosis (therapeutic and sub-diagnostic category), type of treatments under review (prescription drugs, imaging, testing, mental health treatment, residential treatment, etc.), and whether the claim was subject to a benefit utilization policy.[14]

- **Establish a Public, Searchable Claims Transparency Database:** Publish all aggregate data on a user-friendly public database, enabling the public to easily identify plans with high denials and overturn rates. This transparency would also support the public sector and governmental agencies in identifying potential bad actors.
    - Simply requiring health plans to post this information on their own websites is less effective, as we found this information difficult for consumers to locate and interpret meaningfully.

- **Strengthen Benefit Denial Notices to Empower Consumers:** Ensure benefit denial letters are including a specific rationale for the denial, information on alternative treatments covered by the health plan, and clear instructions on how to file internal appeals, external appeals, and consumer complaints with the state insurance agency.

IV. Conclusion

In conclusion, the concerns outlined above highlight a range of troubling practices by external reviewers that hinder consumers' access to medically necessary treatments and leave health care providers without the guidance needed to establish medical necessity within the plan terms. Please contact us at avantrees@aimedalliance.org if you have any questions regarding this comment.

Sincerely,

Ashira Vantrees
Director of Legal Strategy & Advocacy

[14] The California Department of Insurance, *Interactive Independent Medical Review Statistics,* https://interactive.web.insurance.ca.gov/apex_extprd/f?p=192:1:12831202701089.