



American Association of  
Clinical Urologists, Inc.

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## **AACU Statement on CMS Implementation of Refund Provision for Discarded Units**

The November 2021 Infrastructure Investment and Jobs Act (IIJA) requires manufacturers of separately paid, single use/single dose container Part B drugs and biologics to provide rebates for discarded units above a 10% threshold of separately paid spending for these products. Refunds apply to quarters beginning January 1, 2023. CMS is expected to issue proposed regulations implementing these provisions this summer.

The AACU believes that urologic patients should have access to beneficial therapies without interruption. This soon-to-be-implemented IIJA requirement may interrupt access for some patients to certain crucial treatments, and AACU believes CMS should allow manufacturers the time they need to comply with the law while also maintaining access to the therapies required for patient treatment plans.

We believe that one potential solution would be allowing manufacturers to be temporarily exempt from compliance with the IIAJ while they work to develop new vial sizes for approval by the Food and Drug Administration (FDA). Additionally, we believe that CMS should seek other mutually agreed upon solutions, such as treatment exclusion from the Act if and only if agreed upon by CMS when it becomes apparent that compliance would negatively impact patient access.

We also suggest that CMS consider developing a process for considering and approving these requests for exemption, and subsequently providing a temporary stay of the Act for the requesting party. This would provide time for a complete and thorough discussion with all stakeholders on the merits of an exemption and would maintain patient access to the therapies they need.

The AACU believes in developing collaborative solutions that provide the best options for our patients while also supporting CMS regulations. For questions or comments, please contact Kristin Jimison, Associate Director, Legislative Affairs at [kjimison@veritasamc.com](mailto:kjimison@veritasamc.com).

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