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AUA Statement on CMS Implementation of Refund Provision for Discarded Units

The AUA believes strongly in the uninterrupted access for urologic patients to therapies that benefit them. A soon to be implemented law could potentially interrupt access for some patients to certain treatments and the AUA believes the Centers for Medicare and Medicaid Services (CMS) should consider solutions that provides manufactures time to comply with the law without causing disruption to a patient's treatment plan.

The Infrastructure Investment and Jobs Act was passed in November 2021 and contains a requirement that manufacturers of separately paid, single use/single dose container Part B drugs and biologics 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 has issued proposed regulations implementing these provisions in the CY2023 Medicare Physician Fee Schedule proposed rule.

A solution may be a temporary exemption from compliance with the Infrastructure Investment and Jobs Act while a manufacturer works to develop new vial sizes for approval by the Food and Drug Administration (FDA), or other mutually agreed upon solutions such as excluding a treatment from the Act if and only if agreed upon by CMS when it becomes apparent that compliance would negatively impact access. We believe in a solution that is in the best interest of our urologic patients while being supportive of CMS policies.

CMS should also develop a process for considering these exemption requests and a temporary stay of the Act for the requesting party so that a thorough discussion on the merits of an exemption can be had to ensure an appropriate solution for all stakeholders.

For questions or comments, please reach out to Raymond Wezik, Director of Policy and Advocacy at rwezik@auanet.org.

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Sincerely,

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