

Discarded Drug Refund Policy Town Hall

American Society of Retina Specialists

Michael M. Lai, MD PhD

Chairman, ASRS Federal Affairs Committee

Member, ASRS Board of Directors

About ASRS and Retina Specialists

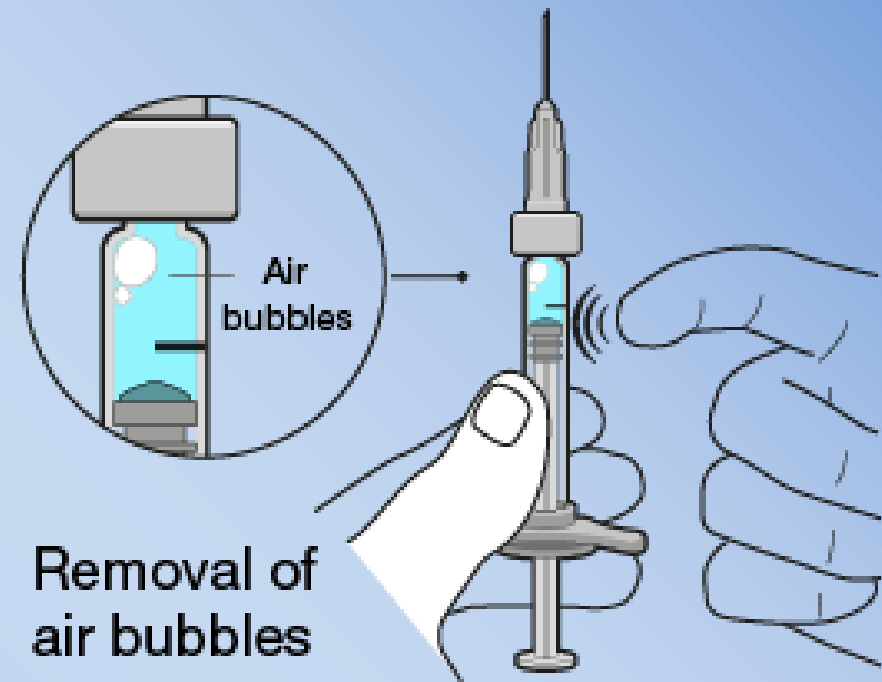
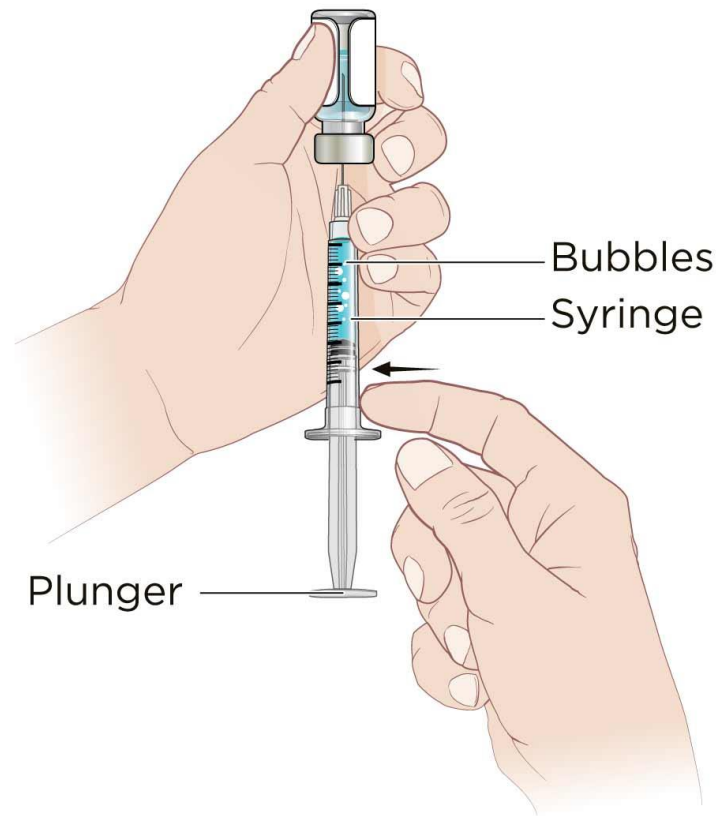
- The American Society of Retina Specialists (ASRS) is the largest organization of retina specialists in the world, representing over 3,000 physicians in every state, the District of Columbia, Puerto Rico, and 63 countries.
- Retina specialists are board-certified ophthalmologists who have undergone additional fellowship training to become subspecialized in the surgical and medical treatment of vitreoretinal diseases.

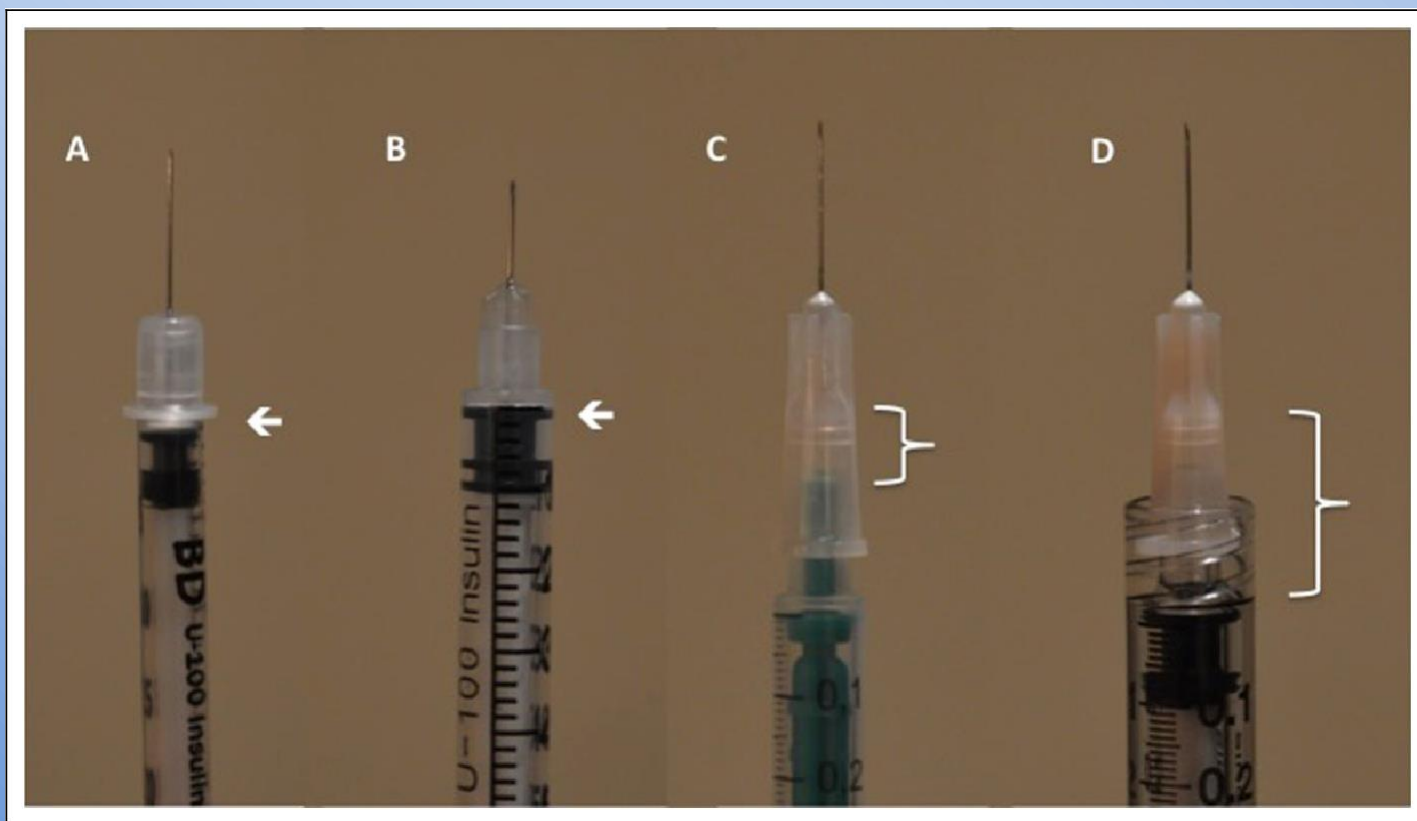
Treatment of Chronic Retinal Disease

- Retina specialists typically treat patients with age-related macular degeneration (AMD) and diabetic retinopathy – the most common causes of blindness.
 - Other diseases include diabetic macular edema, uveitis, retinal vein occlusion, etc.
- Treatment and management involves regular intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) drugs administered by a retina specialist and paid for under Medicare Part B.
 - Standard doses, not based on weight or body surface area.

Anti-VEGFs & Other Intraocular Injectables

- When first approved by the FDA, retina specialists had difficulty ensuring the correct doses of anti-VEGFs were drawn into the syringe because of the small volume (**0.05mL**), the viscous nature of the drugs, air pockets and dead space.
- Overfill is necessary to prime the syringe and ensure a full dose is administered. May be more than 10% of total volume.
- Pre-filled injectable syringes have addressed the issue and are currently the most-widely used options, but new products do not typically initially come to market as pre-filled syringes.





Anti-VEGFs & Other Intraocular Injectables

- Ensuring patients receive the full dose is necessary to achieve the best outcomes and prevent the need for more frequent dosing.
 - More frequent dosing increases patient burden and Medicare expenditures.
 - Patients on 8-week dosing schedules who are under-dosed may require moving to 4-6 week schedules.
- For anti-VEGF and all other injectable intraocular drugs, FDA sets exacting standards to ensure correct dosing. **Significant additional volume is often required for optimal drug delivery.**

Potential Unintended Impact on Patients

- Manufacturers may reduce or eliminate the overfill in single-use containers to side-step rebate provisions, potentially preventing patients from receiving the full dose and necessitating more frequent injections and/or suffering worse visual outcomes.
- Manufacturers may drastically increase their prices to make up for the rebate amount, and significantly increase patient co-pays.
- Patients may lose out on innovative treatments in the pipeline that cannot be produced without significant unused units.
- **All patients, not just those with original Medicare, would be impacted.**

ASRS Recommendations

- ASRS recognizes that CMS does not intend for overfill to be defined as unused and discarded drug, however, the ***risk of underdosing is top of mind for retina specialists.***
- CMS should use its statutory flexibility to expand exclusions to ensure patients with potentially-blinding disease have access to the drugs they need now and in the future.

ASRS Recommendations

- CMS should create a broad, categorical exemption, rather than make drug-by-drug exclusions.
 - **All ophthalmic drugs and/or**
 - **All drugs under 1 mL volume.**
- CMS should increase the percentage threshold to 100% for these drugs.