ASRS American Society of Retina Specialists

May 25, 2022

Lina M. Kahn
Chair
Federal Trade Commission
600 Pennsylvania Ave., NW
Washington DC 20580

Re: FTC-2022-0015-0001; Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Chair Kahn,

On behalf the American Society of Retina Specialists (ASRS) we appreciate the opportunity to provide comments on the increasingly common practice of insurers requiring physician administered drugs to be obtained through pharmacy benefit manager (PBM)-affiliated specialty pharmacies. Retina specialists administer a high volume of sight-saving drugs to their patients and need just-in-time inventory to prevent patient harm and irreversible vision loss. The logistical challenges of obtaining drugs through specialty pharmacies threaten that ability.

ASRS is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

Retina specialists treat several types of chronic retinal disease, including age-related macular degeneration and diabetic retinopathy. These diseases are the leading causes of blindness in the United States, but advances in drug therapy have greatly reduced the likelihood that patients with these diseases will go completely blind. With regular doses of anti-vascular endothelial growth factor (anti-VEGF) drugs administered through intravitreal injection by a retina specialist, most patients' disease can be well-managed allowing them to maintain a normal lifestyle, and for working-age patients, remain employed. In addition, treatment to prevent blindness is well-documented to prevent other co-morbidities, such as depression, and prevent falls or other accidents.

Despite the advances in outcomes for retinal disease, the treatments do come with some burden for the patient. Anti-VEGF drugs must be administered roughly monthly, requiring the patient and an accompanying family member or caregiver to make regular trips to the retina specialist's office. Some patients may be well-managed through a treat-and-extend protocol that allows for longer intervals between injections, but they still require regular monitoring to ensure there is no disease progression or changes in the fellow eye. To ensure that they can treat any patient at any stage in their disease when necessary, retina specialists' practices maintain a significant inventory of a variety of anti-VEGF agents to respond to patient need. **Introducing a specialty pharmacy requirement into this carefully managed treatment protocol risks major disruptions to patient care and becomes an unmanageable logistical burden for practices.**

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Over the last several years, Medicare Advantage (MA) and commercial plans have increasingly erected barriers to care for retinal diseases through utilization management techniques, such as prior authorization and step therapy. Currently, most private plans require patients who need anti-VEGF treatment to begin with bevacizumab (Avastin)—which is off-label and compounded for ocular use—before approving the use of branded FDA-approved drugs because it is less expensive. Dealing with the administrative burden of step therapy and prior authorization has become a significant unreimbursed expense for retina practices—many of which are small or solo practices—and prevent patients' timely access to care.

In addition to these established utilization management policies, insurers have recently begun implementing requirements that the higher cost branded FDA-approved drugs—usually aflibercept (Eylea) and ranibizumab (Lucentis)—be obtained from PBM-affiliated specialty pharmacies. Not only does this requirement prevent retina specialists from providing same-day treatment to patients, it disrupts the timeliness of care over the entire course of their treatment.

Typically, the practice must order the drug from the specialty pharmacy and then the specialty pharmacy contacts the patient for authorization. If the patient misses the confirmation request from the pharmacy or does not have updated contact information on file, the drug may not be available at the physician's office when the patient comes in for his or her scheduled appointment. Retina practices also report that if they have multiple locations, the specialty pharmacy may not ship the drug to the correct location or it may arrive at a remote or rural location that is not open every day with no one to receive and properly handle the drug. In other cases, the insurer might be slow to process a prior authorization request, thereby not allowing enough time to obtain the drug through the specialty pharmacy system. Shipping delays or improper handling of the drug may result in practices receiving unusable drugs. Any of these scenarios—which are not mutually exclusive—could prevent the patient from receiving treatment at the optimal interval.

Even if none of the potential pitfalls that would prevent the drug being available at the right time happen, managing drugs from different pharmacies means that each patient's individual drug would have to be ordered, tracked and stored. The work required as a result of using a specialty pharmacy is uncompensated staff time that adds unnecessary costs and no value to the healthcare system. In fact, the use of specialty pharmacy for retina drugs may actually cost insurers more because if the patient's condition necessitates a change in dose or specific drug or if the patient is determined not to need an injection at an appointment time, the insurer is left with the cost of an unused drug. Similarly, the insurer is liable for drugs that arrive late or are not handled under proper conditions and thus rendered unusable.

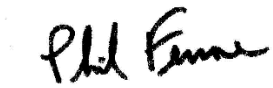
Several states have recognized the threat to patient safety that specialty pharmacy requirements pose and have enacted, or are considering, so-called "white bagging" laws. These state-level initiatives seek to prevent insurers from implementing required use of specialty pharmacy for physician-administered drugs or for penalizing patients when they receive treatment with drugs obtained outside the insurer's preferred pharmacy system. ASRS supports these efforts and recommends the FTC explore how similar safeguards could be implemented at a federal level.

ASRS recognizes that specialty pharmacies do have a role to play in the healthcare system as some specialties may rely on them to source difficult to obtain or infrequently used drugs. For retina specialists, however, their use is not workable as part of standard clinical practice and should not be mandated by payers. ASRS recommends that as FTC studies PMBs in general, it focus on solutions to

ensure that retina specialists have the just-in-time inventory they need on hand to ensure they can provide timely, sight-saving care.

Thank you again for the opportunity to provide comments on this important topic. If you have questions or need additional information, do not hesitate to contact Allison Madson, vice president of health policy, at allison.madson@asrs.org or 312-578-8760.

Sincerely,



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