May 25, 2022

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*

Submitted electronically

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 7,000 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. In the paragraphs that follow, we provide feedback on the key questions posed by the Federal Trade Commission in the aforementioned solicitation for comments.

The main way in which the business practices of pharmacy benefit managers (PBMs) affect AAAAI members and the patients we treat is via opaque and often nonsensical formularies and utilization management strategies. Much of what we refer to as utilization "management" is more aptly characterized as utilization delay or denial.

Examples of the Harm of Insurer and PBM Business Practices

There is now a significant body of research quantifying the harms caused by PBM business practices, but we want to provide the FTC with three recent examples from AAAAI members. All identifying information has been removed, but we assure the Commission that each of these stories describes a real patient treated by one of our members.

One of our members wrote that it took two months and significant involvement from subspecialists to gain approval for indicated immunoglobulin replacement therapy for an immunocompromised twelve-year-old. This delay not only put the child at increased risk for severe infection, it also caused a delay in his ability to return to school. Although the school was accommodating, there was an unnecessary loss of socialization and likely learning loss during this time period. This shows that, while utilization control protocols most directly affect patients' health, they often also impact other areas of patients' lives, and those of their families.

Another member described a six-year-old patient in Medicaid managed care, who suffered from severe atopic dermatitis on 95% of her body. This condition caused significant discomfort and interruption of normal childhood activities, as well as an inability to sleep for any lengthy period of time due to the severe itching. The child had no response to multiple topical steroid regimens. Her allergist wanted to prescribe dupilumab, an approved injectable medication approved for this indication, but was told by the insurance company that the girl had to first try and fail yet another topical treatment. For a month, the child tried – and indeed failed – this additional topical treatment. Following that non-response, the insurer demanded that the child try and fail oral methotrexate or cyclosporine (non-FDA approved therapies), both of which have significant toxicities and require regular blood monitoring for safety. The

allergist's appeal of this demand was denied. Because the allergist was concerned about putting the child on a potentially toxic treatment, especially when there is a safe and effective product approved for this precise indication, the allergist contacted the manufacturer directly. The manufacturer enrolled the girl in a sponsored program for free dupilumab. After only three injections, the child's atopic dermatitis went down from 95% to 35% of body surface and became far less severe. For the first time in four years, the child slept through the night. In other words, months were wasted on insurance requirements that contradicted the prescribing physician's clinical judgment and denied a child access to a readily available, safe FDA-approved medication. In the end, the child only gained access through circumventing her insurer altogether.

For a third and final example, a patient who was five and ¾ years old with severe asthma, required four oral steroids and one hospitalization per year. The insurer refused a trial of omalizumab because the child was under six, even after a year of paperwork and case reports showing its efficacy in children under the age of six. To add insult to injury, this same patient was refused a renewal on her existing treatment at the beginning of a new plan year, when a different drug became preferred on formulary. The girl failed on the newly preferred treatment. In an attempt to keep the child out of the hospital, her allergist currently maintains her treatment with free samples of the first product.

These are but three of countless examples. Taxpayers send billions of dollars to insurers and PBMs to administer federal drug benefits via Medicaid managed care, Medicare Advantage, and Medicare Part D, but patients covered by these insurers are frequently denied medically necessary and indicated medications. As these examples illustrate, our current system leaves some patients in the position of circumventing their insurers altogether and relying on the charity of drug companies instead. This is not only deeply unfair; it is also unsustainable.

The Purpose of Utilization Control Protocols

Utilization control protocols seem to serve two main purposes: to reduce expenditures by the insurer and to drive patients to the medications that increase revenues to the PBM. With regard to the first purpose, theoretically, ensuring appropriate utilization is a key function of insurers. In practice, utilization management is not about meaningful reviews of clinical utility but about delaying medical expenditures for as long as possible, if the main goal of outright denial cannot be justified.

The Office of the Inspector General (OIG) recently conducted a review of prior authorization in Medicare Advantage, finding that insurers "used clinical criteria that are not contained in Medicare coverage rules (e.g., requiring an x-ray before approving more advanced imaging), which led them to deny requests for services that our physician reviewers determined were medically necessary."[1] Additionally, the OIG found that insurers "indicated that some prior authorization requests did not have enough documentation to support approval, yet our reviewers found that the beneficiary medical records already in the case file were sufficient to support the medical necessity of the services."[2] Practicing physicians are all too familiar with these findings. With each passing year, physicians – including allergists and immunologists – spend more time on paperwork to battle insurers and less time on patient care. This is one of the main reasons for the decline of the independent practice and consolidation into systems, which we know is another topic the FTC is exploring.

[1] U.S. Department of Health and Human Services Office of Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" Christi A. Grimm, April 2022, OEI-09-00260.
[2] *Id.*

With regard to the second purpose of utilization control, formulary design is the direct result of negotiations between drug companies and the PBMs, which is why medications often move among tiers from one year to the next despite the fact that there has been no change in safety or efficacy of the products. The logical end point of this system is that the PBM may place on the preferred tier medications with higher list prices over therapeutic equivalents with lower net costs, because higher list prices provide higher price concession potential for the PBM.

Here too, the OIG recently analyzed Medicare data that helps illustrate the issue. The OIG found that the majority of Part D formularies placed all of the reviewed biosimilars on the same tier as their reference products and, furthermore, did not leverage any utilization management to drive biosimilar uptake. The OIG warned that this dynamic exists "because drug manufacturers pay substantial rebates to Part D plans, potentially encouraging Part D plans to cover the manufacturers' reference products instead of the corresponding biosimilars, or to give the reference products preferential treatment."[3] A similar dynamic has been found to exist with regard to certain cancer medications: a $10,000 brand product is covered on the preferred tier while its $450 generic is relegated to the specialty tier – or not covered at all.[4]

In other words, not only do the current business practices of PBMs and insurers result in delayed or even denied necessary medical care, they may even result in patients being driven to the most expensive treatment options. **We urge the FTC to conduct a comprehensive investigation of all aspects of the PBM industry to determine the extent to which this behavior occurs and to suggest solutions for legislators.**

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@AAAAI.org or (414) 272-6071.

Sincerely,

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President
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[3] U.S. Department of Health and Human Services Office of Inspector General, "Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use" Suzanne Murrin, March 2022, OEI-05-20-00480.

[4] *Endpoints News*, "When the $10K brand name drug is more affordable than its $450 generic: How PBMs control the system" by Zachary Brennan, Feb. 18, 2022.