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April 26, 2022

The Honorable Lina M. Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Solicitation for Public Comment on the Business Practices of Pharmacy Benefit Managers

Dear Chairperson Khan:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Federal Trade Commission (FTC) about the practices of pharmacy benefit managers (PBMs) and their impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the pharmaceutical distribution system.

The ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. PBMs, representing payers, including health insurers and self-insured employers, negotiate discounts on the prices of prescription drugs and rebates based on volume of sales with pharmaceutical companies. In turn, payers determine which drugs to cover and how much patients pay. The AMA believes that the role of PBMs as "middlemen" among payers, pharmaceutical companies, and pharmacies goes beyond the negotiation of drug prices on behalf of their clients. PBMs are more frequently fully administering the drug benefit of their clients, creating formularies, making coverage decisions, and determining medical necessity using utilization management tools. They also create networks of pharmacies and negotiate reductions in dispensing fees. Accordingly, the AMA welcomes FTC studying the wide array of PBM practices and issues outlined in its solicitation for public comments.

The Need for Transparency in PBM Operations

The AMA recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders—but not patients. Where discounts or other reductions in price are available on certain prescription drugs, patients should see the benefit of those rebates directly. Price reductions on certain products should not serve as an opportunity for PBMs and health plans to profit while patients pay co-pays and other co-insurance amounts based on high list prices that even the plans themselves are not paying. We agree with policy experts who believe the current system of providing rebates or other price reductions to health plans/PBMs has kept drug prices inflated, as a health plan/PBM can negotiate a larger rebate on a higher-priced product, and neither PBMs nor manufacturers currently have an incentive to lower list prices.

The opaque nature of PBM negotiations and operations makes it exceedingly difficult for physicians to determine what treatments are preferred by a particular payer at the point-of-care, what level of cost-sharing their patients will face, and whether medications are subject to any step therapy or other utilization management requirements. For patients, lack of transparency in their drug coverage may lead to delays in necessary medication treatment, as well as being unaware of their formulary and cost-sharing responsibilities, which can lead to an inability to afford the medications they need.

To improve transparency in this space, the AMA supports PBMs disclosing:

- Utilization information;
- Rebate and discount information;
- Financial incentive information;
- Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed from the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization, and step therapy;
- Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
- Methodology and sources utilized to determine drug classification and multiple source generic pricing;
- Percentage of sole source contracts awarded annually; and
- Utilization management program information, including disclosure of approval, denial, and appeal rates and average processing time for prior authorization and step therapy override requests.

The AMA also supports requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale, and encourages increased transparency in how DIR fees are determined and calculated. These policies would add much needed transparency and ensure that beneficiaries benefit from discounts. Addressing DIR fees specifically, the AMA is pleased that the Centers for Medicare & Medicaid Services is taking action on this front and has supported the agency's proposal to ensure that all pharmacy price concessions, including retroactive DIR fees, are included in the definition of "negotiated price." The proposed change to the definition of "negotiated price" is significant, as the negotiated price in Part D is the cornerstone that determines beneficiary cost-sharing at the point-of-sale, as well as health plan and government liabilities. The collection of DIR fees well after the sale of a prescription drug to a patient has long created needless uncertainty for pharmacies and has resulted in higher than necessary out-of-pocket costs for patients, while benefiting Part D plan administrators and pharmacy benefit managers. Ensuring that all pharmacy concessions, including DIR fees, are included in the definition of "negotiated price" at the point-of-sale provides much needed pricing transparency for pharmacies, allowing them to appropriately capture the full picture of their ultimate reimbursement for a drug upfront, as well as plan for the future without facing unknown fees or clawbacks well after the fact. While larger chain and retail pharmacies are likely well equipped to handle potential uncertainty, smaller independent and community pharmacies, including practice-based pharmacies, are not well situated to deal with uncertainty regarding reimbursement and continuously absorb unexpected financial losses.

More broadly, the AMA supports the regulation of PBMs, which no longer simply negotiate drug prices on behalf of their clients, but rather fully administer the drug benefit creating formularies, making coverage decisions, and determining medical necessity using utilization management tools. Their "benefit management" now largely resembles the typical role of insurers, and they should be treated as such by regulators. Regulators must better understand and control the costs to patients and the system that are resulting from PBM practices.

PBM Utilization Control Methods: Impacting Patient Outcomes and Administrative Burdens

Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on their patients, on physician practices, and the broader health care system. The burden, however, is not solely caused by the escalating cost of pharmaceuticals, but the increase in medication utilization management policies as well, some of which are the result of increased pharmaceutical costs but also may be driven by other imbalances in the current drug supply chain. As a result, patients and physicians often must navigate complex and resource-intensive requirements imposed by health insurers and PBMs. These are consequential problems that may negatively impact the ability of patients to obtain needed medications in a timely manner and to maintain treatment. If patients delay, forgo, or ration their pharmaceutical treatment, their health status may deteriorate and eventually require medical interventions in more costly care settings, such as emergency departments, when their condition is at a more advanced stage of disease.

The time and expense that physicians and the extended care team, patients, and their caregivers spend complying with documentation requirements is another significant issue that needs to be addressed. Physicians and their staff will frequently undertake multiple steps before the patient is able to receive their prescription, including finding clinically appropriate but more affordable alternatives, identifying and applying for discounts or patient assistance programs, and filing appeals or exception requests. These time-consuming processes continue to divert the finite resources away from direct patient clinical care to a large volume of paperwork, emails, facsimiles, and phone calls. Administrative burdens have also led to increasing delays in medically necessary care. As outlined below, the high cost of pharmaceuticals not only negatively impacts the patient who requires them and cannot afford them. The cost is also passed on to other patients when physicians and the extended heath care team are consumed with repetitive administrative minutiae documenting, often repeatedly, medical need in order to comply with expanding insurer medication utilization management program policies. In addition, the two pincers that patients and physicians are squeezed between—high-priced pharmaceuticals and increasingly onerous documentation requirements—continue to erode the patient-physician relationship, as well as lower morale and fuel burn-out among the health care team members.

Prior Authorization

Insurers outline in their coverage design that certain pharmaceuticals are subject to the insurer's review and approval before a prescription will be covered, even if it is on the formulary. Frequently, a physician and patient learn that prior authorization is required when the pharmacy staff notify them—that is, after the prescription has been received by the pharmacy and the medication claim has been rejected by the insurer or PBM. The physician and clinical staff will then need to provide documentation in the format required by the insurer and meet the insurer's criteria. This will often entail a significant amount of physician, pharmacist, and their extended teams' time. Every insurer has its own forms, criteria, and processes. This lack of standardization exacerbates delays and overall complexity. If an adverse decision is made by the insurer or PBM, the physician and staff will often need to assist the patient with filing an

exceptions request or an appeal. Both an exceptions request and an appeal involve additional time and paperwork. But more importantly, the entire process results in significant delays in patient care or patients not receiving covered care that was determined by their physician to be medically necessary. In a 2021 AMA survey,[1] 93 percent of physicians reported that prior authorization is associated with delays in care and 91 percent also reported that prior authorization can have a negative impact on patient clinical outcomes. Significantly, 34 percent of physicians reported prior authorization led to a serious adverse event (e.g., hospitalization, disability, or even death) for a patient in their care. Moreover, 82 percent of surveyed physicians reported that prior authorization can lead to treatment abandonment, meaning the patient never received the care prescribed. This is a common occurrence with pharmacy-dispensed pharmaceuticals, as patients who arrive at the pharmacy to pick up their medication and learn that there is a delay due to prior authorization requirements may not return. Prior authorization is thus an important contributor to medication nonadherence.

Step Therapy

Insurers and PBMs have developed formularies that require a patient for certain covered pharmaceuticals to try a preferred drug to ascertain whether it is effective before other alternatives will be covered. This step therapy requirement may not be known to the patient or physician in advance. The pharmacy staff will frequently notify the patient and physician practice after the patient submits the prescription to the pharmacy and the medication claim is rejected by the insurer or PBM. This, in turn, will require additional clinician and staff time (for both the physician practice and the pharmacy) to determine whether the alternative medication is appropriate based on the particular medical needs of the patient. If it is not, the physician will, after consulting with the patient, submit an exceptions request or appeal requiring the submission of additional documentation. In addition, it may require a subsequent patient visit and more time to assess the effectiveness of the treatment including submitting documentation to satisfy the insurer that the less expensive alternative was not effective for the patient. For patients who have had to complete a step therapy protocol, they may be required to re-do it again if they switch plans. These therapy interruptions can have devastating consequences for chronically ill patients, who may lose control of their disease until the original treatment can be reinitiated. Treatment disruptions for complex biological medications may result in long-term term loss of disease control if the therapy is no longer effective or causes adverse events when the drug is reintroduced.

Quantity and Dosing Limits

Increasingly, insurers are placing quantity and dosing limits on certain pharmaceuticals that are part of the covered formulary. Certain drugs may be limited to the amount that a patient may be prescribed per prescription for a certain time period. Physicians may have to navigate the appeals or exceptions process for the patient, delaying necessary treatment and expending additional time and resources. In addition, insurers may alter the dose that they will cover midway through treatment, which can cause confusion and potentially life-threatening consequences for patients.

Modifications to Formularies

Health plans and PBMs may also change their formularies at any point during a patient's plan year to remove one pharmaceutical in favor of another. This means that the patient may be forced to switch to a drug that is less effective or experience care disruptions during an exceptions process, and it also is highly

[1] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

unlikely the patient will receive a cost discount when the change is made. This switch may destabilize a patient's condition, or it will require additional resource expenditure by the physician and extended health care team to file an exceptions request and/or to file an appeal. This is exacerbated by the continued restrictions of formularies by PBMs to remove previously covered medications.

The foregoing can create significant barriers for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes. The manual and time-consuming processes used in these insurer utilization management programs place excessive burdens on patients whose medically necessary treatment is delayed, as well as physicians, the health care team, and pharmacies, and divert valuable resources away from direct patient care. Commercial and public health insurers tout the benefits of these programs to drive value. This comes, however, at the cost of delayed or denied patient care and wasted time and increased inefficiencies on the part of physicians and other clinical staff. As detailed in the 2021 AMA survey, practices report completing an average of 41 prior authorizations per physician per week, a workload that consumes nearly two business days of physician and staff time every week.

Specialty Drugs and Pharmacies

Physicians treating patients with complex and/or serious conditions such as cancer or autoimmune diseases often prescribe specialty medications. Unfortunately, ensuring patient access to these highly effective therapies can prove to be administratively burdensome for physician practices due to the complicated benefit structures and restrictions health plans and PBMs place on specialty medications. The first challenge for physicians and practice staff is often just discerning if a particular specialty medication is covered under a patient's medical or pharmacy benefit, as this varies widely from plan to plan and even from year to year for the same plan.

Once the overall coverage path for a particular specialty medication has been determined, physicians then struggle with locating and understanding the requirements health plans and PBMs place around specialty medication distribution/dispensing for their members. Physicians may send an electronic prescription for a specialty medication to the patient's preferred local pharmacy, only to later learn that the PBM will only cover the medication if it is dispensed by a specialty pharmacy owned by (or contracted with) the PBM. The lack of transparency and resulting confusion regarding requirements for specialty medication dispensing results in onerous prescription re-work for physician practices, and more concerningly, harmful care delays.

For specialty medications that are typically administered in the physician office, health plan and PBM policies can be even more disruptive and burdensome. Many plans require medications infused in the physician office to be obtained from their designated specialty pharmacy—a process often referred to as "white bagging"—which interferes with the "buy and bill" practice model traditionally used for these drugs. White bagging causes myriad problems for both physicians and patients, including disruption of the practice's inventory management system and typical safety and storage protocols. Moreover, physicians report concerns with patient care being disrupted and delayed when the medication from the specialty pharmacy does not arrive for a scheduled appointment, with a very real potential for negative clinical consequences for patients receiving chemotherapy or requiring timely therapy to retain remission for an autoimmune condition. Finally, white bagging requirements can lead to waste of expensive specialty medications if the patient does not receive the infusion for any number of reasons, as the specialty pharmacy labels the medication for a particular patient, thus preventing the practice from using the drug for another patient.

Another tactic employed by health plans and PBMs to control specialty medication sourcing is "brown bagging," which requires the patient to order the drug from the designated specialty pharmacy and bring it to the physician's office for administration. Beyond the previously mentioned concerns with disrupting the traditional "buy and bill" model for office-administered drugs, brown bagging raises grave patient safety concerns, as the physician cannot be certain that the medication has properly been stored prior to administration. Brown bagging policies essentially force physicians to assume liability for treating a patient with a potentially compromised drug product—a highly objectionable position for any clinician.

Health plans and PBMs impose these requirements regarding specialty pharmacy usage to purportedly control care costs. However, a more holistic approach that considers the substantial administrative practice burdens, potential care disruptions, and safety concerns associated with these onerous specialty pharmacy programs suggest that any drug cost savings may be easily outweighed by the negative impact on physician practices and patient outcomes.

Horizontal and Vertical Consolidation: Conflicts of Interest and Anticompetitive Effects

The AMA urges careful monitoring, and intervention when needed, of both horizontal and vertical consolidation in the PBM space to ensure competition in the health insurance markets and patient access to care. The AMA was heavily engaged in the CVS-Aetna merger after concluding the merger would likely substantially lessen competition in many health care markets, to the detriment of patients, and urged the Department of Justice to block that merger. While the merger unfortunately went forward, the AMA suggests the need to consider the impact and outcome on patients continues. For example, in 2021, Aetna dropped Walgreens—a major competitor of CVS—from its pharmacy network for Illinois Medicaid patients, many of whom lack transportation and have been disproportionately impacted by the COVID-19 pandemic.[2] The AMA urges regulators to carefully study the market impact of the CVS-Aetna merger, as well as other mergers and consolidation in this space, in order to better evaluate merger proposals in the future that may raise prices, lower quality, reducing choice and stifling innovation.

In summary, the AMA has serious concerns about the business practices of pharmacy benefit managers and believes that the potential detrimental impacts from PBM practices on both the cost of and access to prescription drugs necessitates further investigation and action. We look forward to continuing to work with you on this critical issue and to find meaningful paths forward to address the serious issues faced by patients in accessing and affording their prescriptions. For questions or to further discuss please contact Shannon Curtis, AMA Assistant Director of Federal Affairs at shannon.curtis@ama-assn.org.

Sincerely,

James L. Madara, MD

[2] https://www.healthcarefinancenews.com/news/aetna-drops-walgreens-its-illinois-medicaid-plan.