AMERICAN PSYCHIATRIC ASSOCIATION

800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

May 25, 2022

The Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
Submitted electronically

The American Psychiatric Association (APA), the national medical specialty society representing over 37,400 psychiatric physicians who treat mental health and substance use disorders (MH/SUD), appreciates the opportunity to submit these comments in response to the Federal Trade Commission's request for information about the practices of Pharmacy Benefit Managers (PBMs) and their impact on patients and physicians. The following feedback from our members highlights concerns we have about the impact current PBM practices have on patient safety and physician burnout.

Concerns regarding quantity

A common practice of PBMs is to incentivize patients to procure 90-day supplies of medications from their physicians. This potentially unfair practice of requiring patients to purchase a 90-day supply of medication can provide significant cost savings, particularly for patients who are on stable doses of medications over long periods of time. However, our members also understand that provision of large quantities of medications all at once – which would occur with a 90-day supply – is a practice that has the potential to threaten the safety of certain patients.

As psychiatrists, our members treat patients who have disorders of mood and thought that can impair their insight and judgment, at times producing suicidal thoughts. Medication such as antidepressants, and antipsychotics are proven effective in treating patients' mental health disorders, but they may also be addictive or lethal if taken in large quantities. For example, see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4140701/ (antidepressants contribute to morbidity as noted in the Food and Drug Administration's Drug Abuse Warning Network data, and are also subject to nonmedical use and abuse) and https://www.medscape.com/viewarticle/817961 (there are many case reports regarding the misuse of atypical antipsychotics and in combination alcohol and other drugs).

Our members have reported that at times they have specified the need for a pharmacist to dispense a specific quantity due to safety concerns, however the pharmacists still dispensed a 90-day supply without the doctor's consent. Members have also reported that some of their patients have been unable to fill prescriptions

they have written for fewer than 90 days. There is always a risk that a patient could use these medications to harm him/herself, and the risk is elevated when large quantities of medication are dispensed. Our members consider this risk when assessing their patients and writing their prescriptions and when a pharmacist changes the quantity and/or duration of a prescription it is done without the psychiatrist's knowledge and approval and threatens the patient's safety.

Physicians will sometimes prescribe limited amounts of medications when initiating or changing a patient's medication or to encourage a patient's adherence to treatment. For some maintenance medications, physicians will prescribe a trial medication, then evaluate the patient to determine whether the patient is responding as expected and without unpleasant side effects. Sometimes a prescriber needs to monitor a patient's blood work or vital signs to ensure the medication is working correctly and not adversely affecting the patient. Typically, this trial period is shorter than 90 days. If a 90-day prescription is provided and found to not be effective or causes unwanted side effects, the wasted medication is costly to the patient and has the potential to be stockpiled, misused by a patient, household member or disposed of incorrectly.

In addition, prescribers will sometimes use shorter prescription refills to encourage patients to return for appointments and adhere to medications. When a pharmacist changes the duration of a prescription from 30 days to 90 days, the treating physician loses an effective tool for encouraging patient adherence to treatment and ensuring patient safety. When prescriptions for less than 90 days are denied, patients' access to care is delayed.

PBM companies need to leave prescribing (amount and duration) in the hands of the physician. They should offer physicians flexibility in determining when dispensing of an entire 90-day supply of a medication is clinically dangerous and should offer alternatives that would enable dispensing a 90-day supply in multiple shipments without financial penalty to the patient. The treating physician's determination of the quantity of medication prescribed for the care and health of the patient should outweigh any cost considerations. In addition, pharmacists should be prohibited from changing the quantity or duration of medications unless the prescriber has provided approval.

<u>Prior authorization process</u>

The American Psychiatric Association is opposed to any requirement of prior authorization for psychotropic medications prescribed by psychiatrists prior to payment by insurers, except for instances of clear outlier practices or an established evidence base which implicates concern for patient safety. In those instances, the decision to require prior authorization or documentation should be made only by a Board-Certified Psychiatrist.

Another common PBM practice is the use of prior authorization for medications widely used to treat MH/SUD conditions. Prior authorization is often required for inexpensive, widely used and highly effective medications for otherwise stable patients, such as generic medications used to treat mild to moderate depression. Sometimes the PBM will put the generic medications in to a higher tier making them more expensive than the brand name medications and patients that are otherwise stable face having to try

another medication. According to our members, long-acting injectable medications, often used to treat patients suffering from serious mental illness, usually require prior authorization, which is always approved, however, the waiting time to process the authorization results in patients languishing in the emergency room or inpatient setting. This delay negatively impacts patient care as their symptoms remain unaddressed. These approval processes are often required again if patients change insurance plans, or the doctor changes the dose or version (i.e. capsule or tablet) for an already approved medication. An established course of care should be available between a patient and provider, when warranted, without necessitating a duplicative electronic prior authorization process to be initiated between providers and payers.

APA members have reported that the prior authorization process itself is overly burdensome. Administrative burdens include requiring a fax machine to secure approval for a patient's medication (when fax machines have not been in use in most systems for years), being provided with incorrect phone numbers and being bounced between the PBM and the insurer, waiting on hold for up to 40 minutes when trying to get approval for patient medications, and a lack of transparency about which medications, what form (e.g., capsule or tablet) and what dosage require prior authorization. Not only does this impact patient care and results in psychiatrists having less time available for treating patients, it also contributes to physician burnout.

APA supports increased transparency regarding the formulary (what is included and the process to determine coverage), and pricing information as well as a streamlined prior authorization process, when one is required, to, for example, eliminate the need for patients and providers to repeat the prior authorization process with the new payer and for maintenance medications for otherwise stable patients. Thank you for considering our comments. If you have additional questions, please contact Maureen Maguire at MMaguire@psych.org.

Sincerely,

Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPsych
CEO and Medical Director
American Psychiatric Association