PSSNY

Pharmacists Society of the State of New York, Inc.

SENATE TASK FORCE ON OPIOIDS, ADDICTION, AND OVERDOSE PREVENTION

TESTIMONY

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Honorable Chairs Senator Harckham, Senator Rivera, Senator Carlucci, and other trusted members of the Task Force on Opioids, Addiction, and Overdose Prevention,

The Pharmacists Society of the State of New York (PSSNY) is the largest pharmacy professional association in the State of New York. Established in 1879, we represent New York's pharmacists in all practice settings, including community pharmacies, hospital in-patient pharmacies, and correctional facilities. More than 350 million times a year, patients access a pharmacy and pharmacist in New York, making our members the most accessible health care providers in your communities. Pharmacists play a vital role in the custody of prescription opioids, opioid reversal agents, and medication assisted treatments for substance abuse disorder. We take our role as educators very seriously, as we interact with patients from all walks of life every day.

PREVENTION

Pharmacists have long played an integral role in the fight to limit the **illegitimate distribution** of prescription opioids. Pharmacists can dispense only what is prescribed, and we are also subject to federal and state law to be sure opioids are prescribed and dispensed appropriately. For this reason, pharmacists have been notoriously vigilant by scrutinizing every order, and evaluating patient demeanor for signs of misuse. Pharmacists are trained to alert prescribers and fellow pharmacists if we suspect fraudulent prescriptions. We call the police and the Bureau of Narcotic Enforcement (BNE) when we believe a crime may have been committed.

Recent years have brought changes to controlled substance handling by New York pharmacists, making our jobs much easier and the public considerably safer with regards to prescription opioids. Mandated in 2013, New York's Internet System for Tracking Overprescribing (I-STOP) created the Prescription Monitoring Program (PMP) which requires prescribers to query a patient's history of prescribed controlled substance usage before issuing a prescription. BNE reports that this system has reduced "doctor shopping" by 95% in our state. With access to the PMP, dispensing pharmacists can view a patient's controlled substance history before filling a prescription; dispensing information for over 30 other states is also available and that list continues to grow. The PMP has provided us with an additional tool to ensure that every prescription we dispense is, indeed, for a legitimate medical purpose.

Mandatory electronic prescribing, implemented in 2016, virtually eliminated forged and altered opioid prescriptions. Encrypted orders are securely transmitted directly from prescriber to pharmacy, greatly reducing the potential for opioid diversion through altered or stolen prescriptions. Also effective in 2016, New York's 7 day limit on opioids for acute pain has greatly reduced the amount of unnecessary medication left in patient's homes, where it may be subject to diversion.

Reducing excess medication available for misuse and diversion through proper disposal is another initiative involving pharmacies. The New York State Department of Environmental Conservation Drug Take Back Pilot program enabled pharmacies to provide an affordable, safe, and secure method for patients to dispose of excess

medication. More than 250 pharmacies are participating in the program, which has kept nearly 10 tons of medication out of landfills and away from inappropriate hands. New York's 2018 Drug Take Back Act expanded upon the DEC effort by mandating that drug manufacturers bear the burden of the cost for drug take back and disposal. Under this program, more pharmacies will be able to serve as collection sites across the state

The New York State Department of Health (DOH) partnered with the New York State Office of Alcoholism and Substance Abuse Services (OASAS) in 2016, to create an educational controlled substance fact sheet for patients. This 2-page bulletin outlines the dangers of medication misuse and addiction, as well as providing treatment resources and disposal guidelines. All New York pharmacies are required to distribute the fact sheet to the patient whenever a controlled substance is dispensed. The document is comprehensive and is in addition to the drug monograph and pharmacist counseling services the patient receives.

Updated CDC and HHS guidelines have been issued recently regarding opioid prescribing, and the message is clearer than what was previously issued in 2016: Do not abruptly reduce or discontinue opioids in chronic users, but carefully decrease doses to an effective, but safe level. Pharmacists understand that chronic pain is real, and the use of opioid analgesics may be necessary to maintain a patient's functionality and quality of life. Frequently, PBMs interpret guidelines and laws to impose strict limitations on opioid prescriptions. The 7 day opioid limit for acute pain is one such example. PBMs may reject a prescription because they do not have the patient's

complete history. This can be confusing and distressing for patients, who may feel they're being singled out as misusing the medication. Pharmacists act as the patient's advocate and the liaison between the prescriber, the pharmacy, and the PBM to resolve these issues. By communicating compassionately, we can help patients understand that PBM rules are not individualized, but that we believe their care should be.

By utilizing all these regulatory and technological tools, pharmacists have enhanced their opioid abuse prevention efforts, and intensified our counseling activities for patients with opioid therapies or concerns.

TREATMENT

The opioid reversal agent naloxone is a life-saving medication administered to prevent death by opioid overdose. Once carried only by first responders, this product has now become a household word, as availability and accessibility has been increased through legislative efforts and the help of the medical community. Although carried by the majority of pharmacies, barriers to widespread, convenient naloxone availability continue to plague community pharmacists and our patients.

Naloxone remains a legend drug, requiring a prescription. Pharmacists may only dispense it when authorized by an individual patient prescription, or via a non-patient-specific order with strict dispensing criteria. Often times, prescribers are hesitant to issue a patient specific order, possibly due to the stigma associated with substance use disorder. It's not easy for a pediatrician to give a young mom a naloxone prescription

when she's worried about her teenager and his or her friends. It takes a delicate finesse to co-prescribe naloxone with a senior citizen's chronic pain opioid prescription.

PSSNY actively encourages our members to obtain the necessary training and subsequent standing order required to dispense naloxone without a patient-specific prescription. The NYS Department of Health reports that over 2,600 New York pharmacies now have a non-patient specific order to dispense naloxone. Once the standing order is in place, pharmacists are able to not only dispense naloxone to anyone who asks for it, but they can also suggest it to anyone deemed at risk of opioid overdose. PSSNY supports efforts to authorize the NYS Commissioner of Health to issue a statewide standing order available for use by all pharmacies, which could effectively double the community pharmacy locations for naloxone access. Yet even with a statewide naloxone order, barriers would still exist.

Naloxone co-prescribing is recommended by the Centers for Disease Control and the US Department of Health and Human Services. Yet co-prescribing continues to be an underutilized tool in the fight against opioid overdose deaths. Just as prescribers might have difficulty discussing overdose risk with a patient, so, too, are pharmacists faced with an uncomfortable conversation when advising a naloxone co-prescription for chronic pain patients or other at-risk people. Patients might feel defensive, offended, or ashamed. Public education about co-prescribing would certainly be a step in the right direction to get naloxone into the hands of those who might benefit most.

Naloxone is not free for pharmacies. Pharmacies must purchase naloxone from wholesalers, and then hold the expensive inventory just in case it is needed. We are no strangers to this type of inventory diversity, but as businesses, we must be mindful of inventory value. Each pharmacy isn't able to stock more than a few packages of naloxone because the inventory is expensive to maintain. In recent years, pharmacy benefit managers (PBMs) have so drastically cut reimbursements to pharmacies across ALL therapeutic categories, that many community pharmacies have been closing, or at least battling to pay their bills, including those from wholesalers. The extensive time pharmacists spend on consumer education when dispensing naloxone, coupled with the administrative burden of coverage determination and the below-cost reimbursement for the product by the PBM, add up to an almost certain loss of pharmacy revenue with every naloxone prescription. In these ways, stocking naloxone products puts much more financial burden on these already struggling local businesses.

Naloxone is not free for all patients at the pharmacy. While the New York State co-pay assistance program (N-CAP) helps address patient copayments, the program can only be utilized in pharmacies enrolled in the AIDS Drug Assistance Program (ADAP). Even then, N-CAP covers only $40, and copayments and deductibles are commonly much more than that.

Insurance coverage is as varied as the patients and families affected by substance use disorder. In theory, opioid antagonists are covered by most prescription policies. However, individual plan formularies, copayments, deductibles, quantity limits, prior

authorization processes, and refill allowances differ greatly from plan to plan. Coverage criteria are confusing to patients, and increasingly time consuming for pharmacists, prescribers, and caregivers. Narcan, the easily administered branded naloxone nasal spray, may be covered for one patient, but generic injectable naloxone might be the only option for the next patient – who may or may not have the dexterity or medical savvy to administer the product. Standardized insurance coverage, or a "prescriber prevails" mandate for naloxone products for all New York plans would increase accessibility.

Medication Assisted Treatment (MAT) relies on behavioral therapy coupled with specific FDA-approved prescription medications to treat those with substance use disorder. These medications do not substitute one drug for another; rather they help with withdrawal symptoms and cravings. In this way, the "whole patient" is treated and full recovery is the goal. Methadone, buprenorphine, and naltrexone are used for patients addicted to short acting drugs such as prescription oxycodone and hydrocodone, as well as the more prevalently abused heroin. MAT may be taken for months, years, or even a lifetime. Patients enrolled in a MAT program rely heavily on their physician and their pharmacist to ensure consistent medication availability, which in turn prevents relapse and treatment failure. Pharmacists have embraced their role in MAT, but as with opioid reversal agents, we face barriers beyond our control.

MAT medications are available in many strengths and dosage forms, as these therapies are highly individualized for each patient. Tablets, sublingual tablets, and orally

dissolving films in different strengths results in a diverse inventory requirement for the pharmacy. Again, this is typical for a community pharmacy who prides itself on providing immediate service. Prescribers make a clinical decision regarding the best product for a given patient, but that product may not be what the patient ultimately receives.

Just as with naloxone, insurance coverage varies widely for MAT medications. PBMs create formularies, which may exclude one or more MAT formulations. Prior authorization might be required for certain products or quantities, compelling increased administrative efforts by the pharmacist and the prescriber. Treatment delays are possible. Deductibles can make MAT financially out of reach, as an initial prescription may be several hundred dollars. Copays vary by formulation; and patients may have to choose between the best product and the cheapest product. As with naloxone, standardizing insurance coverage or mandating "prescriber prevails" for this class of medication would ease the process of MAT.

Other Barriers to Progress

Pharmacy benefit managers, under the guise of keeping costs down for covered individuals and health plans, control who can get what medication and when. They control prescription quantities and treatment duration. They make treatments affordable or financially out of reach. Through take-it-or leave it contracting, PBMs control pharmacy reimbursement, which can be below the cost of the products, and certainly does not cover the cost of filling a life-saving prescription. This control by PBMs

overshadows prescriber decisions, patient preferences, and a pharmacist's ability to get the right drug to the patient in a timely fashion. These practices affect ALL medications and ALL diseases; substance use disorder and the current opioid crisis are certainly not immune to PBM control.

A particularly disturbing example of a PBM's contribution to the opioid crisis came to the PSSNY office from one of our pharmacist members. A Medicaid Managed Care patient was denied a prescription for lidocaine topical ointment, as it was not covered on the formulary for the Affinity Health Plan. CVS Caremark sent the Adverse Determination Letter, which closed with, "Please use the preferred formulary alternatives: Oxycodone, Tramadol."

Both these "formulary alternatives" are potent, potentially addictive medications – they are opioids (as included on the New York State Opioid Excise Tax drug list). Not only is the originally prescribed drug NOT an opioid, it is a topical product, which is generally safer than a systemic medication. We believe that the PBM's decision about which medication was right for this patient was based on PBM profit, not safety or therapeutic appropriateness.

The Future

Opioid overdose is not the only health consequence of the current crisis. Intravenous drug use is also a risk factor for tetanus, HIV/AIDs and both hepatitis B and C. PSSNY supports S5227 (May) / A6511-A (Paulin) which would allow pharmacists to administer all CDC recommended adult vaccines. Another bill, S5092 (Rivera) / A3867-A (McDonald), would authorize pharmacists to perform CLIA-waived testing as determined appropriate by the Commissioner of Health. Hepatitis C and HIV testing by

a pharmacist would improve public health by making these tests more accessible, especially in underserved areas plagued by the opioid misuse epidemic.

Conclusion

Through every initiative and solution for this country's current opioid crisis, the pharmacists in our New York communities are continuing to work diligently along with prescribers, regulators, and legislators, just as we always have. Pharmacists are highly trained medication experts with a connection to the public that is unique among healthcare providers. Integrated in the communities we serve, pharmacists provide education and interventions for every healthcare problem, and substance use disorder is no exception. We hope to be part of the policy solutions considered by the Task Force, and welcome the opportunity to continue this discussion. Studies show the positive impact pharmaceutical care has on diseases like hypertension, high cholesterol and diabetes. It stands to reason that pharmacists will continue to similarly impact the opioid crisis.