Foundation *for* Opioid Response Efforts

Program Advisory Meeting:
Pharmacy Interventions to Improve Access to Medications for Opioid Use Disorder

Executive Summary

Note: This summary captures the breadth of discussion and guidance provided to the Foundation for Opioid Response Efforts (FORE) during the meeting but is not intended to be a consensus document. The use of the term "participants" does not imply majority agreement.

On September 8, 2022, FORE convened an advisory meeting in New York City to identify the barriers that patients with opioid use disorder (OUD) commonly face in filling their prescriptions for medications for OUD (MOUD), focusing in particular on access to buprenorphine. The participants considered ways to change pharmacy delivery models as well as state and federal policies, regulations, and pharmacy payments to make it easier for people to fill their buprenorphine prescriptions. The meeting objectives were:

- to enhance FORE's understanding of what barriers are hindering pharmacies from stocking and dispensing buprenorphine, as well as barriers patients face in finding pharmacies that dispense it;
- to identify opportunities for FORE to promote better access to buprenorphine through grantmaking, convening, and publishing;
- to consider state and federal policy or regulatory changes as well as payment changes that could promote better access to buprenorphine;
- to consider which organizations and groups FORE should seek to partner with in its efforts to increase access to buprenorphine dispensing; and
- to obtain guidance on topics FORE should avoid.

This report summarizes the attendees' discussion.

I. BARRIERS TO ACCESSING MOUD IN PHARMACIES

Research Findings

To launch the discussion, one participant shared his and colleagues' research on access to MOUD in pharmacies. He shared the results of a review of 30 studies which found that access to naloxone — not a controlled substance like buprenorphine and theoretically easier to access in that providers don't need a waiver to prescribe it — varies greatly among pharmacies, with independent pharmacies much less likely than chains to stock it. He then shared results of a "secret shopper" study in which people called pharmacies in 11 states and asked to fill prescriptions for buprenorphine/naloxone films and naloxone nasal spray. Based on data from 4,984 pharmacies, slightly fewer than half of pharmacies were prepared to dispense buprenorphine/naloxone films promptly, and 36 percent of those that were not prepared to do so indicated they were unwilling to order it. Lack of access was mostly pronounced in independent pharmacies, though some county and state factors appeared to mediate access.

To understand these data, the researchers surveyed 281 pharmacists about their organizations' policies and their own perceptions related to buprenorphine prescribing. Two-thirds of the pharmacists reported they could always or usually fill buprenorphine prescriptions without delay. Pharmacists working at independent community pharmacies were most likely to point to policies that hinder access, such as dispensing only to patients of local prescribers, patients with local addresses, and/or to those who'd already been taking buprenorphine (i.e., established patients). When asked to identify barriers to dispensing, substantial numbers of pharmacists in chains and independents pointed to diversion risk, risk of investigation from the Drug Enforcement Agency (DEA), payer reimbursement, prior authorization requirements, and other factors. There was little consensus across the barriers, suggesting that rather than one dominant barrier, several barriers hinder dispensing.

The survey found greater agreement among pharmacists on the facilitators of buprenorphine dispensing: trusting relationships with prescribers and patients, good communication with prescribers, and higher reimbursement. Based on this body of research, this participant suggested that efforts to increase access to buprenorphine need to address pharmacists' concerns about stocking and dispensing it, and such efforts may need to be tailored to different types of pharmacies (e.g., chains vs. independents).

Next, participants reacted to these findings and shared their own views of the barriers to dispensing buprenorphine, noting that reduced access to treatment at the pharmacy can be the result of the accumulation of multiple barriers.

Insufficient Incentives and Lack of Training

Participants agreed that payment is a key barrier: the costs of dispensing buprenorphine may be greater than what pharmacists are paid to do. Because of steps like checking Prescription Drug Monitoring Programs (PDMPs) — the state databases that track controlled substances — and state regulations, communicating with providers, and offering counseling to patients, dispensing buprenorphine can take more time than dispensing medications for high cholesterol, for example, and payers may not adequately compensate pharmacists for this additional work. While some payers reimburse pharmacists for counseling or other services, most pharmacists are still paid based on how many prescriptions they dispense. Pharmacists may also run into problems with stocking buprenorphine, due to wholesalers' monitoring of opioid orders.

Several participants noted that many pharmacists did not receive sufficient training on opioid overdose prevention and MOUD while in school, particularly those who have been out in practice longer. They are also not included in the X Waiver program to prescribe buprenorphine, so they are not being trained in this way. Many pointed to the need for training to overcome the stigma against people who use drugs. One participant suggested that pharmacists could play a more active role in harm reduction by dispensing clean syringes, for example. But another shared the results of a "secret shopper" study that found widespread stigma among pharmacists in two large cities: nearly all pharmacists contacted were unwilling to sell syringes to clients who requested them "to protect themselves from hepatitis or HIV."

In addition to education on clinical and patient aspects, pharmacists need ongoing education and communication regarding federal and state regulatory policies. All these aspects of education are needed to shift the culture to treatment rather than protection from diversion.

Others noted that like many parts of health care system, pharmacies are experiencing workforce shortages and may lack the bandwidth to take on what they perceive as extra time needed to dispense MOUD.

Regulations and Litigation Have Chilling Effects

One participant noted that even though pharmacists may point to the risk of DEA investigation as a barrier to buprenorphine dispensing, such investigations are unlikely in the absence of egregious behavior. Still, general fears of DEA investigations, wholesaler audits, and loss of ordering privileges have a chilling effect on dispensing, as does pharmacies' involvement in opioid litigation. Noting that independent pharmacists have greater legal exposure than those working in chains, one participant noted that targeted efforts are needed to encourage them to

dispense buprenorphine. Participants noted that policy barriers exist at the federal and state levels as well as within organizations.

Another participant noted that there is variation among state regulations related to buprenorphine prescribing. Some regulations — such as mandatory use of the PDMPs to review red flags for diversion, need for face-to-face dispensing, and identification requirements — while intended to increase patient safety, may have the unintended consequence of hindering access to treatment.

To round out this discussion of barriers, one participant shared findings from a pilot that connected women to OUD treatment upon their release from prison. Many women were unwilling to visit clinics for treatment because they distrusted physicians and other health care providers. However, some women were willing to visit pharmacies to fill their MOUD prescriptions since they felt more comfortable there. This suggests that if barriers to dispensing MOUD can be overcome, pharmacies may have a key role to play in engaging people in treatment and serving as key parts of the care continuum.

SOLUTIONS: CHANGES TO PHARMACY PRACTICE

Next, participants discussed ways to reduce barriers to buprenorphine prescribing, focusing on interventions that target pharmacists' behavior or workplace policies.

Reducing Stigma and Offering Innovative Training Approaches

Many said that efforts to reduce stigma against people with OUD are foundational to all other interventions. Hearts-and-minds campaigns are needed to help pharmacists understand that buprenorphine is a safe, effective, and lifechanging treatment. Some suggested a need to showcase models of how pharmacists can play key roles in providing MOUD, perhaps looking to the Veterans Health Administration, the Indian Health Service, or other integrated health systems where payment and other policies pose fewer barriers.

New training programs are also needed. In developing them, one participant called for approaches that rely less on lectures or passive instruction and more on adult learning techniques, such as simulations or other interactive approaches. Another suggested the need for one-on-one conversations with pharmacists, similar to academic detailing in which clinicians reach out to colleagues to share the best evidence for a given treatment.

Developing Best Practice Guidance and New Treatment Approaches

Another suggested that the Substance Abuse and Mental Health Services Administration (SAMSHA) or another body could convene pharmacists to develop guidance for buprenorphine

dispensing. While some groups such as the American Society of Health-System Pharmacists have published handbooks for pharmacists to help patients with OUD, these resources are little used outside of academic or pharmacy leadership circles. Participants said this and other pharmacy associations could play a greater role in educating their members about best practices. One also suggested that state boards of pharmacy could play more active roles in informing pharmacists about relevant laws and regulations regarding MOUD.

Participants called for pilots of new OUD treatment approaches that involve pharmacists in supporting patients, not just by dispensing MOUD but by offering education and other supports. One suggested that peer recovery specialists could partner with pharmacists in supporting OUD patients. Others suggested we can learn from COVID-era adaptations, including use of telehealth and mobile health clinics, when developing new pharmacy models.

Reconsider Algorithms That Flag Risk

One participant noted that PDMPs don't distinguish between buprenorphine and other opioids, meaning that MOUD patients may be flagged as higher risk. In addition, many pharmacies rely on third-party algorithms that use PDMP data to predict patients' risk of opioid overdose. These algorithms may not be reliable and may stigmatize MOUD patients. Efforts are needed to develop better, more reliable decision support tools.

Participants noted that PDMP data, rather than being a tool for law enforcement, should be used to explore public health questions, including: where do we need more prescribers, and where do we need more pharmacies? For example, one participant shared the results of a study analyzing one state's PDMP. The study found nearly half of pharmacies dispensed no buprenorphine; among those that did, a minority dispensed high volumes of the drug. Given these realities, many people have to go far afield to find dispensing pharmacies, putting them at risk of treatment disruption and relapse. Another evaluation found buprenorphine-dispensing pharmacies in 11 states were more likely to be chains and in white, middle-class suburbs — not necessarily the neighborhoods where there is likely to be greater need.

Build Bridges Between Pharmacists and Prescribers

One participant noted the benefits of having prescribers and pharmacists working together to help people with OUD and called for ways to foster such partnerships. Some pharmacists are located inside clinics, and there may be other ways to build trusting relationships among prescribers and pharmacists.

One participant noted that prescribers often send the majority of their MOUD prescriptions to a single pharmacy and need encouragement to develop larger networks. Another noted that some

behavioral health organizations and pharmacies set up dispensing agreements and suggested that similar agreements could be created to give pharmacies the reassurance they may need to dispense buprenorphine. Another suggested that there could be a legal defense fund or other resources to provide legal support to independent pharmacies and encourage more to dispense buprenorphine.

Target Workplace Policies That Hinder Access

Participants noted pharmacies' workplace or corporate policies related to productivity, liability insurance, and other issues may hinder access to buprenorphine. One noted that changing such policies, particularly at chains, could have a substantial effect. For example, one major pharmacy chain set up a hotline for people to report problems getting naloxone. Perhaps a similar hotline could be set up for consumers or pharmacists to report problems with buprenorphine dispensing. Professional organizations could also encourage their members to develop best-practice policies that facilitate access to MOUD.

While chain pharmacies serve more people overall, independent pharmacies are often more common in rural and low-income communities. For this reason, participants noted that efforts are needed to encourage independent pharmacies in particular to serve OUD patients.

SOLUTIONS: PAYMENT AND POLICY CHANGES

Next, participants discussed state or federal regulatory or policy changes as well as different payment policies that could increase access to buprenorphine. To inform the discussion, participants reviewed a recent Viewpoint commentary published in the *Journal of the American Medical Association* about policy or regulatory changes that could increase access to buprenorphine at retail pharmacies.

State Policy Changes

The Viewpoint authors suggest that states could pass legislation requiring pharmacists to fill all valid buprenorphine prescriptions for OUD. Most participants disagreed with the notion of mandating pharmacists to do so, suggesting instead that pharmacists need to be able to exercise their clinical judgment and should be given support and incentives to make good choices. Others said that instead of mandates, pharmacists should be subject to reviews of their performance and patients should be given tools to file complaints of discrimination.

Participants noted that state boards of pharmacy have key roles to play in reviewing regulations and making sure they are not hindering access to MOUD. For example, states could remove requirements for in-person dispensing to enable home delivery of buprenorphine.

Participants also suggested the need to reform PDMPs by convening vendors and states to discuss steps such as: distinguishing or removing buprenorphine from other opioids that are monitored through PDMPs, increasing use of the data collected for public health purposes, and addressing concerns with the quality of algorithms and decision support tools that rely on PDMP data.

Federal Policy Changes

Participants noted that current federal legislation has the effect of casting buprenorphine as a dangerous and readily misused drug. Participants agreed that passing federal legislation to remove buprenorphine from the Controlled Substances Act when prescribed for OUD would reduce regulatory barriers to buprenorphine access. One noted that pharmacists could increase access to injectable buprenorphine, but lack of clarity from the DEA about what is permissible hinders this approach.

In general, participants agreed that the DEA should provide greater clarity about what agency leaders are looking for in terms of compliance. One participant noted that better communications channels are needed to ensure DEA guidance trickles down to states, regions, and individual pharmacies.

Others agreed with the Viewpoint authors' suggestion that the DEA and SAMSHA could either exempt buprenorphine from federally mandated wholesaler and distributor monitoring and reporting of pharmacy orders of opioid products or could report buprenorphine separately from other opioids. They noted that pharmacies respond to these ordering concerns by limiting the amount of medication in stock, which means that pharmacists may be unable to serve new patients or fill their prescriptions in a timely manner.

Stronger Financial Incentives

Participants agreed that insufficient financial incentives hinder access. One suggested pilots of different incentives to promote stocking and dispensing buprenorphine, such as incentives for communicating with prescribers or providing patient education. Payers could also reimburse pharmacies if their buprenorphine stock expires on the shelf due to unpredictable demand.

State Medicaid programs have the ability to implement different types of incentives, though participants noted politically conservative states are unlikely to do so. Already, Medicaid programs can pay pharmacists for providing some types of additional services, such as reviewing a patient's list of prescribed medications or offering education about a treatment regimen.

Medicaid and other payers could ensure these types of extra services are covered for MOUD patients.

One participant noted that pharmacists' ability to diversify their revenue streams is limited by the fact that they bill through patients' pharmacy, rather than medical, benefits. More innovative treatment models would be more feasible if pharmacists could bill through medical insurance. Participants also suggested that the federal government could recognize pharmacists as providers under Medicare Part D services, which would create more pathways for reimbursement.

PRIORITIES FOR FORE

Next, participants discussed how FORE could play a role in expanding access to buprenorphine in pharmacies through grantmaking, convening, and publishing. Drawing on the daylong conversation, they suggested the following priorities:

- supporting qualitative research to understand pharmacists' perspectives on the barriers to stocking and dispensing buprenorphine;
- building the evidence base for what works, including looking at effective approaches in systems such as the Veterans Health Administration;
- supporting development of alternative payment models for reimbursing pharmacies;
- developing innovative approaches to educating pharmacists to reduce stigma against people with OUD and educate them about treatment with MOUD and recovery;
- working with SAMSHA to produce tip sheets for pharmacists;
- fostering collaborative relationships, or dyads, between prescribers and pharmacies, including through pilots;
- involving Community Pharmacy Enhanced Services Networks (networks of advanced independent pharmacies) in research and pilots;
- developing metrics for MOUD dispensing to assess access, quality, and disparities;

- convening meetings to identify ways to improve PDMPs, for example by separating buprenorphine from other opioids and using the data to identify places where people have greatest trouble accessing buprenorphine;

- publishing a report identifying the practice, regulatory, and policy barriers to buprenorphine dispensing;

- identifying opportunities to communicate with DEA on these barriers and needed solutions; and

- engaging with larger chain pharmacies, which could have large impacts on population health, as well as small, independent pharmacies that serve rural and low-income communities.

Improving Access to Methadone

While the focus of this meeting was on buprenorphine, a few comments were also focused on the need to make methadone more accessible as well. These included suggestions on working to make methadone accessible in pharmacies, taking into account the experiences and recommendations of patients as captured in the Methadone Manifesto.

PARTNERS AND PARTNER ORGANIZATIONS

To broaden the discussion and develop solutions, participants said the following should be represented:

- opioid treatment programs
- student pharmacists
- people with lived experience of OUD and MOUD
- community pharmacy enhanced services networks
- chain pharmacies
- payers
- prescribers
- DEA
- State Boards on Pharmacy
- PDMP vendors

Participants mentioned the following organizations as having conferences where FORE may be able to learn, participate, and disseminate information:

- Compliant Pharmacy Alliance
- National Community Pharmacists Association
- American Pharmacists Association
- American Associated Pharmacies
- National Association of Chain Drug Stores
- Joint Commission for Pharmacy Practice
- American Association of Colleges of Pharmacy
- American Council for Pharmacy Education

ATTENDEES

The following individuals attended the advisory board meeting. Their participation does not constitute their endorsement of this document.

Chair: Thomas D'Aunno, PhD, Chair Professor of Management, Wagner Graduate School of Public Service, New York University

- Josh Bolin, Associate Executive Director, Federal Affairs and Strategy, National Association of Boards of Pharmacy
- Julie Burns, President and CEO, RIZE Massachusetts Foundation
- Taleed El-Sabawi, JD, MS, PhD, Assistant Professor, Florida International University College of Law; Research Scholar, Addiction and Public Policy Initiative, O'Neill Institute for National and Global Health Law, Georgetown Law Center
- Hannah Fish, PharmD, CPHQ, Director, Strategic Initiatives, National Community Pharmacists Association
- Careen-Joan Franklin, PharmD, Clinical Assistant Professor, Clinical & Administrative Pharmacy Sciences, College of Pharmacy, Howard University
- Lucas G. Hill, PharmD, BCACP, Clinical Associate Professor, The University of Texas at Austin College of Pharmacy, PhARM Program Director & Bergen Brunswig Corporation Centennial Fellow
- Adriane N. Irwin, MS, PharmD, BCACP, CDE, Chair, Department of Pharmacy Practice, Oregon State University/Oregon Health & Science University College of Pharmacy
- Sarah Merrefield, Senior Program Officer, RIZE Massachusetts Foundation
- Danielle Russell, Doctoral candidate, Arizona State University

- Tyler J. Varisco, PharmD, PhD, Assistant Professor, Department of Pharmaceutical Health Outcomes and Policy and Assistant Director of Research Development, Prescription Drug Misuse Education and Research Center, University of Houston College of Pharmacy

FORE Staff and Consultant:

- Karen Scott, MD, MPH, President of FORE
- Ken Shatzkes, PhD, Program Director at FORE
- Bryan Bird, MPA, Senior Program Officer at FORE
- Katherine Hamilton, MA, Operations Associate
- Martha Hostetter, MFA, Pear Tree Communications, Inc., consultant