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Interested Party Testimony on House Bill 193
House Health Committee
Lora Miller, Ohio Council of Retail Merchants

May 4, 2021

Good morning Chairman Lipps, Vice Chairman Holmes, Ranking Member Russo, and members of the House Health Committee. My name is Lora Miller. I am Director of Governmental Affairs & Public Relations for the Ohio Council of Retail Merchants. On behalf of the 1,600 pharmacies and more than 6,700 pharmacists operating and providing patient care in Ohio, the Ohio Council of Retail Merchants (OCRM) and the National Association of Chain Drug Stores (NACDS), I would like to offer additional comments concerning House Bill 193.

Several weeks ago, I presented testimony in support of House Bill 193 and asked that both a safe harbor provision for pharmacists and the federal exemptions for Medicare prescribers be included in the bill. It is my understanding that there have been some reservations expressed about doing so.

The federal Medicare law that requires electronic prescribing for all scheduled drugs dispensed in the Part D program provides safe harbor language for pharmacies, as do the electronic prescribing laws of our neighboring states Indiana, Kentucky and Pennsylvania, along with many others. The safe harbor provision is necessary to prevent delays in patient care because it does not require pharmacists to track down prescribers for proof of exempt status when non-electronic prescriptions for schedule II drugs are presented at pharmacies. Absent such a provision, a patient could have to wait days to receive his or her pain medication while the pharmacy attempts to reach the prescriber. If a prescriber's exempt status cannot be verified, without a safe harbor in statute, the prescription will most likely not be dispensed. Pharmacists are already required by both federal and state laws and regulations to take every precaution to ensure that fraudulent prescriptions are not dispensed. Allowing them to use their professional judgement without fear of liability will ensure that legitimate prescriptions are dispensed to patients in need of relief in a timely manner.

As for aligning Ohio law with the federal law regarding prescribing exemptions, this is helpful to both prescribers and pharmacists for purposes of consistency. The issues surrounding these exemptions have been thoroughly vetted at the federal level and in the states that have adopted those exemptions. There is no reason for Ohio to be an outlier in this regard. The same rationale applies in our state as all others. They have been identified as wholly legitimate exemptions to prevent delays in patient care. The state of New York—the first state to adopt mandatory electronic prescribing—has experienced a 22% decline in prescription opioid overdoses since the law went into effect in 2016.[1] The exemptions in New York's law served as a model for the federal law. New York's law also provides a safe harbor for pharmacists who are presented with prescriptions that are not electronically prescribed. Despite the prescribing exemptions and safe harbor for pharmacists in the New York statute, **many lives have been saved**.

[1]https://pubmed.ncbi.nlm.nih.gov/33865194/#:~:text=We%20study%20how%20adoption%20of,%2Dsynthetic%20opioids%20by%2022%20%25 (*Journal of Economics & Human Biology*)

In closing, I would like to share with you the responses to the questions I received from some of you when I testified on House Bill 193 the first time. I am not going to read them; I just want to highlight just a few things:

Rep. Russo – Q: What do we know about the prescribers that aren't currently using EPCS?
A:

- To clarify, according to Surescripts data: 79.8% of prescribers in OH are actively e-prescribing drugs generally. 79.2% have e-prescribing systems that are certified with the extra level of security required by the Drug Enforcement Administration (DEA) that allows them to e-prescribe *controlled substances* (EPCS), but only 62.4% have enabled or "turned on" the extra level of security required to EPCS and are **actively/regularly** e-prescribing *controlled substances*.
- Thus, 37.6% of Ohio's prescribers are not currently routinely e-prescribing controlled substances.
- This 37.6% could be for a variety of reasons that can overlap: there's no current state mandate; the practice does not involve prescribing of controlled substances; no access to wifi/tech issues; the prescriber does not have Medicare patients (or they would have been required to be in compliance under Federal law by Jan 1, 2021) or are waiting until the enforcement provisions under Medicare are in place in Jan 2022; or, they qualify for an exemption under Medicare law. Also, misperceptions on the time/energy/cost of adopting.

Q: Are the exceptions you suggest needed to accommodate those?
A:

- The exemptions are meant to accommodate only instances when a controlled substance prescription cannot be prescribed electronically for practical and legitimate reasons, i.e.: technological issues, EPCS certified software doesn't have fields to accommodate that type of prescription, the setting doesn't lend itself to having or needing prescribing equipment (non-retail fills, clinical trials, hospice), etc. Additionally, most if not all of the 30+ states that have mandated electronic prescribing have adopted most of the exemptions we recommend.
- *However, also note that they are narrow enough, especially combined with OARRS, to significantly decrease illegal prescription fraud. The exceptions are based on the NY law that went into effect in 2016.* ***Within approximately two years of implementation in NY, new orders for paper prescriptions were down 71% and reports of lost/stolen paper prescriptions and pads decreased 73%.***

Q: What option is there for them other than a paper prescription if they cannot electronically prescribe?
A:
For Schedule IIs, DEA allows hard copy written, faxed[1] and electronic prescriptions. Prescribers can orally authorize a schedule II prescription in emergency situations, but the prescriber has to follow that up with a written prescription. For schedule III-V, DEA allows hard copy written, faxed, electronic and oral prescriptions. OAC 4729-5-30, Manner of Issuance of a Prescription, references federal law for purposes of electronic prescribing.

[1] when Schedule IIs are faxed, the DEA requires that the original schedule II prescription must be presented to the pharmacist and verified against the facsimile prior to the actual dispensing of the controlled substance.

Rep. Bird – Q: How secure is EPCS in terms of being able to be hacked and used to issue a fraudulent prescription?
A: For controlled substance prescriptions e-prescribing adds new dimensions of authentication and security as electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for electronic controlled substances prescriptions establish strict security measures, such as prescriber identity proofing, which leads to the issuance of a two-factor authentication credentials, both of which dramatically reduce the likelihood of fraudulent prescribing. Two-factor authentication utilizes a combination of two of the following: something one has (e.g., a card), something one knows (e.g., a code), or something one is (e.g., a fingerprint). A common example is the card and four-digit code for an ATM user. The prescriber must log into the authorized system and then use a combination of two different factors (card, fob token, USB thumb drive, biometrics, or a code via device) to complete and digitally sign the controlled substance prescription. Only then can the prescriber transmit the prescription to the pharmacy of the patient's choice. A concise explanation of the EPCS enablement process can be found at: https://getepcs.com/

Rep. Lipps –
Q: What are the costs associated with EPCS?
A:

- There are 700+ EHR software companies that provide electronic prescribing capabilities. EPCS systems must meet rigorous Drug Enforcement Administration (DEA) requirements for credentialing, certification of the software and two-factor authentication. To cover the additional costs, software vendors have set fees that vary widely. Currently in Ohio, 79.2% % of prescribers are using an EHR system that has EPCS capability and 62.4% are actively e-prescribing. An April 2018 report published by Point-of-Care Partners contains a chart listing the costs reported by the 15 most widely used EHR software providers. The report shows EPCS costs vary from "included in ongoing cost" up to $250 per prescriber annually. One company, GE Centricity, is an outlier and has a posted cost of $5,988 per physician.
- *Additionally, we strongly believe the ROI for EPCS far outweighs the costs* - evidenced by the fact that 97% of the pharmacies in OH are EPCS enabled. The efficiency allows all providers more time to spend with patients and less time dealing with insurance formulary issues and calls from pharmacies to address handwriting questions and other notation errors on paper prescriptions. For patients, it makes the prescribing process immediate – no need to drop off the prescription at the pharmacy and wait or return for it. Lastly, e-prescribing of controlled substances gives prescribers greater flexibility when prescribing medications such as opioids, allowing them to prescribe lesser quantities, knowing that with e-prescribing, it is an easy matter to prescribe additional supplies of a patient's medication if their clinical condition warrants it.
- This link takes you to a website that compares e-prescribing software along with reviews and pricing.

Rep. White – Q. What requirements are currently in place that serve to prevent pharmacists from filling a potentially fraudulent prescription?
A. Pharmacists have an important legal and ethical role in addressing prescription drug abuse. The legal requirements are numerous on both the state and federal level as outlined below. Bottom line, if Ohio passed HB 193 and mandates EPCS, identification of fraudulent prescriptions will be exponentially easier as fewer paper prescriptions will be presented overall.

- DEA Title 21 "**§1306.04 Purpose of issue of prescription:**
  (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. *The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription*. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
- Pharmacists are trained on DEA "Red Flags" Guidance for Drug Diversion – include numerous situations covering the content of the prescription, patient behavior, the medication quantity/amount/refills.
- Pharmacists are statutorily required to check OARRS to look for patterns that indicate diversion and/or misuse.
- State has limits on maximum days' supply of controlled substances allowed and limits on refills.

Q. Is there a way for OARRS to track that the prescription was submitted via paper because it was subject to one of the exemptions included in the amendment?
A: It is our understanding that such a field exists in the software platform standards available to prescription drug monitoring databases. We would defer to the Ohio Board of Pharmacy as to whether it is feasible for them to adopt it.

Thank you again, Mr. Chairman, Vice Chair Holmes, Ranking Member Russo and members of the House Health Committee for your time and consideration. I am hopeful that my testimony has provide clarity on these important issues. I would be happy to answer any questions you may have.