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3 **In re National Prescription Opiate Litigation – A Federal Judge Talks to Us About Responsibility in the Pharmacy**

ACPE Program Number: 0487-0000-20-004-H03-P and 0487-0000-20-004-H03-T (knowledge-based activity)
Release Date: December 9, 2020
Expiration Date: December 9, 2023
Contact Hour(s): 1.0
Program Fee: $15.00

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Ohio Pharmacist Continuing Education (CE)
Reporting Requirements

Updated 8/21/2020[1]

Effective September 16, 2018, rule 4729:1-5-02 of the Ohio Administrative Code updated the required minimum continuing education units (CEUs) pharmacists are required to obtain and aligns the reporting period to the biennial (two-year) renewal cycle.

Specifically, pharmacists are required to obtain a minimum of 4.0 CEUs (40 hours) every two years prior to license renewal.

Continuing Education Requirements by License Number

License Number	2021 Reporting Cycle*
03-1-XXXXX 03-2-XXXXX 03-3-XXXXX	Total Hours – 40 Law/Jurisprudence – 2 Patient Safety/Medication Errors – 2 Earned between **Sept. 16, 2019** and **Sept. 15, 2021**

*Pharmacists who meet the continuing education requirements via a Board approved pharmacy practice-specific specialty certification are still required to obtain the required CEUs in pharmacy law and patient or medication safety listed above.

Program Title: **In Re National Prescription Opiate Litigation – A Federal Judge Talks to Us About Responsibility in the Pharmacy**

Target Audience: Pharmacists and Pharmacy Technicians

Release Date: December 9, 2020

Expiration Date: December 9, 2023

ACPE Program No.: 0487-0000-20-004-H03-P or 0487-0000-20-004-H03-T (knowledge-based activity)

Accreditations: This CE activity is ACPE-accredited for 1.0 contact hour, or 0.10 C.E.U.'s, for pharmacists and pharmacy technicians.

1 https://www.pharmacy.ohio.gov/Licensing/Pharmacist.aspx

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Media: Enduring print material and interactive test-taking at **www.selectce.org.**

Program Fee: $15.00

Estimated Time to Complete the Activity: 60 minutes

Procedures: To receive a credit for this CE activity, you must supply your CPE Monitor ID number (also known as your NABP eProfile ID) and month/day of birth. Other procedures are to read this program, complete the post-test questions and evaluation questions on the Answer Sheet, and either:

i) mail the Answer Sheet and program fee to us. You will receive an Assessment Feedback mailed to you within 2 weeks. Checks or money orders are encouraged. Mail to: Select CE, P.O. Box 21186, Columbus, Ohio 43221-0186;
or
ii) use the online test-taking website www.selectce.org. Follow the instructions on the website, using any major credit card to pay the program fee. Upon passing the test, you will receive immediate confirmation via email, and your Assessment Feedback will be sent within 5 days. Refunds are not generally provided, unless you mistakenly make too many online payments or some such other snafu.

A minimum score of 70% on the post-test is required to earn credit.

Faculty: Patti Nussle, R.Ph., J.D., is a healthcare attorney who has written and published continuing education programs in pharmacy law and nursing law for healthcare professionals since 2001. Peer reviewers are Robyn Satterfield, PharmD and Michael Piccolo, PharmD.

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Objective: At the conclusion of this program, pharmacists and pharmacy technicians should be able to:
(a) describe who has the duty under the CSA to prevent diversion, and
(b) describe who has the duty under Ohio controlled substance laws to prevent diversion.

Important Note: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority.

Contact Us: By phone (614) 481-8711 or email at patti@selectce.org.

Thank you! We truly enjoy serving you!

Introduction

Rarely do we get to see a federal judge delve into the specifics of pharmacy responsibility and the law. Yet the federal judge in the National Prescription Opiate Litigation did just that. Judge Daniel Polster's in-depth analysis of the federal Controlled Substance Act (CSA) to answer the question "Who has the duty to prevent diversion?" is both an interesting read and a teaching moment for anyone who works in a pharmacy or owns a pharmacy.

Background

Seeking to recover the costs of fighting the opioid epidemic, the National Prescription Opiate Litigation consolidated more than 2,000 pending lawsuits brought by thousands of the nation's cities, counties, state governments, tribal authorities, and individuals against hundreds of manufacturers, marketers, distributors, and dispensers of opioids. By some accounts, this is the most complex case in U.S. history.[2]

Plaintiffs (people bringing the case to court) allege that the manufacturers of prescription opioids grossly misrepresented the risks of long-term use of those drugs for persons with chronic pain, and distributors and dispensers failed to properly monitor suspicious orders of those prescription drugs--all of which contributed to the current opioid epidemic.[3]

This case was assigned to Judge Daniel Polster of the U.S. District Court for the Northern District of Ohio. For a complete and up-to-date list of court documents filed in this case, see the web page created specifically for it at https://www.ohnd.uscourts.gov/mdl-2804.

Question 1 (pre-test to get you thinking; please provide an answer but none will be graded as incorrect):

Persons with a duty to prevent diversion of controlled substances include:

a. individual pharmacists;
b. pharmacy owners;
c. both a and b.

In this CE activity, we are only going to examine one section of one Opinion in this case. On pages 13-21 of the Opinion and Order dated August 6, 2020, the Judge addressed the claims of 5 large pharmacy chains that the CSA requires only **individual pharmacists**, and not the **pharmacies**, to prevent diversion of controlled substances.

What follows is the relevant text of the court's decision, with some footnotes and citations removed for brevity and readability. The boxed questions are designed to test whether you are actively learning and meeting the objectives of this CE activity. We begin at Section B of this Opinion and Order.[4]

B. Pharmacy Duties Under the CSA

The Pharmacy Defendants[5] next argue they are entitled to dismissal of Plaintiff's claims because ***only*** their pharmacist-employees – and not they, themselves – have a duty under the Controlled Substances Act

2 https://judicature.duke.edu/articles/the-negotiation-class/

3 https://www.ohnd.uscourts.gov/mdl-2804

4 *In re* National Prescription Opiate Litigation, MDL No. 2804, No. 1:17-CV-2804 (N.D. Ohio August 6, 2020) Doc # 3403 Opinion and Order at page 13 – 21.

("CSA") to prevent diversion of opioids via illegitimate prescriptions. This contention is deeply troubling and, for the reasons below, the Court firmly rejects it.

In [our earlier opinion and order], this Court held that, "as a matter of law, Section 1301.74 [of Title 21 of the Code of Federal Regulations] imposes a legal duty on registrants to design and operate a system to disclose to the registrant suspicious orders." Doc. #2483 at 15. Section 1301.74 applies specifically to non-practitioners – that is, manufacturers and distributors, but *not* pharmacies. The Pharmacy Defendants acknowledge that corporate *distributors* of opioids have a duty to prevent diversion by monitoring suspicious orders, but assert "there is no equivalent corporate-level obligation with respect to *dispensing*." Doc. #3340-1 at 14 (emphasis added). Defendants contend, instead, that "the responsibility to guard against invalid prescriptions rests with individual pharmacists, and ***only*** with individual pharmacists." *Id.* (emphasis in original). In other words, the Pharmacy Defendants now ask the Court to conclude that the CSA, as a matter of law, does not impose any obligation on a pharmacy-registrant, itself, to identify or investigate dubious prescriptions prior to filling them. The Court declines to do so, as this strained interpretation of the CSA would turn the fundamental purpose of the Act on its head.

Question 2:

The Pharmacy Defendants assert that there is a corporate-level obligation to prevent diversion with respect to:

a. dispensing, but not distributing;
b. distributing, but not dispensing;
c. both distributing and dispensing.

In a prior opinion, the Court described the statutory and regulatory framework of the CSA and its implementing regulations. Doc. #2483 at 5. In short, all persons who dispense controlled substances (including pharmacies) must register with the Attorney General [who then delegated this authority to the DEA Administrator] 21 U.S.C. § 822. Generally, in the case of pharmacies, the Attorney General must issue them a registration so long as they are authorized to dispense controlled substances by and in the State where they practice. 21 U.S.C. § 823(f). However, the Attorney General may deny a registration if he deems it inconsistent with the public interest. *Id.; see also* 21 U.S.C. § 824(a)(4).

To help the Attorney General determine the public interest, the CSA provides a nonexclusive list of five factors the Attorney General must consider, including "[t]he applicant's experience in dispensing … controlled substances." 21 U.S.C. § 823(f)(2), (4). Chapter II of Title 21 of the Code of Federal Regulations further expands upon these general provisions. *See generally* 21 C.F.R. Ch. II.

The Regulations at Title 21, Chapter II have been properly promulgated pursuant to Congressional authorization and, thus, carry the full force and effect of law. Doc. # 2483 at 6, 15 (citing *Chevron USA, Inc. v. Nat. Res. Def. Council, Inc*., 467 U.S. 837, 843-844 (1984)). The CSA – as interpreted through these implementing regulations – is unequivocal:

> ***All*** applicants and registrants shall provide effective controls and procedures to guard against [i] theft ***and*** [ii] diversion of controlled substances.

5 The "Pharmacies" or "Pharmacy Defendants" referred to by the court are Walmart, CVS, Rite Aid, Walgreens, and Giant Eagle; Case 1:17-mdl-02804 Doc # 3403 at page 1.

21 C.F.R. § 1301.71(a) (emphasis added). The Court has previously explained that, "pursuant to this [Congressional] authorization, the DEA has promulgated regulations that set forth security requirements for registered manufacturers, distributors, and dispensers of controlled substances." Doc. #2483 at 6 (citing 21 C.F.R. §§ 1301.71-77 (the "Security Requirements")).

The Pharmacy Defendants do not disagree that the CSA's Security Requirements apply them. But they assert that, at least with respect to pharmacies, these regulations "only impose[] requirements for in-store physical security controls and ha[ve] never been understood to require a 'system' for monitoring prescriptions and disclosing "suspicious orders of controlled substances."" Doc. # 3340-1 at 16 n.6. In other words, even though ***all*** other registrants (including their own pharmacist-employees) need to guard against theft ***and*** other species of diversion, the Pharmacy Defendants assert ***they*** need only guard against theft.

Question 3:

The Pharmacy Defendants contend that under the Controlled Substances Act (CSA or Act) the responsibility to guard against invalid prescriptions rests with:

a. individual pharmacists only;
b. both pharmacists and technicians;
c. both pharmacists and the pharmacy.

Question 4:

The Pharmacy Defendants contend that the CSA imposes on a pharmacy the requirement that it guard against:

a. theft only;
b. diversion only;
c. both theft and diversion.

The Regulation's use of the word "and," however, unambiguously indicates that ***all*** registrants have an affirmative obligation to protect not only against diversion via theft but also other forms of diversion broadly. To conclude otherwise, as the Pharmacy Defendants suggest, disregards the plain meaning of the text, undermines the purpose of the CSA, and would allow a frightening abdication of responsibility. Furthermore, as explained below, the CSA ***explicitly*** requires pharmacies to collect prescription data and use it to monitor for questionable prescriptions that might lead to diversion.

1. Statutory Obligations of Registrants.

The Pharmacy Defendants are certainly correct that the CSA includes provisions addressing physical theft of drugs from pharmacies. Specifically, the Regulation's Security Requirements lay out a non-exhaustive list of controls that a registrant must implement in order to store and dispense Schedule II controlled substances safely at their stores. *See* 21 C.F.R. § 1301.75-76.

But it is equally certain that the Pharmacy Defendants' statutory obligations do not end there. With respect to diversion more broadly, the CSA and its implementing regulations impose many other obligations on registrants – ***all*** registrants – that serve to advance the CSA's overall stated purpose of preventing diversion. For example, the CSA imposes specific record-keeping requirements on registrants who handle controlled substances. Specifically, a pharmacy-registrant must, at a minimum and among other things, record and maintain:

> the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the [controlled] substance on behalf of the dispenser.

21 C.F.R. § 1304.22(c). Whatever other information a pharmacy may choose to collect about its own dispensing practices, those of its stores, or those of its pharmacists, the CSA mandates the collection and retention of

specific data-points that would inarguably be useful to the pharmacy (or the DEA) in identifying suspicious prescribing and dispensing activity. This record-keeping requirement is clearly intended as a guard against diversion. [citations omitted] It would undermine the entire purpose of the CSA (and defy logic) for the Act to require a pharmacy to collect the dispensing data listed in § 1304.22(c), but then allow the pharmacy to ignore this data when fulfilling its fundamental obligation to guard against diversion.

In addition to the Security Requirements and record-keeping requirements, the CSA also mandates that a pharmacy-registrant must employ a properly licensed and trained pharmacist. The Pharmacy Defendants, as non-pharmacist corporate entities, attempt to interpose this requirement to insulate themselves from liability. But the result the Pharmacy Defendants espouse can only be reached through a strained reading of the CSA as a whole.

Under the CSA, a pharmacy itself is a "Practitioner." *See* 21 U.S.C. § 802(21)("The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, **pharmacy,** hospital or other person licensed, registered, or otherwise permitted . . . to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice.")(emphasis added). Further, a pharmacy is also a "dispenser." *See* 21 C.F.R. § 1300.01 ("Dispenser means an individual practitioner, institutional practitioner, ***pharmacy*** or pharmacist who dispenses a controlled substance.") (emphasis added); *see also* 21 U.S.C. § 802(10)(a dispenser is "a practitioner who so delivers a controlled substance to an ultimate user").

Question 5:

The Court found a pharmacy-registrant under the CSA must:

a. use controls to guard against theft;
b. collect certain dispensing data;
c. employ a properly licensed and trained pharmacist;
d. all of the above.

Question 6:

Under the CSA, practitioners include:

a. physicians;
b. pharmacies;
c. hospitals;
d. all of the above.

The Pharmacy Defendants attempt to draw a distinction between the roles of the pharmacist and a pharmacy. The Pharmacy Defendants then insist that individual, licensed pharmacists, and only those pharmacists, bear responsibility for dispensing controlled substances improperly. *See* Doc. #: 3340-1 at 17 (citing 21 C.F.R. § 1306.04(a)). But the CSA does not make this distinction. ***Both*** pharmacists and pharmacies are 'practitioners" under the Act. And ***both*** are "dispensers." Accordingly, both pharmacists and pharmacies bear all the obligations imposed upon practitioners and dispensers. And, the statutory definitions of these two terms – especially the statutory definition of "practitioner" – expressly anticipate that a pharmacy has the ability to dispense controlled substances in the course of its own professional practice. Thus, under the CSA, any ***person*** (which, to be clear, includes corporate entities) who dispenses or delivers a controlled substance to an ultimate user must adhere to all of the obligations imposed by the Act.

This understanding is further confirmed by the language of Section 1306.04(a):

> 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 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.

21 C.F.R. § 1306.04(a) although this regulation who physically hands patient, the regulation ***the person*** – which is a to the pharmacist but for violation of the adopted and ratified by district court. *See Top 78 FR 26069-01, 26082* corresponding dispensing of valid itself.")(citing multiple *States v. Appalachian* 3d 1184, 1189-90 (E.D. inconsistent about individual practitioners simultaneously subject to penalties for prescriptions.").

Question 7:

Under the CSA, pharmacists and pharmacies are:

a. practitioners;
b. dispensers;
c. both practitioners and dispensers.

Question 8:

Under the CSA, a pharmacy has the ability to dispense controlled substances in the course of its own professional practice.

a. true;
b. false.

Question 9:

Under the CSA, any ***person*** (which, to be clear, includes corporate entities) who dispenses or delivers a controlled substance to an ultimate user must adhere to all of the obligations imposed by the Act.

a. true;
b. false.

Seeking Pharmacy Defendants supports their pharmacist – not the pharmacy – may Motion at 15. Defendants rely on person not a conducts a pharmacy, full and actual charge of Defendants submit this pharmacist can be held pharmacy, because prescription judgment, and skill, and Defendants cannot lawfully usurp from their pharmacists." *Id.*

(emphasis added). Put plainly, recognizes it is "***the pharmacist***" the controlled substance over to the intentionally and explicitly subjects much broader term, applying not just also to the pharmacy – to penalties CSA. This interpretation has been the DEA and at least one other *RX Pharmacy; Decision and Order,* (DEA May 13, 2013)("The responsibility to ensure the prescriptions extends to the pharmacy agency rulings); *see also United Reg'l Healthcare, Inc.*, 246 F. Supp. Ky. 2017)(finding "nothing articulating the responsibilities of and pharmacists while indicating that other entities may be their role in issuing and filling valid

support outside the CSA itself, the also turn to Ohio law, asserting it contention that '[o]nly a licensed non-pharmacists corporate owner of a engage in the practice of pharmacy." Specifically, the Pharmacy O.R.C. § 4729.27, which states: A pharmacist, who owns, manages, or shall employ a pharmacist to be in such pharmacy." The Pharmacy language indicates that only a liable for the dispensing practices of a "[q]uestioning the validity of a requires . . . specialized knowledge, this is a task that Pharmacy

This logic fails. Ohio controlled substance law largely mirrors the federal scheme and sets out identical obligations. In Ohio, the Pharmacy Defendants are classified as "Terminal Distributors." The Ohio Revised Code defines "Terminal Distributor of Dangerous Drugs" as:

> a ***person*** who is engaged in the sale of dangerous drugs at retail, or any person, ***other than a . . . pharmacist***, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.

> "Terminal distributor" includes ***pharmacies*** . . . who procure dangerous drugs for sale or other distribution ***by or under the supervision of a pharmacist*** . . . authorized by the state board of pharmacy.

O.R.C. § 4729.01(Q)(emphasis added). Furthermore, the licensure requirements for Terminal Distributors of Dangerous Drugs, pursuant to O.R.C. § 4729.55, require that:

> No license shall be issued to an applicant for licensure as a terminal distributor of dangerous drugs unless the applicant has furnished satisfactory proof to the state board of pharmacy that:
>
> * * *
>
> (B) A pharmacist . . . authorized by the board . . . will maintain supervision and control over the possession and custody of dangerous drugs and controlled substances that may be acquired by or ***on behalf of the applicant***.
>
> * * *
>
> (D) Adequate safeguards are assured that the applicant will ***carry on the business of a terminal distributor*** of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.

O.R.C. § 4729.55 (emphasis added).

Combined, these provisions mean that a pharmacy owner, who is not him- or herself a licensed pharmacist, must employ a licensed pharmacist as a control against diversion, and the pharmacy must conduct its business in a way that allows its pharmacist to properly dispense the pharmacy-licensee's controlled substances on its behalf. These provisions cannot be read to mean that pharmacy owners who ***are not themselves pharmacists*** are absolved of responsibility for their own dispensing practices simply because they must employ a pharmacist, whereas pharmacy owners who ***are pharmacists*** – and thus need not employ a separate pharmacist – are not.[6] Such a reading would undermine the purpose of Ohio's controlled substance law, and would disincentivize licensed pharmacists from owning and operating their own pharmacies.

In sum, the Court concludes the Pharmacy Defendants have not shown that sole responsibility for their dispensing practices rests with their pharmacist-employees. Rather, the CSA makes clear that any ***person***, which includes a pharmacy itself, who knowingly fills or allows to be filled an illegitimate prescription is in violation of the Act.

6 Such a reading would be tantamount to a statutory "safe harbor" by providing that a pharmacy owner could not be held liable for its role in dispensing controlled substances simply by employing a pharmacist. Employment of a properly licensed pharmacist must be read a feature of the law, not a way to subvert it.

Question 10:

Ohio controlled substance law:

a. is read to mean that pharmacy owners who ***are not themselves pharmacists*** are absolved of responsibility;
b. provides a safe harbor for pharmacy owners once they employ a pharmacist;
c. neither of the above are true.

Question 11:

It is a violation of Ohio controlled substance laws if a ***pharmacy*** fails to conduct its business in a way that allows its ***pharmacists*** to be effective.

a. true;
b. false.

Question 12:

In the National Prescription Opiate Litigation, the Court concluded:

a. the Pharmacy Defendants did not show that sole responsibility for their dispensing practices rests with their pharmacist-employees;
b. the CSA makes clear that any person, which includes a pharmacy itself, who knowingly fills or allows to be filled an illegitimate prescription is in violation of the Act;
c. both of the above.

Return this ANSWER SHEET with the $15.00 Program Fee payable to:

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ANSWERS: In re National Prescription Opiate Litigation – A Federal Judge Talks to Us About Responsibility in the Pharmacy

(#0487-0000-20-004-H03; Expires December 9, 2023)

Circle the answer for each question (questions are imbedded in the program).

1.	a	b	c		7.	a	b	c
2.	a	b	c		8.	a	b	
3.	a	b	c		9.	a	b	
4.	a	b	c		10.	a	b	c
5.	a	b	c	d	11.	a	b	
6.	a	b	c	d	12.	a	b	c

13. I am a pharmacist: Yes No
14. I am a pharmacy technician: Yes No
15. After completing this CE activity, I am able to describe who has the duty under the CSA to prevent diversion:
Yes Maybe No
16. After completing this CE activity, I am able to describe who has the duty under Ohio controlled substance laws to prevent diversion:
Yes Maybe No
17. This CE activity filled a learning gap of mine: Yes Maybe No
18. The learning material was useful: Yes Maybe No
19. The teaching and learning methods (e.g., format; questions embedded in the program) fostered active learning and were effective:
Yes Maybe No
20. The test questions were relevant to the goals of the CE activity: Yes No
21. The test questions were at an appropriate level of difficulty: Yes No
22. The CE activity was presented in a fair and unbiased manner: Yes No
23. If you perceived any bias or commercialism, please describe:
_____
24. How long did it take you to complete this CE activity? _____
25. Please tell us about any gaps in your knowledge we can address in our next CE activity:_____