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Achieving Better Care in Pennsylvania by Allowing Pharmacists to Practice Pharmacy

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Achieving Better Care in Pennsylvania by Allowing Pharmacists to Practice Pharmacy

Travis J. Murray*

ABSTRACT

Traditionally, state legislatures implemented Prescription Drug Monitoring Programs (“PDMPs”) to assist prescribers, pharmacists, and law enforcement in identifying patients likely to misuse, abuse, or divert controlled substances. PDMP databases contain a catalog of a patient’s recent controlled substances that pharmacies have filled, including the date, location, the quantity of medication filled, and the prescribing health care provider. Prescribers in Pennsylvania have a duty to query the PDMP before prescribing controlled substances in most clinical settings. Pharmacists have a similar duty in Pennsylvania to dispense safe and effective medication therapy to patients and to screen patients for potential signs of misuse, abuse, or diversion.

However, Pennsylvania’s most recent PDMP laws, The Achieving Better Care by Monitoring All Prescriptions Program Act (“ABC-MAP” Act) and the Safe Emergency Prescribing Act (“SEP” Act), restrict a pharmacist’s access to the PDMP in the hospital’s emergency room. Pharmacists need PDMP access to screen for drug-drug interactions and for potential misuse, abuse, or diversion. Pharmacists’ need for this tool is especially great in light of the current drug epidemic.

As licensed medication experts, pharmacists have the training and expertise to identify patients at risk for chemical dependence and addiction. However, a pharmacist who accesses the PDMP for a patient who has been prescribed a controlled substance without authorization under these laws may face criminal, civil, and administrative liability that could affect his ability to maintain a license and practice pharmacy.

This Comment first explains the unique standard of care that a Pennsylvania pharmacist owes to his or her patients and the

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interprofessional relationship between prescribers and pharmacists. This Comment then will argue that pharmacists, as essential health care providers, require PDMP access to improve patient outcomes, especially in the emergency room setting.

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I. INTRODUCTION

Imagine a young woman afflicted with breast cancer who lives in the Commonwealth of Pennsylvania with her husband and chil-

dren.¹ The oncologist is optimistic about her prognosis with radiation and adjuvant chemotherapy.² The oncologist prescribes her extended-release morphine to ameliorate the pain associated with treatment. Unbeknownst to her husband, the young woman also sees a psychiatrist who prescribes her alprazolam three times daily as needed for anxiety associated with the existential stress of her cancer. The young woman also develops a cough, possibly from a chemotherapy-induced weakened immune system, and receives a prescription for guaifenesin and hydrocodone from an urgent care physician. The next day, her husband finds her unconscious, and an ambulance rushes her to the emergency room. The young woman cannot void to produce a urine drug screen, and she does not adequately respond to naloxone, the reversal agent for opioids. She slips into a medically induced coma before dying. The combination of morphine, alprazolam, and hydrocodone is a lethal cocktail with black-boxed warnings from the United States Food and Drug Administration (FDA) that any reasonable pharmacist would be able to identify and alert to her prescribers.³ The young woman may have survived had she received flumazenil, the reversal agent for alprazolam, in combination with naloxone.⁴

Had the young woman's pharmacist been able to access the Prescription Drug Monitoring Program ("PDMP"), a database which is capable of providing a history of controlled substances filled by pharmacies, the system may have alerted pharmacists and prescribers that she was experiencing this life-threatening drug interaction.⁵ However, Pennsylvania state law restricts pharmacists from accessing this database in certain settings, such as emergency

1. This Comment uses a fictional scenario to demonstrate how the law that governs Pennsylvania prescribing and dispensing laws in emergency rooms between June 30, 2015, and November 10, 2020, could apply in a factual situation.

2. See *Adjuvant Therapy*, NATIONAL CANCER INST. DICTIONARY OF CANCER TERMS, <https://bit.ly/2J1Fbo7> [<https://perma.cc/K2RV-MAP7>] (last visited Dec. 4., 2020) (defining "adjuvant therapy").

3. See Press Release, FDA Requires Strong Warnings for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepine Labeling Related to Serious Risk and Death from Combined Use, U.S. Food & Drug Admin. (Aug. 31, 2016), <https://bit.ly/2SfFpun> [<https://perma.cc/EHT6-P4K4>] (warning against the combination of benzodiazepines and opioids due to the increased risk of central nervous system depression and toxicity).

4. See Genentech, Romazicon® Prescribing Information, lines 250–54 <https://bit.ly/2pYQww2> [<https://perma.cc/JLM4-3BGK>] (last revised Apr. 2010) (explaining that flumazenil is indicated for the management of benzodiazepine overdose).

5. See Achieving Better Care by Monitoring All Prescriptions Program Act, 35 PA. STAT. AND CONS. STAT. § 872.2 (West 2015).

rooms, inpatient hospital admissions, and certain community pharmacy situations.⁶

The PDMP is a powerful resource for health care professionals. To understand why the PDMP is so powerful, it is important to contextualize the interdisciplinary process of verifying and dispensing prescriptions. This, in turn, requires an overview of the pharmacist's role in modern American health care. Part II will provide the background of the pharmacy profession, from ancient history to modern-day American pharmacy science and practice.⁷ Part II will also discuss the regulation of pharmacists, particularly in Pennsylvania, under federal and state law as well as under Pennsylvania's Board of Pharmacy.⁸ The next section of Part II will discuss the regulation of pharmaceuticals in the United States, including opioids and other controlled substances.⁹ This section will also provide an overview of prescribing and dispensing guidelines for controlled substances in light of the current opioid epidemic.¹⁰ The final section of Part II will cover the special duty of care that pharmacists owe to patients and, subsequently, how pharmacists can protect themselves from professional malpractice in Pennsylvania.¹¹ Specifically, this section will introduce the conflicts that arise between a traditional pharmacist's duty of care and how this duty is modified under key pieces of Pennsylvania legislation, the Achieving Better Care by Monitoring All Prescriptions Act ("ABC-MAP Act") and the Safe Emergency Prescribing Act ("SEP Act").¹² Part III will analyze how the ABC-MAP Act and the SEP Act have placed Pennsylvania pharmacists in a position that makes it difficult for them to faithfully execute their duty of care to patients without violating the law.¹³ These laws appear to directly conflict with clinical practice guidelines, the formal training

6. See 35 PA. STAT. AND CONS. STAT. § 873.5 (West 2017) (requiring prescribers query the PDMP to determine if a patient is being treated with an opioid drug product by another prescriber, except in emergency room treatment, even if the pharmacist has not queried the system). See also Act of Nov. 2, 2016, 2016 Pa. Laws 124 (amending Achieving Better Care by Monitoring All Prescriptions Program Act, 2014 Pa. Laws 191 (permitting a prescriber to not query the PDMP if a patient is admitted to the hospital or remains in observation status)).

7. See *infra* Part II.A.

8. See *infra* Part II.B.

9. See *infra* Part II.B.

10. See *infra* Part II.B.

11. See *infra* Part II.D.

12. See *infra* Part II.D.

13. See *infra* Part III.

and education of pharmacists, and the oath of the pharmacy profession.¹⁴

II. BACKGROUND

A. *Historical Background of the Pharmacy Profession*

1. *Ancient World to the Middle Ages*

Modern-day pharmacists rank as one of the most trusted groups of professionals.¹⁵ While the roots of the science and practice of American pharmacy directly descended from European apothecaries, the profession is one that was present in virtually every civilization throughout history.¹⁶ Ancient apothecaries appear to have existed in antiquity, as recorded history identifies early pharmacist-like persons in Babylon and China's Yellow River Valley civilizations who used herbal extracts to treat common maladies in 2600 and 2000 B.C., respectively.¹⁷ Ancient Egyptian apothecaries recorded prescriptions and detailed compounding methods in *Ebers Papyrus*, a collection of hundreds of prescriptions and formulas from plants and substances from 1500 B.C.¹⁸ The Greek pharmacologist Dioscorides wrote the first substantive pharmacopeia, which spread throughout Europe, the Middle East, and North Africa and which apothecaries used for over one thousand years.¹⁹ As knowledge spread, apothecaries developed guilds across Europe to train future apothecaries to compound and expand the known pharmacopeia.²⁰ The first semblances of pharmacies appeared on the Arabian and Italian peninsulas during the late-Middle Ages and the Islamic Golden Age, respectively, as apothecaries began incor-

14. See *infra* Part III.

15. See *Honesty/Ethics in Professions*, GALLUP, <https://bit.ly/34MSxKn> [<https://perma.cc/X898-SHTC>] (last visited Dec. 4, 2020) (determining that 64 percent of respondents rated the honesty and ethical standards of pharmacists as “very high” or “high”).

16. See generally George B. Griffenhagen, *Great Moments in Pharmacy: Development of Robert Thom Series Depicting Pharmacy's History*, 42 J. AM. PHARM. ASSOC. 170 (2002) (describing the evolution of pharmacists across civilizations and millennia).

17. GEORGE A. BENDER, A HISTORY OF PHARMACY IN PICTURES 5 (1965).

18. ANCIENT EGYPTIAN MEDICINE: THE PAPYRUS EBERS (Cyril P. Bryan trans. 1930).

19. *Dioscorides: Early Pharmacology*, NATIONAL INSTITUTES OF HEALTH, <https://bit.ly/34hSgPv> [<https://perma.cc/F738-SGAC>] (last visited Dec. 4, 2020). See also KEVIN M. G. TAYLOR & GEOFFREY HARDING, PHARMACY PRACTICE 4-5 (2016); *pharmacopoeia*, MERRIAM-WEBSTER, <https://bit.ly/2EKQVpE> [<https://perma.cc/C7RC-V6M8>] (last visited Dec. 4, 2020) (defining a pharmacopoeia as “a book describing drugs, chemicals, and medicinal preparations”).

20. *Apothecaries*, SCIENCE MUSEUM, <https://bit.ly/2pvoO9Z> [<https://perma.cc/WL6U-EA2M>] (last visited Dec. 4, 2020).

porating pharmacology and toxicology to understand the physiological effects of herbs and substances.²¹

2. Renaissance and the Age of Enlightenment

Medicine and apothecary split into two distinct professions in 1240 A.D. in Sicily—a distinction that spread throughout Europe and continues to this day.²² In Florence, the Guild of Apothecaries produced an updated official pharmacopeia, *Nuovo Receptario*, which became widely adopted in Western Europe.²³ By the 1600s, London apothecaries formed the Society of Apothecaries, which aimed to train pharmacists to be skilled medication experts and to be directly involved with contemporaneous advances in chemistry, the new frontier for drug synthesis and discovery.²⁴ This method of training carried across the Atlantic and was the norm for training pharmacists until the mid-1800s.²⁵

3. Modern American Pharmacist

The year 1821 marked the beginning of American pharmacological education when the Philadelphia College of Pharmacy became the first American academic institute to train pharmacists in chemistry and biology.²⁶ The Accreditation Council for Pharmacy Education (“ACPE”) began to accredit pharmacy schools, and the individual state boards of pharmacy began to require graduation from these ACPE-accredited schools to receive a pharmacist license.²⁷ Today, pharmacy students must learn evidence-based pharmacotherapeutics, pharmacology, and pharmaceuticals and engage in extensive experiential training in homage to the early

21. David W. Tschanz, *The Islamic Roots of Modern Pharmacy*, ARAMCO WORLD, May/June 2016, 19–23.

22. HASTINGS RASHDALL, *THE UNIVERSITIES OF EUROPE IN THE MIDDLE AGES* 85 (1895); James J. Walsh, *The Earliest Modern Law for the Regulation of the Practice of Medicine*, BULL. N.Y. ACAD. MED. 523–24 (1935). This distinction, as will be discussed *infra* Part II.C., is an important one since the roles that physicians—the practice of medication—and pharmacists—the practice of pharmacy—play in treating patients and the medication use process are consequential in both professions needing PDMP access.

23. KEVIN M. G. TAYLOR & GEOFFREY HARDING, *PHARMACY PRACTICE* 6 (2016).

24. *Id.* at 7–8.

25. *Id.*

26. Krantz & Hartley, *Pharmacy*, BRITANNICA, <https://bit.ly/2WqmvAW> [<https://perma.cc/VJB4-WG79>] (last visited Dec. 4, 2020); *Our History*, UNIVERSITY OF THE SCIENCES, <https://bit.ly/2JB191j> [<https://perma.cc/845Q-VL9F>] (last visited Dec. 4, 2020).

27. *Our History*, ACCREDITATION COUNCIL FOR PHARMACY EDUC., <https://bit.ly/2qIYWb6> [<https://perma.cc/9P75-BNP2>] (last visited Dec. 4, 2020).

American and English apothecary apprenticeship systems.²⁸ The National Association of Boards of Pharmacy (“NABP”) offers two exams that pharmacy school graduates must pass to practice in most states: the North American Pharmacist Licensure Examination® (“NAPLEX®”) and the Multistate Pharmacy Jurisprudence Examination® (“MPJE®”).²⁹ This combination of intense experiential and didactic training allows pharmacists to provide competent care.³⁰

With all of the trust and confidence that society has placed in pharmacists, and the severity of the risks inherent to pharmaceuticals, pharmacists owe a duty of care to patients, which requires them to rely on as much information as possible to make the best clinical decisions when dispensing and compounding medications.³¹ Pharmacists have been integral in the development of medicinal botany, pharmacology, toxicology, and chemistry for millennia, which have advanced society and public health.³² For the profession to survive and provide competent patient care, pharmacists must continue to show the same compassion and expertise that the world has relied upon, and they must have access to every resource possible to effectively serve patients.³³ However, as this Comment will explain, certain laws and regulations obstruct the pharmacist’s ability to provide safe, effective, and trustworthy care to combat one of America’s gravest public health emergencies—the opioid epidemic. In order to understand these laws, it is important to discuss the regulation of pharmacists and pharmaceuticals as well as the extent of the current epidemic.

28. ACCREDITATION COUNCIL FOR PHARMACY EDUC., ACCREDITATION STANDARDS AND KEY ELEMENTS FOR THE PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR OF PHARMACY DEGREE 5–9 (2015), <https://bit.ly/2Q8GXFp> [<https://perma.cc/X9YC-XVC7>] [hereinafter Accreditation Standards].

29. *Id.* at preamble; *MPJE*, NATL. ASS’N BDS. PHARMACY, <https://bit.ly/2qEGm3L> [<https://perma.cc/QKC6-6MKH>] (last visited Dec. 4, 2020) (requiring a pharmacist to demonstrate competency in pharmaceutical indications, interactions, and calculations, as well as knowledge of the laws and regulations governing pharmacy practice, respectively).

30. Accreditation Standards, *supra* note 28, at Preamble.

31. *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1251 (Pa. Super. 1986); 49 PA. CODE § 27.18 (2019).

32. *See generally* Griffenhagen, *supra* note 16 (indicating the role of apothecaries in identifying plants and substances that could be used and compounded to treat ailments or reverse symptoms, synthesizing pharmaceuticals using chemistry, and becoming trusted medication and supplement experts across civilizations).

33. *See* Kristy Malacos, *PDMPs Can Help Curb the Opioid Epidemic*, PHARMACY TIMES (Nov. 20, 2019), <https://bit.ly/2sVhfum> [<https://perma.cc/H2TG-CLQ2>].

B. Regulation of Pharmaceuticals, Controlled Substances, and the Practice of Pharmacy

1. Federal and State Law

Generally, federal law regulates pharmaceuticals, and the states regulate the practice of pharmacy. The United States first regulated pharmaceuticals under the Pure Food and Drug Act (“PFDA”)³⁴ and the Food, Drug, and Cosmetic Act (“FDCA”),³⁵ which created the FDA.³⁶ A pharmacist or practitioner can dispense a medication that is designated as “prescription only.”³⁷ Apart from prescription and non-prescription medications, prescription medications can be further classified by their abuse potential using the scheduling system that the Controlled Substances Act created.³⁸ Schedule I through V designations indicate medications with potential for abuse, with Schedule I being substances that serve no “currently accepted medical use,” have a “high abuse potential,” and cannot be legally dispensed by a pharmacist.³⁹ Schedule I includes heroin and methamphetamine.⁴⁰ Schedule II encompasses medications with “accepted medical uses[] but high abuse potential leading to psychological or physical dependence” and includes most opioids such as oxycodone, fentanyl, and morphine.⁴¹ Further down the schedule list is Schedule IV, which includes benzodiazepines, such as Xanax®, Klonopin®, and Ativan®.⁴² A medication’s schedule limits the number of refills and day supply of medication that a pharmacist may dispense.⁴³ State laws

34. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768.

35. Fed. Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

36. *Milestones in U.S. Food and Drug Law History*, U.S. FOOD & DRUG ADMIN., <https://bit.ly/2Nvgfnz> [<https://perma.cc/3U79-SXSD>] (last visited Dec. 4, 2020) (regulating drugs to prevent adulteration and misbranding first appeared in the PFDA and requiring drugs to demonstrate safety before being approved by the FDA occurred in the FDCA).

37. 35 PA. STAT. AND CONS. STAT. § 780-113(a)(10) (West 2019).

38. *See* Controlled Substances Act, 21 U.S.C. § 812 (2019) (defining the federal schedule of controlled substances).

39. Schedule I Controlled Substances, 21 C.F.R. § 1308.11 (2019).

40. *Id.*

41. Schedule II Controlled Substances, 21 C.F.R. § 1308.12 (2019).

42. Schedule IV Controlled Substances, 21 C.F.R. § 1308.14 (2019).

43. U.S. DRUG ENF’T AGENCY, PHARMACIST’S MANUAL 62–70 (2020), <https://bit.ly/3kAt27G> [<https://perma.cc/JTL9-9NRV>].

can place heightened prescribing and dispensing requirements⁴⁴ as well as re-classify a medication's schedule.⁴⁵

2. *Duty of a Pennsylvania Pharmacist*

In Pennsylvania, pharmacists perform their duties in compliance with statutory law, the Board of Pharmacy regulations, common law, evidence-based education and clinical practice guidelines, and the oath of a pharmacist.

a. Pennsylvania State Law and Administrative Law

In Pennsylvania, the Pennsylvania Pharmacy Act regulates pharmacists.⁴⁶ This Act created the Board of Pharmacy, which is responsible for licensing Pennsylvania's pharmacists, overseeing disciplinary actions against them, and promulgating regulations to which they must adhere.⁴⁷ The Board can conduct its own hearings and proceedings, and can sanction pharmacists.⁴⁸ Examples of sanctions include suspension, probation, and revocation of a pharmacist's license.⁴⁹ The Board may revoke or suspend a pharmacist's license for incompetence, malpractice, or "the departure from, or failure to conform to, the standards of acceptable and prevailing pharmacy practice," even in the absence of an actual injury occurring.⁵⁰ Regarding the duty of a pharmacist,

A pharmacist may not knowingly fill or refill a prescription for a controlled substance or nonproprietary drug of device if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription was written, or will be otherwise diverted, abused, or misused. In addition, a pharmacist may decline to fill or refill a prescription if, in the pharmacist's professional judgment exercised in the interest of the safety of the patient, the pharmacist believes the prescription should not be filled or refilled.⁵¹

44. *See, e.g.*, 49 PA. CODE. § 27.18 (2019) (including stricter requirements for pharmacists dispensing opioids than those required by the Federal Controlled Substances Act, 21 U.S.C. §§ 801–904 (2020) and the Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471–76 (2020)).

45. *See, e.g.*, 35 PA. STAT. AND CONS. STAT. § 780-104 (West 2019); 49 PA. CODE § 27.18 (2019).

46. Pennsylvania Pharmacy Act, 63 PA. STAT. AND CONS. STAT. § 390 (West 2019).

47. *Id.*

48. *Id.* §§ 390-5 to 390-7.

49. *Id.*

50. *Id.* § 390-5(a)(12).

51. 49 PA. CODE § 27.18 (West 2020).

This standard seemingly gives latitude to a pharmacist when deciding to fill a prescription, but similar to the practice of medicine, the pharmacy profession is subject to standards of practice within the profession and clinical practice guidelines.⁵² “The purpose of the Pharmacy Act was to ‘regulate . . . preparing drugs, and dispensing them’” and to prioritize protecting the health and safety of the public.⁵³ The Pennsylvania General Assembly created the Board of Pharmacy, composed of licensed pharmacists, to better regulate the profession and to stay connected with standards and challenges in current practice.⁵⁴

b. Clinical Practice Guidelines and Oath

A pharmacist cannot knowingly fill a prescription if he or she knows or has reason to know another person will use the medication or that the person will divert, misuse, or abuse the medication.⁵⁵ The pharmacist has the burden not only to determine if the prescription will likely be safe and effective for the patient but also to discern the legitimacy of the prescription.⁵⁶ A prescription is facially valid if it complies with the elements of a Pennsylvania prescription and is without signs of forgery and adulteration.⁵⁷ A major concern for pharmacists is a practice known as “doctor-shopping,” which involves a physician writing a prescription for a patient, unaware that the patient is receiving the same or similar medication from another doctor.⁵⁸ Doctor-shopping can be a form of diversion, misuse, and abuse, resulting in duplication of therapy, a known drug-drug interaction that trained pharmacists know how to avoid.⁵⁹ However, determining whether the patient aims to use the prescription for its intended legitimate purpose can be an ardu-

52. 63 PA. STAT. AND CONS. STAT. § 390-5(a)(12) (West 2019).

53. *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1251 (Pa. Super. 1986).

54. 63 PA. STAT. AND CONS. STAT. § 390 (2019).

55. 49 PA. CODE § 27.18 (2019).

56. *Id.* § 27.18(c); *Gabriel v. Giant Eagle, Inc.*, 124 F. Supp. 3d 550, 564 (W.D. Pa. 2015).

57. 49 PA. CODE §§ 27.18(b)(1)–(2), (5) (2019) (describing that prescription label requirements for controlled substances include: name, address, telephone number and DEA number of pharmacy, name of the patient, full directions, name of the prescriber, serial number of prescription and date of original fill, trade or brand name of the drug, drug strength, dosage form, and quantity dispensed); *Gabriel* at 563 (quoting *Forish v. Paul*, 2 Pa. D. & C.4th 413, 416–17 (C.P. 1989)).

58. Randy A. Sansone & Lori A. Sansone, *Doctor Shopping: A Phenomenon of Many Themes*, 9 INNOV. CLIN. NEUROSCI. 41, 41–42 (2012).

59. 49 PA. CODE § 27.18(c), 27.19(a)–(c), (f) (2019) (describing a drug-drug interaction is when two or more drugs react with each other to cause a side effect).

ous task.⁶⁰ To use examples, a prescription is diverted if it is sold to another person, misused if the person takes it more frequently or crushes a tablet instead of swallowing it whole, or abused if it is used in furtherance of chemical dependence or addictive behavior.⁶¹

Additionally, a licensed pharmacist can use “professional judgment” when determining whether to fill a prescription.⁶² A pharmacist can also use professional judgment to deny a prescription or hospital physician order from being dispensed so long as the denial is “in the safety of interest of the patient.”⁶³ This judgment comes from academic training, professional standards issued by evidence-based medicine and clinical practice guidelines, and the principles from the oath of a pharmacist.⁶⁴ Pennsylvania’s legislature, like most state legislatures, is hesitant to legislate the practices of medicine and pharmacy. Instead, the Pennsylvania legislature defers to professional guidelines and the state licensing boards.⁶⁵

Various medical groups and associations publish the aforementioned clinical practice guidelines. While these groups normally publish their own guidelines, professional associations such as the International Association for the Study of Pain recognize The United States Centers for Disease Control and Prevention’s (CDC) recommendations as the current standard of practice for the use of opioids in severe non-cancer pain.⁶⁶ In addition, Pennsylvania’s

60. Purpose of Issue of Prescription, 21 C.F.R. 1306.04 (2020); 35 PA. CONS. STAT. § 780-113(15) (West 2020).

61. Shannon M. Smith et al., *Classification and Definition of Misuse, Abuse, and Related Events in Clinical Trials: ACTION Systemic Review and Recommendations*, 152 PAIN 2287–96, Tables 1–2, 5 (2013).

62. 49 PA. CODE § 27.18(c) (2019).

63. *Id.*

64. 63 PA. CONS. STAT. § 390-3 (2019); *Oath of A Pharmacist*, AMERICAN PHARMACISTS ASS’N, <https://bit.ly/33Iga6X> [<https://perma.cc/NPT5-Q99Z>] (last visited Dec. 4, 2020) (including vows to “apply knowledge, experience, and skills to the best of [one’s] ability to assure optimal outcomes for . . . patients [and to] respect and protect all personal and health information”) [hereinafter Oath].

65. See 2016 PA. LEGIS. J. HOUSE 1447 (June 23, 2016) for a speech by Representative Pamela A. DeLissio of the Pennsylvania General Assembly (stating “[i]t is well documented that opioid drug abuse is in Pennsylvania and affects all of our citizens. However, whenever the legislature attempts to legislate how licensed health-care providers practice . . . I think that is a very dangerous precedent . . . I would not want to be personally in that emergency room or have my constituents in that emergency room with a health-care provider having to say, ‘Gee, I wish I could do this, but the Pennsylvania State Legislature passed this bill and tied my hands.’”); *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1253 (Pa. Super. 1986) (determining that it is not the Court’s task “to delineate the precise bounds of a medical professional’s responsibilities”).

66. See generally CTRS. FOR DISEASE CONTROL & PREVENTION, CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN (2016); 65 MORBIDITY &

Department of Health has its own recommendations for prescribing opioids for non-cancer pain, dispensing opioids, and prescribing benzodiazepines for acute anxiety and insomnia.⁶⁷ A pharmacist's failure to adhere to the CDC and Pennsylvania's dispensing recommendations may constitute a breach of a pharmacist's duty and lead to civil and administrative liability.⁶⁸

c. Common Law

Civil liability can arise in malpractice actions. In Pennsylvania, to establish a *prima facie* case of professional malpractice, the injured party must show the existence of a duty, a breach of that duty, cause-in-fact, proximate cause, and actual harm.⁶⁹ A pharmacist breaches his duty for a "failure to correct improper dosage directions; failure to check on illegible prescriptions; and failure to notice a potentially lethal interaction between drugs on the face of a prescription."⁷⁰ The standard of care is that of a "reasonably prudent pharmacist," and a pharmacist must carry out his duties with the degree of skill and care expected of the pharmaceutical profession as a whole.⁷¹ This duty has become muddled under Pennsylvania's ABC-MAP Act and the SEP Act, which Section D of Part II will discuss.⁷²

MORTALITY WEEKLY REPORTS: RECOMMENDATIONS AND REPORTS 1, 1–50 (2016) (describing the recommendations from the CDC for prescribing and dispensing opioids to patients with pain safely to mitigate abuse, misuse, and diversion); *Development of Clinical Practice Guidelines in the Field of Pain*, INT'L ASS'N FOR STUDY OF PAIN, <https://bit.ly/32CexpR> [<https://perma.cc/AQB4-XPPJ>] (last visited Dec. 4, 2020).

67. See generally *Prescribing Guidelines for Pennsylvania: Opioid Dispensing Guidelines*, PA. DEPT. HEALTH 1, 1–11 (Jan. 14, 2016), <https://bit.ly/36nPYA4> [<https://perma.cc/9HD3-KG5M>] (reaffirming many of the general recommendations from the CDC explaining state-specific requirements for prescribing and dispensing opioids, such as utilizing the PDMP, screening patients for risk of opioid misuse or diversion and referring at-risk patients to specific treatment options or alternative pain therapies); see also *Prescribing Guidelines for Pennsylvania: Non-Cancer Pain Guidelines*, PA. DEPT. HEALTH 1, 1–11 (June 11, 2018), <https://bit.ly/36mLcmx> [<https://perma.cc/RW5B-WFG9>]; see also *Prescribing Guidelines for Pennsylvania: Safe Prescribing Benzodiazepines for Acute Treatment of Anxiety & Insomnia*, PA. DEPT. HEALTH 1, 1–5 (May 15, 2017), <https://bit.ly/34jwIIC> [<https://perma.cc/D6B9-VAAJ>].

68. 63 PA. CONS. STAT. § 390 5(a)(12) (West 2020).

69. See *Riff*, 508 A.2d at 1251.

70. *Id.*

71. *Id.* at 1250; *Forish v. Paul*, 2 Pa. D. & C.4th 413, 416–17 (C.P. 1989).

72. 2014 Pa. Laws 191; 2016 Pa. Laws 122.

C. *Narcotics, the Opioid Epidemic, and the Medication-Use Process*

In 2018, Pennsylvania experienced 4,491 drug-related overdose deaths, which is a 36 percent increase from 2015 to 2018.⁷³ The vast majority of these overdoses are related to opioids and benzodiazepines.⁷⁴ The term “opioids” refers to the general class of substances that are chemically related to opium and act on the mu-opioid receptor in the body to produce an analgesic effect.⁷⁵ The term “opiates” generally refers to naturally occurring opioids that come from the poppy plant; whereas, newer opioids are synthetically created and tend to be more potent.⁷⁶ While opioids are excellent for controlling moderate-to-severe chronic pain, severe acute pain, and cancer-related pain, they come at a cost.⁷⁷ In addition to the analgesic effects, opioids can cause euphoric effects that can lead to misuse, chemical dependence, and addiction, which are recognized as substance use disorders according to the Fifth Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V).⁷⁸ Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them, 4 to 6 percent of those who misuse opioid prescriptions transition to heroin, and about 80 percent of people who use heroin first misused prescription opioids.⁷⁹

73. DRUG ENF’T AGENCY INTEL. PROGRAM—PHILA. FIELD DIV., DRUG-RELATED OVERDOSE DEATHS IN PA., 2018 1, 3 (2018), <https://bit.ly/36qJxjf> [<https://perma.cc/598X-MCSP>].

74. *Id.* at 2 (citing 82 percent of overdose deaths were associated with prescription and illicit opioids and 28 percent were associated with benzodiazepines).

75. Act of Nov. 2, 2016, 2016 Pa. Laws 124; 35 PA. STAT. AND CONS. STAT. § 780-112 (West 2019); Hasan Pathan & John Williams, Basic Opioid Pharmacology: An Update, 6 BR J. PAIN 11, 12–16 (2012) (explaining that an opioid is defined as a chemical that binds to the mu-opioid receptor in humans, resulting in pain relief).

76. See *Prescribing Guidelines for Pennsylvania: Opioid Dispensing Guidelines*, PA. DEPT. HEALTH 6 (Jan. 14, 2016), <https://bit.ly/36nPYA4> [<https://perma.cc/427M-7DES>] (describing how synthetic opioid fentanyl administered intravenously is roughly one hundred times more potent than the natural opioid morphine in intravenous form).

77. See generally CTRS. FOR DISEASE CONTROL & PREVENTION, CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN (2016) (describing the risks of long durations of use or large doses of opioids for mild or non-chronic pain); 65 MORBIDITY & MORTALITY WEEKLY REPORTS: RECOMMENDATIONS AND REPORTS 1, 1–50 (2016) (highlighting the need to use opioids sparingly and appropriately for the controlling pain and to be aware of certain behaviors that may indicate substance use disorder or diversion).

78. AMERICAN PSYCHIATRIC ASS’N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 541–46 (5th ed. 2013).

79. See Kevin E. Vowles et al., *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis*, 156 PAIN 569, 569–70 (2015). See also Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever*

In addition to addiction and death, opioids have many drug-drug interactions, and opioid use disorder can lead to other health and social complications, such as Human Immunodeficiency Virus (HIV) and hepatitis C infections, bacteremia, endocarditis and homelessness.⁸⁰ The analgesic, euphoric, and toxic results from opium and opium-derivatives are documented across history and civilizations and may even predate the pharmacy practice.⁸¹

Benzodiazepines are another cause of drug-related overdose and have a life-threatening drug-drug interaction with opioids that can lead to respiratory depression and death.⁸² Pennsylvania defines a benzodiazepine as “a psychoactive drug . . . [that] works on the central nervous system, acting selectively on gamma-aminobutyric acid type A (GABA(A)) receptors in the brain.”⁸³ Benzodiazepines are used to treat generalized anxiety disorder, among other indications.⁸⁴ Pharmacists often dispense both opioids and benzodiazepines, so screening a patient’s medication profile for proper use is an essential component of the medication-use process.⁸⁵

The medication-use process is the life cycle of a medication from a prescriber’s prescription to consumption by the patient.⁸⁶ The process begins when a prescriber writes a prescription for a patient for a legitimate medical purpose.⁸⁷ If the prescription is for

Use and Initiation of Heroin Use in the United States, CBHSQ DATA REV. (August 2013); Robert G. Carlson et al., *Predictors of Transition to Heroin Use Among Initially Non-opioid Dependent Illicit Pharmaceutical Opioid Users: A Natural History Study*, 160 *DRUG ALCOHOL DEPENDENCE* 127, 127 (2016).

80. *Infectious Disease, Opioids and Injection Drug Use*, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://bit.ly/2NA50Ae> [<https://perma.cc/Q3AZ-67KX>] (last visited Dec. 4, 2020); *Homeless and Housing Services Providers Confront Opioid Overdose*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://bit.ly/2qKHjaw> [<https://perma.cc/JN92-ZMXX>] (last visited Dec. 4, 2020).

81. LUCY INGLIS, *MILK OF PARADISE: A HISTORY OF OPIUM* 14–16 (2018).

82. U.S. FOOD & DRUG ADMIN., FDA News Release: FDA Requires Strong Warnings for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepine Labeling Related to Serious Risk and Death from Combined Use (Aug. 31, 2016), <https://bit.ly/38dlKQ5> [<https://perma.cc/AX9T-N3G4>].

83. Act of Nov. 2, 2016, 2016 Pa. Laws 124.

84. PHARMACIA & UPJOHN CO., XANAX® PRESCRIBING INFORMATION 4–5 (2016), <https://bit.ly/3jAj4S8> [<https://perma.cc/RM3T-Q5Z9>].

85. See F. Randy Vogenberg & David Benjamin, *The Medication-Use Process and the Importance of Mastering Fundamentals*, 36 *P&T* 651, 652 (2011).

86. See *id.* (describing the medication-use process as a “multistep process in which a drug travels from the pharmacy to the patient [that] consists of (1) prescribing, (2) transcribing and documenting, (3) dispensing, (4) administering, and (5) monitoring”).

87. 49 PA. CODE § 16.92(b)(8) (West 2020) (stating that the prescriber must follow the standards of practice in addition for prescribing a medication and properly document the indication for the medication in the patient’s medical record).

a controlled substance, the prescriber must also check the PDMP to screen for abuse, misuse, or diversion.⁸⁸ A pharmacist receives the prescription and determines whether the prescription is valid and contains all necessary components on its face.⁸⁹ A pharmacist then uses his professional judgment to determine if the medication will likely be safe and effective for the patient.⁹⁰ Pharmacists often do this by conducting a drug-drug interaction and allergy check on a patient's prescription profile.⁹¹ At any step, the pharmacist must alert the prescriber to any issues that would prohibit the pharmacist from dispensing the medication, either due to the law or a pharmacist's professional judgment.⁹²

The pharmacist, as indicated earlier, also has a duty to determine if the prescription is likely to be diverted, misused, or abused. This is the point at which a pharmacist would query and enter information into the PDMP.⁹³ However, how and when the PDMP is used depends on the pharmacy setting. In a community pharmacy, the pharmacist or designee⁹⁴ must check the PDMP and comply with state law when determining whether to fill or refill a controlled substance.⁹⁵ In a hospital, when the patient is in observation status, the pharmacist may access the PDMP; but when the patient is in inpatient status, the pharmacist may not access the PDMP.⁹⁶ This disparity in patient status means that there is only one check by the physician before a patient receives a controlled substance. The situ-

88. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191 § 5(viii)(A).

89. For a list of necessary components, see 49 PA. CODE § 27.18 (West 2020).

90. *Id.* § 27.18(m).

91. See *The Pharmacist's Role in Medication Safety*, AGENCY FOR HEALTH-CARE RSCH. & QUALITY, <https://bit.ly/2ZdxUT> [<https://perma.cc/UE2R-RR8E>] (last updated Sept. 7, 2019) (stating the correct medication use involves screening a patient's age, medical condition, physiologic status, and allergies to determine if a prescription is appropriate to dispense).

92. See 49 PA. CODE § 27.18 (stating "if necessary the pharmacist shall attempt to discuss the decision with the prescriber"); see also *Riff v. Morgan Pharmacy*, 508 A.2d 1247, 1251–52 (Pa. Super. 1986) (determining that a pharmacist is a professional and has a legal duty to exercise due care and diligence in the performance of its professional duties and qualifying a pharmacy as "no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and *unquestioningly* obey the written orders of omniscient physicians" as a disregard for a pharmacist's professional duty).

93. See Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191; 49 PA. CODE § 27.18(c).

94. See 2014 Pa. Laws 191 (permitting a pharmacist to appoint a designee, such as a pharmacy technician or pharmacy intern, to query the system on his behalf).

95. *Id.*

96. Act of Nov. 2, 2016, 2016 Pa. Laws 124.

ation is worse in the emergency room when a pharmacist may not access the PDMP and only the prescriber may do so.⁹⁷

D. *The ABC-MAP Act and the SEP Act*

1. *History and Impact of Pennsylvania's PDMP*

A PDMP is a state-specific program used to monitor controlled substance prescriptions and the dispensing of controlled substances.⁹⁸ The Pennsylvania Department of Health administers Pennsylvania's PDMP.⁹⁹ The General Assembly created Pennsylvania's first PDMP in 1972 to collect data on PDMP usage and required pharmacies to send reports to Pennsylvania's Office of Attorney General.¹⁰⁰ The law was limited in scope because the PDMP monitored only Schedule II prescription usage, and pharmacists and physicians could not access the data within the system.¹⁰¹ Additionally, the reports were paper, and they were submitted only monthly, which prohibited any practicable usage of the system by a pharmacist—if he even had access.¹⁰² The Pennsylvania legislature dramatically updated Pennsylvania's PDMP law in 2014 with the passage of the ABC-MAP Act, which modernized Pennsylvania's PDMP by getting the PDMP up to speed with the digital age by making the PDMP accessible online, including pharmacists and prescribers in curbing the opioid epidemic by granting them access to the database¹⁰³ and allowing states to be eligible for federal grants by sharing the data with federal law enforcement.¹⁰⁴

Despite PDMPs' presence in 49 states and implementation in Pennsylvania for decades,¹⁰⁵ the public has scrutinized PDMPs for two reasons: violations of privacy and due process.¹⁰⁶ Pennsylvania, like most states, requires pharmacists to transmit data to the state with personally identifiable information regarding con-

97. 2016 Pa. Laws 122 § 5 (requiring only a health care practitioner, not a dispenser, to query the system in the emergency room department to determine if the patient is receiving an opioid from another practitioner).

98. See Lynn S. Mirigian et al., *The Pennsylvania Prescription Drug Monitoring Program*, 20 *Commonwealth* 138 (2018).

99. See Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191 § 4(a).

100. See Mirigian, *supra* note 98, at 139.

101. See *id.*

102. See *id.*

103. 2014 Pa. Laws 191 § 2.

104. 42 U.S.C. § 290ee-3 (2020) (offering federal grants to states to implement PDMPs).

105. See Mirigian, *supra* note 98, at 139.

106. See Reem Blaik, *Prescriptions at A Price: America's Opioid Crisis and the Increasing Toll on Drug Record Privacy*, 21 *VAND. J. ENT. & TECH. L.* 277, 306–08 (2018).

trolled substances that pharmacists have dispensed to a patient.¹⁰⁷ Typically, only the pharmacist, physician, patient, law enforcement, and payer would have this type of information.¹⁰⁸

Even in light of these concerns, PDMPs have largely remained intact, including third-party access to prescription information.¹⁰⁹ While PDMPs are not expressly included in the Health Insurance Portability and Accountability Act (HIPAA), those who access the information are subject to HIPAA.¹¹⁰ Prescribers and pharmacists have a duty and an incentive to protect their license to use the PDMP for only patient care and not in violations of privacy or security rules of HIPAA.¹¹¹

2. *ABC-MAP Act*

The ABC-MAP Act has three purposes, as articulated in Section 1 of the Act.¹¹² The first purpose was to “increase quality of patient care by giving . . . dispensers access to a patient’s prescription medication history through an electronic system that will alert medical professionals to potential dangers for purposes of making treatment determinations.”¹¹³ This first purpose is explicitly directed at pharmacists. The second purpose is to help patients “have a thorough and easily obtainable record of their prescriptions for purposes of making educated and thoughtful health care decisions.”¹¹⁴ This explicitly references a patient’s rights under the PDMP program. The third purpose is to “[a]id regulatory and law enforcement agencies in the detection and prevention of fraud, drug abuse and in the criminal diversion of controlled sub-

107. 2014 Pa. Laws 191 § 7.

108. *See Covered Entities and Business Associates*, U.S. DEPT. HEALTH & HUM. SERVS. (last updated June 16, 2017), <https://bit.ly/2SiLBIt> [<https://perma.cc/TAN4-PQ3J>].

109. *See generally Oregon Prescription Drug Monitoring Program v. U.S. DEA*, 860 F.3d 1228 (9th Cir. 2017) (permitting a PDMP administered by the Oregon Department of Health to transmit data to the DEA. Proponents of health privacy have argued that sharing opioid prescribing and dispensing information with others outside of the privity of the medication-use process is a violation of one’s privacy, especially when shared with law enforcement. Despite the spillage of information, anyone who has access to the PDMP’s information is required to safeguard that information).

110. *See Stephen P. Wood, Prescription Monitoring Programs: HIPAA, Cybersecurity and Privacy*, HARVARD LAW BILL OF HEALTH (Jun. 17, 2018), <https://bit.ly/3e0FhI5> [<https://perma.cc/SV95-C3Q6>].

111. *See id.*

112. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191 § 1.

113. *See* 2014 Pa. Laws 191 § 2; *see also id.* § 3 (whereby a Pennsylvania-licensed pharmacist is a dispenser, stating “[a] person lawfully authorized to dispense in this Commonwealth . . .”).

114. *See* 2014 Pa. Laws 191 § 2.

stances.”¹¹⁵ This clearly refers to law enforcement’s ability to collect data and coordinate efforts to pursue fraud, waste, abuse, and diversion.

The Pennsylvania General Assembly modernized Pennsylvania’s PDMP by expanding monitoring to Schedules III, IV, and V.¹¹⁶ In addition, prescribers and pharmacists now have real-time access to the system as well as statutory requirements to query the system during the course of each respective practice.¹¹⁷ In a national survey of states that had electronic PDMPs in which prescribers and pharmacists could access the system, researchers observed an average reduction of 1.12 opioid-related deaths per 100,000 people per year.¹¹⁸ In Pennsylvania, specifically, there was an 89 percent reduction in the number of patients who saw more than 5 prescribers and more than 5 dispensers or pharmacies in a 3-month period for Schedule II substances.¹¹⁹

The ABC-MAP Act defines a dispenser as “a person lawfully authorized to dispense in this Commonwealth” but excludes “a licensed health care facility that distributes the controlled substance for the purpose of administration in the licensed care facility.”¹²⁰ The Act classifies a pharmacist as a dispenser and a hospital as an example of a licensed health care facility.¹²¹ Section 7 of the Act outlines the information that a pharmacist must submit before dispensing a controlled substance and permits a pharmacist to designate other pharmacy employees to access the system, as permitted by the Board of Pharmacy.¹²² Section 9 of the Act lays out the limitations for all users of the system.¹²³ A pharmacist or designee, “may query the system for a current patient to whom the dispenser is dispensing or considering dispensing any controlled substance.”¹²⁴ This language gave the pharmacists the option to query

115. *Id.*

116. See Mirigian, *supra* note 98, at 144.

117. See Act of Nov. 2, 2016, 2016 Pa. Laws 124 § 7(c) (stating “[a] dispenser or pharmacy shall submit all information . . . no later than the close of the subsequent business day after dispensing a controlled substance”).

118. Stephen W. Patrick et al., *Implementation of Prescription Drug Monitoring Programs Associated with Reductions in Opioid-Related Death Rates*, 35 Health Affairs 1324, 1328 (2016).

119. See Mirigian, *supra* note 98, at 142 (citing communication with the Pennsylvania Department of Health Prescription Drug Monitoring Program office).

120. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191.

121. See 2014 Pa. Laws 191 § 3; see also *Healthcare Facilities and Licensing*, PA. DEPT. HEALTH, <https://bit.ly/2Q9qa5i> [<https://perma.cc/W3RR-ZRPM>] (last visited Dec. 4, 2020).

122. 2014 Pa. Laws 191 § 7.

123. *Id.* § 9.

124. *Id.* § 9(b)(2).

the system.¹²⁵ The 2016 Amendments of the ABC-MAP Act changed the dispenser's duties and merged the content of Sections 7 and 9.¹²⁶

The new language states, “[A] dispenser shall query the system,” and it created an affirmative statutory duty of a pharmacist during the medication-use process.¹²⁷ Updates of the PDMP in real time now occur as a result of the amendment because a dispenser must enter data regarding dispensing the medication by end of business day.¹²⁸ In addition to these new requirements, the amendment instructs the Board of Pharmacy to require all dispensers to register with the program.¹²⁹ State law also says the following:

[A] dispenser shall query the system before dispensing an opioid drug product or a benzodiazepine described to a patient if any of the following apply: (i) The patient is a new patient of the dispenser. (ii) The patient pays cash when they have insurance. (iii) The patient requests a refill early. (iv) The patient is getting opioid drug products or benzodiazepines from more than one prescriber.¹³⁰

It is not a violation of a patient's privacy rights for pharmacists to check before filing a prescription for a current patient or in consideration of dispensing a controlled substance; however, when a pharmacist does this, he assumes a statutory duty.¹³¹ It is worth noting that the PDMP selectively screens pharmacists from seeing whether a patient is on opioids used to treat opioid use disorder, which complicates the pharmacist's duty to screen a patient's profile for drug interactions.¹³² There are exceptions to this statutory duty such that

[a] dispenser who, in the exercise of sound clinical judgment, does not believe that a patient is abusing or diverting controlled substances shall not be in violation of this act for not seeking or obtaining information from the system prior to prescribing or dispensing so long as the prescriber or dispenser is otherwise in compliance.¹³³

125. *Id.*

126. Act of Nov. 2, 2016, 2016 Pa. Laws 124.

127. *Id.* § 7(e).

128. *Id.* (permitting a pharmacist to access more information about the dispensing history of a medication as well as increasing the pharmacist's ability to comply with the Pharmacy Act).

129. *See* Act of Nov. 2, 2016, 2016 Pa. Laws 124 § 5(5)(xvi).

130. *Id.* § 7(e)(1)(i).

131. *See* 35 PA. STAT. AND CONS. STAT. § 872.9; *see also* 2016 Pa. Laws 124.

132. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191.

133. 35 PA. STAT. AND CONS. STAT. § 872.8 (West 2020).

The ABC-MAP Act contains provisions addressing unlawful acts, including criminal liability, administrative liability through the Board of Pharmacy, and a cause of action for civil liability.¹³⁴ A pharmacist commits a misdemeanor of the first degree if he knowingly or intentionally obtains or attempts to obtain patient information outside of the requirements during the medication-use process to verify legitimate controlled substance dispensing.¹³⁵ Additionally, a pharmacist who knowingly or intentionally “releases, sells, transfers or otherwise makes available” or attempts to release, sell, transfer or otherwise make available information from the PDMP commits a third degree felony.¹³⁶ Unauthorized use of the PDMP or failure to follow the requirements can subject a pharmacist to sanctions imposed by the Pennsylvania Board of Pharmacy and the pharmacist’s employer.¹³⁷ The civil liability provision is the most contentious because it states that “knowing, intentional and negligent release or use of information from the system shall be subject to a civil penalty,” and “other civil penalties shall be assessed in accordance with department regulations.”¹³⁸ Information in the PDMP is protected healthcare information (“PHI”) under HIPAA.¹³⁹ HIPAA allows a patient to sue a pharmacist who improperly accesses his PHI if the violation occurred as a result of professional malpractice.¹⁴⁰

The Pennsylvania courts have developed case law to determine when a pharmacist did or did not breach his duty of care. In *Forish v. Paul*,¹⁴¹ the court refused to find a cause of action against pharmacists under professional malpractice or the implied warranty of merchantability because “[t]o hold a pharmacist accountable for monitoring use makes little practical sense—a patient could have prescriptions filled at a number of different pharmacies, rendering any attempt at comprehensive record-keeping virtually impossible absent some type of state-wide regulatory scheme.”¹⁴² Additionally, because the Board of Pharmacy regulates pharmacies and pharmacists, the court was “precluded from imposing duties in addition to those which the legislative branch has chosen to set

134. 2014 Pa. Laws 191 § 7.

135. *Id.* § 10(a)(1).

136. *Id.* § 10(a)(2).

137. *Id.* § 10(e).

138. *Id.* § 10(c).

139. 42 U.S.C. § 17935.

140. Erica Lindsay, *Can a Patient Sue a Pharmacist for Violating HIPAA?*, PHARMACY TIMES (Nov. 12, 2019), <https://bit.ly/2QavXra> [<https://perma.cc/V4RE-2LGU>].

141. *Forish v. Paul*, 2 Pa. D. & C.4th 413 (C.P. 1989).

142. *Id.* at 416–17.

forth.”¹⁴³ This case was decided decades before the creation of the current electronic PDMP, which established a state-wide regulatory scheme that courts can now view as a duty imposed on pharmacists.

Prescribers also have a duty to check the system before prescribing, and in most instances, a controlled substance prescription requires both a prescriber and pharmacist query.¹⁴⁴ However, in some instances, the law requires only the prescriber to query the system before dispensing and does not permit the pharmacist to do so.¹⁴⁵ In particular circumstances, a pharmacist might end up dispensing lethal drugs because he does not have access to the system and must rely on the prescriber’s having done so under this new Pennsylvania law.¹⁴⁶

3. *The SEP Act*

The Safe Emergency Prescribing Act is another piece of legislation that modified the duties of physicians and pharmacists—but in the emergency room setting.¹⁴⁷ Despite progress to reinforce the need for a pharmacist to access the PDMP in executing his professional judgment in dispensing, the SEP law interferes with the pharmacist’s role in the medication-use process.¹⁴⁸ A pharmacist cannot access the PDMP in the emergency room setting before dispensing a controlled substance.¹⁴⁹ Under this new law, a dispensed controlled substance in the emergency room that harms a patient may not put the pharmacist at legal fault but may violate the pharmacist’s oath or contradict his professional judgment in the medication-use process. The heart of the issue is the conflict between the SEP and ABC-MAP Acts and the pharmacist’s role in the medication-use process— if a pharmacist accessed the PDMP, would the pharmacist be subject to state tort and federal medical privacy claims? Could the pharmacist undergo disciplinary actions? The profession has endured by protecting patients and maintaining respect as a profession in society. This analysis will explore why the

143. *Id.*

144. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191.

145. *Id.*

146. 2016 Pa. Laws 122.

147. *Id.*

148. 2014 Pa. Laws 191; SCOTT GIBERSON, SHERRI YODER, & MICHAEL P. LEE, *IMPROVING PATIENT AND HEALTH SYSTEM OUTCOMES THROUGH ADVANCED PHARMACY PRACTICE 12* (2011) (explaining that pharmacists have embraced expanded patient care roles in the emergency setting and that clinical pharmacists in managing drug treatment may reduce health care costs and improve the quality of care).

149. 2016 Pa. Laws 122.

SEP ACT and the ABC-MAP Act are unnecessarily restrictive and the issues that it has created for pharmacists in the Commonwealth.

III. ANALYSIS

A. *Liability for a Pharmacist Accessing the PDMP in the Emergency Room Setting Under the ABC-MAP Act and the SEP Act*

If a pharmacist accessed the PDMP to dispense a controlled substance to a patient in the emergency room in good faith while exercising professional judgment, he would be in violation of the SEP Act and the ABC-MAP Act.¹⁵⁰ In this instance, the pharmacist would not have committed a felony, but because the PDMP access is unauthorized, he is subject to civil liability and administrative liability.¹⁵¹ The pharmacist is in a difficult situation, especially if he suspects that the patient may be at risk to misuse, abuse, or divert the medication.¹⁵²

Prescribers have no obligation to check the PDMP for patients who enter the emergency room.¹⁵³ This lax protocol heightens the burden on the pharmacist to decide whether it is better to act in the best interests of protecting the patient in the normal course of the medication-use process or to comply with the law. The law forces the pharmacist to rely on the physician's choice to query.¹⁵⁴ Even if it may be in the best interest of the patient's health and safety for the pharmacist to query, doing so may result in criminal, civil, and administrative liability and adverse employment actions.¹⁵⁵

1. *Criminal and Civil Liability*

Pharmacists are subject to state laws and regulations in the normal course of practice, and they are subject to federal law and regulations when handling PHI and controlled substances.¹⁵⁶ The

150. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191; 2016 Pa. Laws 122.

151. 2014 Pa. Laws 191 §§ 10(a), (c).

152. See 49 PA. CODE § 27.18 (2019).

153. See *Questions and Answers (Q&A)*, PA. DEPT. HEALTH, <https://bit.ly/34Qjo7U> [<https://perma.cc/6SBA-HFUK>] (last visited Dec. 4, 2020) (stating “[c]hecking the PDMP is not required for any medication provided to a patient in the course of treatment while undergoing care in an emergency department. This exception does not apply to patient undergoing care in urgent care centers or when in observation status in a health care facility”).

154. *Id.*

155. See *infra* Part III.A.1.–2.

156. See *supra* Part II.B.1; 49 PA. CODE, § 27.18 (2020); 63 PA. STAT. AND CONS. STAT. § 390 (stating uses and disclosures for which an authorization or opportunity to agree or object is not required); 45 C.F.R. § 164.512(a) (2020); 21 U.S.C. § 812 (2020).

less regulated area is the use of professional judgment in the medication-use process, which is deferential to a pharmacist's training, knowledge, principles in the oath of a pharmacist, and the profession's use of clinical practice guidelines.¹⁵⁷ Regulation by the profession's standards grants a pharmacist freedom to practice in the best interest of the patient's unique situation without fear of having to follow a law created by non-pharmacists for determining how to treat patients.¹⁵⁸

Recall the young woman who passed away from an unintentional overdose; this serves as a tragic example of a case in which the ABC-MAP Act and SEP Act could directly result in worsened patient care by hampering the pharmacist's professional judgment. The pharmacist is in a very difficult situation when he receives the medication order in this scenario because when verifying a medication order for an opioid or a benzodiazepine in the emergency room, these laws blind the pharmacist to information that would otherwise be available to him in other clinical settings—such as the outpatient setting.¹⁵⁹ On one hand, he could potentially violate his oath and ignore currently accepted clinical practice guidelines and his extensive training to comply with the law.¹⁶⁰ On the other hand, the pharmacist could query the patient's name and date of birth in the PDMP to find an objective medication history and alert the prescriber who may or may not have queried the PDMP himself.¹⁶¹ In the latter case, the young woman may have survived but potentially at the expense of the pharmacist's license.

The Pennsylvania General Assembly expressed that it did not intend to regulate the medicine and pharmacy professions, but that is exactly what it did with the passage of the ABC-MAP and SEP Acts.¹⁶² Under the ABC-MEP Act, which incorporates the SEP Act, the state could charge the pharmacist with a misdemeanor.¹⁶³

157. 49 PA. CODE § 27.18 (2020); 63 PA. STAT. AND CONS. STAT. § 390-3; *See Oath*, *supra* note 64.

158. *See Oath*, *supra* note 64.

159. 2016 Pa. Laws 124; 35 PA. STAT. AND CONS. STAT. § 873.5.

160. *See Oath*, *supra* note 64; CTRES. FOR DISEASE CONTROL & PREVENTION, CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN (2016); *see also* 65 MORBIDITY & MORTALITY WEEKLY REPORTS: RECOMMENDATIONS AND REPORTS 1, 1–50 (2016).

161. 2016 Pa. Laws 122 § 5 (mandating that only a prescriber has the authority to query the PDMP). The liability is solely on the prescriber unless there exists an issue on the face of the prescription or in issues of adulteration or misbranding. *See, e.g.,* Makripodis v. Merrell-Dow Pharm., 523 A.2d 374, 375 (Pa. Super. 1987); *Forish v. Paul*, 2 Pa. D. & C.4th 413, 417 (C.P. 1989).

162. Pa. Representative Pamela A. DeLissio Speech, Pennsylvania General Assembly, PA. LEGIS. J. HOUSE 1447 (June 23, 2016).

163. 2014 Pa. Laws 191 § 10(a)(1).

A less likely but possible additional claim against the pharmacist is that the pharmacist mishandled PHI by inquiring into the young woman's medical history.¹⁶⁴ The PDMP inquiry constitutes an invasion of privacy, and the hospital, as a covered entity, could be held liable for a privacy breach.¹⁶⁵ The hospital could also take adverse employment action against the pharmacist.¹⁶⁶

2. *Administrative Liability*

The Pennsylvania Board of Pharmacy may initiate disciplinary proceedings against the pharmacist and suspend or revoke the pharmacist's license to practice in the Commonwealth.¹⁶⁷ Disciplinary action in one state is often mandatory reporting to other states in which the pharmacist holds a license to practice.¹⁶⁸ Additionally, if the pharmacist attempts to obtain licensure in a new state, most states require him to report the status of his license in other states, including if any disciplinary actions are pending or have taken place.¹⁶⁹ A pharmacist cannot practice without a license.¹⁷⁰ An attempt to protect the patient from a drug-drug interaction, a pillar of the oath of a pharmacist in the use of his professional judgment, could cost him his license to practice.¹⁷¹

B. The ABC-MAP Act and SEP Act Should be Amended to Protect Patients and Pharmacists

1. Statutory Changes

The Pennsylvania General Assembly should amend the SEP Act and the ABC-MAP Act to better reflect the purpose of the

164. 45 C.F.R. § 164.512(a) (2019).

165. *Id.* § 164.506 (stating “whereby no authorization to access PHI from the patient by the prescriber is necessary, the pharmacist may not be privy to that information if state law does not permit the dispenser to know that information under § 164.506(c)(5)”).

166. *Id.* § 164.306 (stating “whereby the hospital must conduct an inquiry into the HIPAA violation and may take action to restrict future breaches, including up to termination of the offending employee according to hospital policies and employment contracts”).

167. 63 PA. STAT. AND CONS. STAT. §§ 390(5), (7) (2019); *see generally* *Gaynor v. Commonwealth, State Bd. of Pharmacy*, 513 A.2d 521, 524 (Pa. Commw. Ct. 1986) (stating the Board of Pharmacy may discipline a pharmacist absent any criminal or civil liability).

168. *Boards, NABP Examine Concurrent Sister-State Disciplinary Actions*, 47 INNOVATIONS (Nat'l Ass'n Bds. Pharmacy, Mount Prospect, IL), Oct. 2018, at 10–12.

169. *Id.*

170. 63 P.S. § 390(3)(h) (2019).

171. *See Oath, supra* note 64; *see also* Vogenberg, *supra* note 85, at 651–52.

ABC-MAP Act.¹⁷² The SEP Act Section 5 states that only the *prescribing* health care practitioner shall query the PDMP to determine if a patient is under treatment with an opioid drug product.¹⁷³ The prescribing health care practitioner does not have to check the PDMP before administering a medication in the emergency department.¹⁷⁴ This requirement limits who can check the PDMP and the purpose for checking the PDMP.¹⁷⁵ First, the law should include *dispensing* health care practitioners in addition to *prescribing* health care practitioners as people who must query the PDMP to determine whether a patient may be under treatment with an opioid drug product. This amendment would better reflect clinical practice guidelines and the pharmacist's role in the medication-use process, as well as provide a double check that already exists in other pharmacy settings.¹⁷⁶ Pharmacists are trained and qualified to assess a patient for drug interactions, more so than the pharmacist's physician counterpart, and a pharmacist's duty to provide safe and effective treatment is burdened when essential resources, such as the PDMP, are inaccessible. Second, the purpose of the query should extend beyond the suspected use of an opioid product to include benzodiazepines. While opioids frequently overshadow benzodiazepines, the latter are commonly responsible for overdose deaths, especially in combination with opioids.¹⁷⁷ Finally, the Pennsylvania General Assembly should extend the law to apply to medications provided to a patient in the course of treatment while

172. Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191; *supra* note 50.

173. 2016 Pa. Laws 122(5).

174. *Id.*

175. *Id.*

176. See Vogenberg, *supra* note 85, at 651–52. See generally *Prescribing Guidelines for Pennsylvania: Opioid Dispensing Guidelines*, PA. DEPT. HEALTH (Jan. 14, 2016), <https://bit.ly/36nPYA4> [<https://perma.cc/TQL3-85AQ>]; *Prescribing Guidelines for Pennsylvania: Non-Cancer Pain Guidelines*, PA. DEPT. HEALTH (June 11, 2018), <https://bit.ly/36mLcmx> [<https://perma.cc/Y5F7-FPNC>]; *Prescribing Guidelines for Pennsylvania: Safe Prescribing Benzodiazepines for Acute Treatment of Anxiety & Insomnia*, PA. DEPT. HEALTH (May 15, 2017), <https://bit.ly/34jwIIC> [<https://perma.cc/FV6V-R6KN>] (describing the appropriate indications and dosing for opioids and benzodiazepines for pain, anxiety, and insomnia, as well as best practices for curbing misuse, abuse, and diversion).

177. See DRUG ENF'T AGENCY INTEL. PROGRAM—PHILA. FIELD DIV., DRUG-RELATED OVERDOSE DEATHS IN PA., 2018, 1 (2018), <https://bit.ly/36qJxfF> [<https://perma.cc/HH7W-3WGV>] (reporting that twenty-eight percent of drug overdose decedents had benzodiazepines in their systems); see also U.S. FOOD & DRUG ADMIN., FDA News Release: FDA Requires Strong Warnings for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepine Labeling Related to Serious Risk and Death from Combined Use (Aug. 31, 2016), <https://bit.ly/38dIKQ5> [<https://perma.cc/B8VU-WMBS>] (warning prescribers and dispensers of the combination of benzodiazepines and opioids in patient due to the risk of toxicity and central nervous system depression).

undergoing care in an emergency department. Prescribers are already required to query the PDMP when writing a prescription in the emergency department for patients to fill at an outpatient pharmacy.¹⁷⁸ Why should this requirement not apply while undergoing care in the emergency department? The obvious counterargument is that the query takes time away from the patient to perform, but a query can be done in seconds, and a prescriber's designee can be the one to query the PDMP.¹⁷⁹ The Pennsylvania legislature does not want to regulate the practices of pharmacy and medicine,¹⁸⁰ but it is already doing so by choosing to exclude a pharmacist's essential part of the medical-use process in the acute care setting.

The ABC-MAP Act Section 8(e) states that a licensing board shall not discipline or hold civilly liable a dispenser who submits or receives information in a PDMP inquiry under Section 7.¹⁸¹ However, this same immunity does not extend to the SEP Act. In conjunction with amending the SEP Act, the Pennsylvania General Assembly should amend the immunity provision of the ABC-MAP Act to protect pharmacists who query the PDMP in the emergency room, as authorized by an amended SEP Act.¹⁸² This immunity provision is vital to the implementation because even though a pharmacist is granted the authority to access the PDMP, he may be hesitant to do so if he thinks he could still be held liable.

2. *Public Policy*

A couple words added to a statute may be trivial, but they could drastically affect patient outcomes for the better. They could even save lives. The ABC-MAP Act and the SEP Act have made some profound steps to address the opioid epidemic in the Commonwealth. Every two years, licensed pharmacists must perform two hours of continuing education credits regarding pain management, identification of addiction, or dispensing opioids.¹⁸³ Also, if a prescriber identifies a patient in the PDMP query with suspicion for

178. Pa. Dept. of Health, *PDMP Questions and Answers*, <https://bit.ly/2S27TpV> [<https://perma.cc/P4B9-A6PL>] (last visited Dec 4., 2020).

179. 2014 Pa. Laws 191 § 8(c) (indicating that the prescriber herself does not need to perform the actual inquiry, and a designee, such as a registered nurse, is a preferred surrogate for the prescriber).

180. *See* 2016 PA. LEGIS. J. HOUSE 1447 (describing a “dangerous precedent” when the state legislature attempts to legislate how licensed health-care providers practice, instead of allowing providers to defer to clinical practice guidelines and training).

181. 2014 Pa. Laws 191 § 8(e).

182. 2014 Pa. Laws 191 § 8(e); *Gabriel v. Giant Eagle, Inc.*, 124 F. Supp. 3d 550, 5642 (W.D. Pa. 2015).

183. 2016 Pa. Laws 124 § 9.1(a)(1).

addiction in the emergency room, he is required to refer the patient to treatment.¹⁸⁴ Despite all the aforementioned evidence-based methods to combat addiction and diversion that the state chose to adopt, patient care still suffers when pharmacists are withheld from accessing vital tools while dispensing opioids and benzodiazepines.¹⁸⁵

In Pennsylvania, a pharmacist has a duty to remedy inadequacies on the face of a physician's prescriptions so that the prescription will be safe and effective for the patient and complies with clinical practice guidelines.¹⁸⁶ This duty includes a "duty to alert the physician and make proper adjustments."¹⁸⁷ Failure to notice a potentially lethal interaction between drugs on the face of a prescription falls within this duty.¹⁸⁸ At the time the court decided *Forish v. Paul*, there was "no authority in Pennsylvania which would place on the profession the . . . [duty] . . . to be familiar with the patient's medical history and/or medical records."¹⁸⁹ The court feared that this might blend two distinct professions, pharmacy and medicine, and there was no authority to create such a duty.¹⁹⁰ Since *Forish v. Paul* was decided, the professions have developed, but each has its own distinct roles in the medication-use process and continue to require separate licenses, just as they have operated since 1240 A.D.¹⁹¹ In addition, the ABC-MAP Act has created a statutory duty that requires a pharmacist to now be familiar with a patient's medical records.¹⁹² A pharmacist's training and expertise means that he will use the PDMP information differently than a

184. 2016 Pa. Laws 122 § 4.

185. See Mirigian, *supra* note 98, at 142 (citing communication with the Pennsylvania Department of Health Prescription Drug Monitoring Program office).

186. *Forish v. Paul*, 2 Pa. D. & C.4th 413, 417 (C.P. 1989).

187. *Id.* at 416.

188. *Id.*

189. *Id.* at 417.

190. *Id.*

191. 63 P.S. §§ 390(3), 422(3) (2019) (creating the Pennsylvania State Board of Medicine, which licenses and disciplines physicians and surgeons); HASTINGS RASHDALL, *THE UNIVERSITIES OF EUROPE IN THE MIDDLE AGES* 85 (1895); James J. Walsh, *The Earliest Modern Law for the Regulation of the Practice of Medicine*, BULL. N.Y. ACAD. MED. 523–24 (1935).

192. *Gabriel v. Giant Eagle, Inc.*, 124 F. Supp. 3d 550, 563 (W.D. Pa. 2015) (quoting *Forish*, 2 Pa. D. & C.4th at 417) ("[t]o hold a pharmacist accountable for monitoring use makes little practical sense—a patient could have prescriptions filed at a number of different pharmacies, rendering any attempt at comprehensive record-keeping virtually impossible absent some type of state-wide regulatory scheme" because the court could not "impose a duty that neither the legislature nor the State Board of Pharmacy have imposed."). Since *Gabriel* was decided, the ABC-MAP Act was enacted, which created a duty from the legislature. See Act of Nov. 2, 2016, 2016 Pa. Laws 124 § 7(e).

prescriber would use the PDMP information at the dispensing stage of the medication-use process.¹⁹³

Since a Pennsylvania pharmacist now has access to the PDMP before filling certain controlled substances in specific clinical settings, a new duty exists to query the PDMP.¹⁹⁴ However, this duty is hard to fulfill because of the roadblocks that inhibit pharmacist's access, especially in the emergency department setting.¹⁹⁵ The aforementioned changes to the ABC-MAP Act and the SEP Act are necessary for pharmacists to remain the trusted and respected members of society, and for improving the medication-use process as a matter of public health policy.¹⁹⁶

IV. CONCLUSION

This Comment has examined Pennsylvania's PDMP statutes for physicians and pharmacists.¹⁹⁷ The two professions have developed over the millennia to develop professionals that are trained and educated to handle distinct but interconnected roles in the medication-use process.¹⁹⁸ If each professional uses the PDMP during his ordinary course of the medication-use process for prescribing and dispensing opioids and benzodiazepines, both the prescriber and the pharmacist will be able to provide safe and effective treatment to patients.¹⁹⁹ Physicians and pharmacists are expected to follow common law and statutory duties of care in their respective professional capacities,²⁰⁰ but Pennsylvania's PDMP statutes do not provide the same level of assurance to both professions.²⁰¹

In the emergency room setting in particular, pharmacists are prohibited from accessing the PDMP in the ordinary course of verification and dispensing opioids and benzodiazepines.²⁰² The pharmacist must rely on a physician's query of the system.²⁰³ If a

193. See Vogenberg, *supra* note 85, at 651–52.

194. 2016 Pa. Laws 124; Act of Oct. 27, 2014, No. 191, 2014 Pa. Laws 191.

195. 2016 Pa. Laws 122.

196. See generally *Honesty/Ethics in Professions*, GALLUP, <https://bit.ly/34MSxKn> [<https://perma.cc/BHG5-URZK>] (last visited Dec 4., 2020); Accreditation Standards, *supra* note 28; Kristy Malacos, *PDMPs Can Help Curb the Opioid Epidemic*, PHARMACY TIMES (Nov. 20, 2019), <https://bit.ly/2sVhfum> [<https://perma.cc/WSJ4-QSY8>] (describing how PDMP programs provide information to quickly identify possible drug seeking behavior and inappropriate prescribing).

197. See *supra* Part II.D.

198. See *supra* Part II.A., II.C.

199. See *supra* Part II.C.

200. See *supra* Part II.A.2.

201. See *supra* Part III.

202. See *supra* Part II.D.3.

203. See *supra* Part II.D.2.

pharmacist were to query the system to check for a drug-drug interaction in the emergency room setting, it would not rise to the level of criminal activity under the laws, but it could potentially trigger civil liability, administrative liability, and adverse employment action.²⁰⁴ Civil liability can stem from the PDMP statute itself for an unauthorized query and may also rise to the level of a federal HIPAA regulation violation.²⁰⁵ The State Board of Pharmacy has the authority to administer disciplinary action to any pharmacist that the state licenses.²⁰⁶ The employer, such as the hospital or health system, can also suspend or terminate pharmacists that violate the PDMP laws.²⁰⁷

The pharmacist is not the only one who suffers from accessing the PDMP in the course of the medication-use process. The public also suffers a major disservice when pharmacists cannot act to the full limit of their license and in accordance with evidence-based practice in clinical practice guidelines.²⁰⁸ Pharmacists may be able to detect a potential overdose, misuse, abuse, or drug diversion with a simple PDMP query.²⁰⁹ As this Comment explains, the Pennsylvania legislature should amend ABC-MAP Act and the SEP Act to provide pharmacists the same immunity as physicians and expand the PDMP query access so that pharmacists can effectively practice pharmacy in Pennsylvania.²¹⁰

204. *See supra* Part III.

205. *See supra* Part II.

206. *See supra* Part III.A.2.

207. *See supra* Part III.A.1.

208. *See supra* Part II.B.

209. *See supra* Part II.B.2.

210. *See supra* Part III.B.
