Of Remand And Responsibility: Oakey v. May Maple Pharmacy and the Pharmacist’s Professional Standard of Care in New Mexico

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INTRODUCTION

The United States is in the grip of a growing opioid crisis that shows no signs of slowing down.1 Millions of Americans abuse prescriptions each year.2 In 2016, opioid drug overdoses claimed 42,249 lives,3 and nearly half of those deaths involved a prescription.4 In the same year, 497 individuals died in New Mexico from drug overdose, and nearly three out of four of those overdoses involved opioids.5

The fight to curb overdose deaths from prescription opioids has involved government and private entities at all levels, from federal agencies to large companies like CVS.6 The looming problem has also prompted President Trump to declare a national public health emergency7 which has sent government agencies scrambling to find a solution.

Physicians have long been exposed to liability for drug overdoses, but the development of pharmacist liability has been slow in American jurisprudence.8

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1 Prescription Opioid Overdose Data, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/data/overdose.html (last updated Aug. 1, 2017) (citations omitted) (“Overdose deaths involving prescription opioids were five times higher in 2016 than 1999.”).
2 See id.
4 CTRS. FOR DISEASE CONTROL AND PREVENTION, supra note 1.
Jurisdictional positions are mixed on the scope of the standard of care required of pharmacists when dispensing Schedule II medications such as opioids. In New Mexico, the issue was unexplored until Oakey v. May Maple Pharmacy, Inc. However, the issue remains unresolved. This article will address the scope of a pharmacist’s duty by analyzing law and policy, and recommend that New Mexico is now part of the minority of jurisdictions that require more of pharmacists to avoid exposure to liability.

Part A of this article will describe the history of the pharmacist’s standard of care, an overview of current jurisdictional positions, and a discussion of the corresponding responsibility doctrine found in federal regulation. Part B will examine the New Mexico regulations pertaining to pharmacists, and the case of first impression, Oakey v. May Maple Pharmacy. Part C will discuss the consequences of Oakey, recommend that the corresponding responsibility doctrine be incorporated into case law, and briefly discuss policy concerns supporting an expanded professional standard of care.

A. BACKGROUND

Historically, the traditional standard of care for pharmacists was the “clerical accuracy” standard. This required only accurately filling a valid prescription, making the pharmacist a mere dispenser of drugs. Indeed, the traditional role of drug dispenser focused on “the mechanical tasks of retrieving the correct drug from the shelf and then properly packaging and labeling it” rather than focusing on the patient and his or her well-being. Error in filling prescriptions was a breach of this clerical accuracy standard of care.

The standard was informed by significant policy concerns, “including the potential for pharmacists intruding into the doctor-patient relationship or practicing medicine without a license and burdening pharmacists with the responsibility of second-guessing the judgment of physicians in an effort to avoid liability.”

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11. Id. ¶ 20.


14. Id. at 33, 34.


I. Jurisdictional Positions

A majority of jurisdictions have adopted the clerical accuracy standard. This general duty to accurately fill valid prescriptions is predicated on the physician-patient relationship. A recent case from the Supreme Court of Arkansas illustrates the clerical accuracy standard and explains the majority view. In Kowalski v. Rose Drugs of Dardanelle, a deceased patient’s estate brought a wrongful death action against a pharmacy that dispensed a combination of legally prescribed drugs, including an anti-depressant and an opioid. The plaintiff argued that the pharmacy had a “general duty to warn, to not fill dangerous prescriptions, and to inquire of a prescribing physician.” The court briefly examined the federal Controlled Substances Act and the corresponding responsibility doctrine found in 21 C.F.R. § 1306.04. The court determined that the Controlled Substances Act was enacted “in light of the ‘substantial and detrimental effect’ of ‘[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances . . . on the health and general welfare of the American people,’” and determined that the Act’s purpose was to prevent drug diversion to illegitimate channels. In so determining, the court dismissed any notion that the Act created any expansion of the traditional duty for pharmacists beyond criminal distribution of drugs. The court also dismissed the plaintiff’s argument that the corresponding responsibility found in federal regulation imposed any expanded duty. The court supported its position by stating that the federal regulation focused on circumstances in which a physician or pharmacist illegally manufactured, distributed, or dispensed controlled substances in violation of the Controlled Substances Act. After reviewing Arkansas’ statutory and regulatory framework governing pharmacists, the court stated the plaintiff had no support for an expansion of the pharmacist’s duty.

The court concluded there was no duty; it was the physician who was the “learned intermediary” between the drug manufacturer and the patient, and who

17. Fleischer, supra note 12, at 166, 168.
19. Id. at 112.
20. Id. at 112.
22. Kowalski, 378 S.W.3d at 115–16.
23. Id. at 115.
24. Id.
25. Id.
26. The court simply stated that “looking at the entirety of the regulation, it is clear that a pharmacist has an obligation to ensure that any prescription for a controlled substance is legitimate according to the law. It does not unequivocally impose the duty suggested by the Estate.” Id. at 116.
27. Id. (citing United States v. Hayes, 595 F.2d 258 (5th Cir. 1979)).
28. Id. at 118.
29. The learned-intermediary doctrine “provides an exception to the general rule that a manufacturer has a duty to warn the ultimate user of the risks of its products,” in that “a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug. The physician acts as the “learned intermediary” between the manufacturer and the ultimate consumer.” Id. at 120.
was in the best position to warn the patient about any adverse drug effects. The court determined that the physician-patient relationship was paramount, because “[i]t is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy,” and held that pharmacists do not have a general duty to warn, refuse to fill medication, or consult with the prescribing physician, affirming the trial court’s grant of summary judgment.

Although most jurisdictions currently follow the clerical accuracy standard, the landscape has been slowly shifting. The pharmacist’s role has been quickly developing over time, and has expanded from simply filling prescriptions to encompass “prescription consultation, medication therapy management, immunization administration, blood pressure screening, cholesterol checks, drug compounding, drug interaction safeguarding, and anticoagulation therapy oversight, among others.” This expansion reflects a greater recognition of the pharmacist’s expertise in handling dangerous drugs. Despite the pharmacist’s developing role, courts that recognize expanded liability remain in the minority.

The 1994 Indiana Supreme Court case *Hooks v. McLaughlin* was one of the first cases that created an expansion of liability informed by policy concerns paramount to the doctor-patient relationship. In *Hooks*, McLaughlin, the plaintiff-patient, sustained a back injury and was prescribed propoxyphene. The patient became addicted to the medication, which was being dispensed by a Hooks drugstore, and began filling the prescriptions at an accelerated rate. The patient’s doctor eventually became aware of the faster-than-normal-filling rate, and refused to fill any more prescriptions. Although the patient did not die of an overdose, he became suicidal after being denied prescription refills. Shortly thereafter he entered drug addiction treatment.

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30. See id.
31. Id. at 120–21.
33. See Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 517 (Ind. 1994) (“It is a matter of common expectation . . . that pharmacists possess expertise regarding the dispensing of prescription drugs.”); see also Homer v. Spalitto, 1 S.W.3d 519, 522 (Mo. Ct. App. 1999) (“[T]o hold that a pharmacist was only required to accurately fill a prescription] would denigrate the expertise which a pharmacist’s education provides concerning drugs and their therapeutic use.”).
34. See Gardipee, supra note 32.
36. Id. at 516. See also FDA Drug Safety Communication: FDA recommends against the continued use of propoxyphene, FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/DrugSafety/ucm234338.htm (last visited Dec. 1, 2017). Propoxyphene is a Schedule IV opioid used to treat mild to moderate pain. The U.S. Food & Drug Administration is currently recommending that the product be removed from the U.S. market.
38. Id.
39. Id.
40. Id.
McLaughlin argued that Hooks breached its duty to cease filling his prescriptions in light of his rapid consumption of the drugs. In its duty analysis, the court characterized the relationship between pharmacists and patients as independent of the physician-patient relationship, noting that patients expect the pharmacist to use his or her expertise to protect the patient’s health, and that addiction to prescribed addictive substances is a foreseeable consequence. Additionally, the court weighed competing policy considerations, such as “preventing intentional and unintentional drug abuse, not jeopardizing the physician/patient relationship, and avoiding unnecessary health care costs.” The court also noted that Indiana’s Pharmacy Act weighed in favor of the policy concerns of addiction, health, and safety of the customer, and suggested that “proper dispensing of prescription drugs and preventing drug addiction might be paramount to policy concerns about interfering with the physician-patient relationship.” Specifically, the Indiana Pharmacy Act provides that the pharmacist is immune from civil liability if he or she refuses to dispense medication in the good faith belief that dispensing would contribute to a person’s addictive habit. The court held that where a customer has a prescription for a dangerous drug refilled at an “unreasonably faster rate than prescribed,” the pharmacist must cease refilling the prescription “pending direct and explicit directions from [the] prescribing physician.”

Subsequent cases have further illustrated Hooks’ expanded liability. Horner v. Spalitto stated that the accurate summation of a pharmacist’s “duty was to endeavor to minimize the risks of harm to [the patient] and others which a reasonably careful and prudent pharmacist would foresee.” According to the court, to hold otherwise “would denigrate the expertise which a pharmacist’s education provides concerning drugs and their therapeutic use,” and that this training places pharmacists in the best position to question and inquire about potentially dangerous prescriptions.

In 2015, the Florida Court of Appeals in Oleckna v. Daytona Disc. Pharmacy rejected the clerical accuracy standard in circumstances where a pharmacist consistently dispensed a benzodiazepine and opioids days before the prescriptions should have been exhausted. The court stated that a pharmacist’s duty

41. Id.
42. See id. at 517.
43. Id. at 518.
44. Id.
45. Id. (quoting IND. CODE ANN. § 25-26-13-16 (2010)).
46. Id. at 514.
47. 1 S.W.3d 519 (Mo. Ct. App. 1999).
48. Id. at 522 (emphasis added).
49. Id. at 522–23.
51. Benzodiazepines are medications that act to depress the central nervous system and cause drowsiness. They are often prescribed to treat anxiety, panic disorders, and sleeplessness. Common names include Xanax and Valium. Omudhome Ogbru, Oral Benzodiazepines Names, Side Effects, and Addiction, MEDICINE.NET.COM, https://www.medicinenet.com/benzodiazepines_sleep-inducing-oral/article.htm# what_are_benzodiazepines,_and_how_do_they_work_(mechanism_of_action) (last visited Dec. 17, 2017).
52. Oleckna, 162 So.3d at 179–80.
extended beyond ‘‘robotic compliance’ with the instructions of the prescribing physician.”

In the majority of cases reviewed in this article, the trial courts applied a more narrow standard of care and dismissed the case on summary judgment. These courts found that pharmacists were not required to do anything more than accurately fill out a legal prescription in the circumstances presented. This indicates that the minority standard, that a pharmacist must do more than accurately fill out prescriptions, is an evolving, judicially-created standard, more so informed by statutes and regulations rather than dictated by them.

II. Corresponding Responsibility

Federal regulation states that prescriptions “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,” and that the “responsibility for the proper prescribing and dispensing” of controlled substances is upon the prescribing practitioner. There is, however, “a corresponding responsibility with the pharmacist who fills the prescription.” The responsibilities of the prescribing physician and the pharmacist are not identical, but are distinct and independent duties; the “physician’s responsibility is not to prescribe improperly while the pharmacist’s responsibility is not to dispense a controlled substance for non-medical reasons.” An order that is issued for non-medical reasons is not considered to be a prescription. A pharmacist who knowingly or blindly fills such an order is in violation of federal law and is subject to penalties. Several federal courts have interpreted the corresponding responsibility of a pharmacist as an affirmative duty to responsibly dispense medications that requires vigilance in preventing prescriptions issued for a non-medical purpose.

53. Id. at 182.
55. See cases cited supra note 54.
56. Although the world “dispensing” is used specifically in the federal regulation to denote a physician’s responsibility, it is the author’s understanding that for all intents and purposes, pharmacists dispense medication to the patient.
57. 21 C.F.R. § 1306.04 (2005).
58. Id.
59. United States v. Henry, 727 F.2d 1373, 1379 (5th Cir. 1984), on reh’g, United States v. Henry, 749 F.2d 203 (5th Cir. 1984) abrogated on other grounds by United States v. Jones, 839 F.2d 1041 (5th Cir. 1988)).
60. 21 C.F.R. § 1306.04.
61. Id.
62. United States v. City Pharmacy, LLC, No. 3:16-CV-24 (BAILEY), 2017 WL 1405164, at *3 (N.D.W. Va. Apr. 19, 2017) (quoting United States v. Leal, 75 F.3d 219, 227 (6th Cir. 1996)); see also United States v. Hayes, 595 F.2d 258, 261 (5th Cir. 1979) (“[A] pharmacist can either fill a prescription or decline to do so . . . [w]hat is required of him is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.”); United States v. Lawson, 682 F.2d 480, 482.
The Drug Enforcement Administration’s (“DEA”) 2010 Affirmance of Suspension Order (“Order”) regarding East Main Street Pharmacy is helpful to illustrate the elements of the corresponding responsibility doctrine.63 On April 23, 2009, the DEA issued an order to East Main Street Pharmacy, which proposed the revocation of the pharmacy’s DEA Certificate of Registration as a retail pharmacy.64 The reason alleged was that the pharmacy “had violated its corresponding responsibility under Federal Regulations to not fill unlawful prescriptions.”65 The alleged facts indicated the pharmacy engaged in egregious conduct: a doctor had been prescribing a combination of a benzodiazepine, opioids, and Soma66 to multiple patients.67 The doctor practiced in a city located over an hour away from East Main Street Pharmacy, and directed his patients to the pharmacy, which meant his patients drove a distance of between 45 to 92 miles to fill their prescriptions.68 In addition, most of the doctor’s patients paid for the prescriptions in cash.69 Finally, the pharmacy filled several prescriptions early, “when the patients should have had two to three weeks’ supply of medication from a previous prescription.”70

The Order set out the DEA’s interpretation of corresponding responsibility. The Administration explained that “DEA has consistently interpreted [the pharmacist’s corresponding responsibility] ‘as prohibiting a pharmacist from filling a prescription for a controlled substance when he either “knows or has reason to know that the prescription was not written for a legitimate medical purpose.”’71 Furthermore, a pharmacist who is faced with facts indicating the prescriptions were not issued for a legitimate medical purpose cannot “intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.”72

The Order focused on certain “red flags,” including the benzodiazepine-narcotic-Soma “cocktail” drug combination well-known to pharmacists, large drug dosages, refills dispensed weeks early, and cash payments for the medications.73 The order further noted that even if the pharmacist had “called to verify each and every prescription” that the physician issued, the pharmacist still “knew that [the doctor’s] prescriptions lacked ‘a legitimate medical purpose’ and thus violated Federal law.”74

(4th Cir. 1982) (“When a pharmacist is faced with a large number of prescriptions all written by one doctor and all presented by one person, he has strong evidence that the prescriptions are not legitimate.”).

64. Id.
65. Id.
66. Soma is the common name for carisoprodol, which is an oral muscle relaxant. See Omuahome Ogbru, carisoprodol, MEDICINE.NET.COM, https://www.medicinenet.com/carisoprodol/article.htm (last visited Dec. 17, 2017).
68. Id. at 66149.
69. Id.
70. Id.
71. Id. at 66163. (The Order also noted that “[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect.”) (emphasis added) (quoting the government’s expert in the case, Dr. Donald Sullivan).
72. Id. (emphasis added).
According to the order, if a pharmacist knows or has reason to know the prescription is not written for a legitimate medical purpose, he or she is prohibited by federal law from filling the prescription.\textsuperscript{75} The determination of whether a prescription is written for a legitimate medical purpose is made on an ad hoc basis, taking into consideration unresolved “red flags.”\textsuperscript{76} There is no definitive list of these “red flags,” since they may change or evolve, but they are based on common sense.\textsuperscript{77} The presence of “red flags” does not automatically show that a prescription is illegitimate, but those flags \textit{must} be resolved.\textsuperscript{78} “The steps necessary to resolve” a red flag are necessarily “influenced by the nature of the circumstances giving rise to the red flag.”\textsuperscript{79}

In an administrative order finding against a CVS pharmacy, The DEA clarified the required analysis in determining whether a pharmacy is in violation of its corresponding responsibility by formulating the following “red flag test”: “(1) the pharmacy must have dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.”\textsuperscript{80} In addition, there are several informational sources that act as guides to help pharmacists navigate “red flags.”\textsuperscript{81}

In the DEA orders discussed above, the corresponding responsibility doctrine was given in the context of revoking Certificates of Registration against the pharmacies, rather than in the context of civil court litigation. However, the DEA clearly sees violation of this corresponding responsibility as egregious enough to warrant barring a pharmacy’s ability to practice, because due to the pharmacy’s violation, it is \textit{unfit} to dispense dangerous medications, and presents a \textit{risk} to the public. Thus, it serves as a useful conceptual point in helping to determine pharmacy liability and the professional standard of care. This much is clear, as indicated in the New Mexico case \textit{Oakey v. May Maple Pharmacy}, discussed below, where the court focused on two of the red flags enumerated in 16.19.20 NMAC and present in the

\textsuperscript{75} Id. at 66163.
\textsuperscript{76} Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62316, 62341 (Oct. 12, 2012).
\textsuperscript{77} See Jones Total Health Care Pharmacy, L.L.C., 81 Fed. Reg. 79188, 79209 (Nov. 10, 2016) (“There is no one place where a registrant can go to view a published list of ‘red flags,’” “because ‘[p]harmacy practice isn’t a checkoff list, and the red flags change,’” and “recognizing these flags [is] ‘common sense on a pharmacist’s part[.]’”).
\textsuperscript{78} Id.
\textsuperscript{79} Id.
\textsuperscript{80} Id.
Additionally, the role of the corresponding responsibility doctrine has been affirmed in criminal trials where the defendant was charged in part with violating their corresponding responsibility.

B. THE LAW IN NEW MEXICO

I. Statutes and Regulatory Authority

New Mexico’s Pharmacy Act defines “the practice of pharmacy in New Mexico [as] a professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest,” and states that the purpose of the Act is to “promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.” The Act created the New Mexico Board of Pharmacy, “and delegated to the Board authority and responsibility for adopting rules and regulations governing the pharmacy profession in New Mexico.”

The Administrative Code contains the regulations promulgated under authority from the Pharmacy Act for the practice of pharmacy in New Mexico, and sheds light on the bounds within which a pharmacist can act. 16.19.20.41 NMAC states that “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.” The objective of this part of the regulations is “to protect the public health and welfare of the citizens of New Mexico by controlling and monitoring access to controlled substances.” 16.19.20 NMAC closely resembles 21 C.F.R. § 1306.04, and recites the corresponding responsibility language found in the federal regulation word for word. 16.19.20(C) NMAC actually goes further than the federal regulation by stating that a “prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic dependent person for the sole purpose of continuing his dependence upon such drugs.” This language is absent in the federal regulation, and implies that New Mexico has a particular interest in combating the state’s opioid overdose epidemic. 16.19.20 NMAC also lacks the knowledge requirement that is...
present in the federal regulation. It is unknown whether the conspicuous absence of a knowledge requirement leaves the door open for strict liability against pharmacists when unresolved red flags are present, but future litigation may clarify this.

16.19.4.16(E) NMAC has specifically incorporated several of the red flags that were mentioned in the discussion regarding corresponding responsibility above, including over-utilization, early refills, paying cash when the patient has insurance, or a combination prescription of an opioid and benzodiazepine. If red flags are present, the regulation mandates that the pharmacist consult the Prescription Monitoring Program (“PMP”), and, using professional judgment, “take appropriate steps to avoid or resolve” the issue.

The regulations give pharmacists discretion in deciding the precise action to take when confronted with indications of potential abuse or misuse of drugs. Initially, “prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying . . . clinical abuse/misuse . . . drug-drug interactions[,] incorrect drug dosage . . . [and] incorrect duration of drug treatment . . . .” If the pharmacist recognizes any of the above, then the pharmacist, “using professional judgment, shall take appropriate steps to avoid or resolve the potential problem.”

If the patient presenting an opioid prescription displays potential opioid abuse or misuse, such as “over-utilization, early refills . . . or paying cash when the patient has prescription insurance,” or is “receiving an opioid concurrently with a benzodiazepine,” then the pharmacist is mandated to request and review a PMP report, and use “professional judgment” to “take appropriate steps to avoid or resolve the potential problem.”

II. The Case: Oakey v. May Maple Pharmacy

The New Mexico Court of Appeals case Oakey v. May Maple Pharmacy arose from a lawsuit brought by the personal representative of the estate of a 19-year-old woman named Tawana Lucero, who overdosed and died from using a combination of medications that were validly prescribed by her physician.

Ms. Lucero died on December 1, 2009 due to overdose from a combination of high levels of the opioids Oxycodone and Oxymorphone, and the anti-anxiety

92. Id.
93. N.M. Bd. of Pharmacy, NEW MEXICO PRACTITIONER’S MANUAL: An Informational Outline, N.M. REG. AND LICENSING DEP’T (Revised Aug. 2015), http://www.rld.state.nm.us/uploads/FileLinks/609360b4b797388d488b16532e4518/10/bde0e0d28ef545cba3d8cd277c39749d/NM_Practitioners_Manual_081315.pdf (“The Prescription Monitoring Program is a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.”).
94. See 16.19.4.16(E) NMAC (listing five “red flags” and stating appropriate steps to take if confronted with them).
95. 16.19.4.16(D)(1) NMAC.
96. 16.19.4.16(D)(2) NMAC.
97. 16.19.4.16(E) NMAC.
medication Alprazolam.99 Under federal and state law, the two former drugs are Schedule II controlled substances, and the latter is a Schedule IV controlled substance.100 The Pharmacy dispensed these medications to Ms. Lucero from May 28, 2009 to November 16, 2009.101 During this time period, the pharmacy dispensed opioid medications to Ms. Lucero “between two and twenty-three days early” on at least seven occasions.102 In addition, Ms. Lucero offered to pay cash on multiple occasions, and in one instance paid over $1,000 cash for 90 pills, “even though the drugs would have been free through Medicaid if she waited three days.”103

The plaintiff’s complaint asserted negligence and negligence per se, alleging that, in dispensing the medications to Ms. Lucero, the pharmacy failed to “apply the knowledge ordinarily used by reasonably well-qualified pharmacists” and breached regulatory duties mandated by 16.10 NMAC.105

The pharmacy moved for summary judgment, claiming that the clerical accuracy standard applied. The pharmacy argued that the pharmacist who dispensed medications to Ms. Lucero was only required to ensure that the prescriptions received from the physician were accurately filled as prescribed, absent specific knowledge of potential harm, which the pharmacist did in this case.106 The pharmacy’s motion and reply brief “made no mention of any statutes or regulations” and did not address the Plaintiff’s negligence per se claim.107

Each party offered a differing standard of care, supported by expert affidavits.108 The pharmacy’s expert articulated the clerical accuracy standard, and stated a policy concern that deviating from this narrow standard would encroach on the doctor/patient relationship, and cause the pharmacist to second guess the physician.109 In contrast, the plaintiff’s expert stated that evidence of excess use of a controlled substance requires at minimum that the pharmacist should consult with the patient and physician, and possibly would preclude the pharmacist from filling the prescription.110 The district court agreed with the pharmacy, granted its motion, and dismissed all claims against the pharmacy.111

The Court of Appeals narrowed the question to “the conduct required of retail pharmacists in filling prescriptions for controlled substances with a significant

99. Id. ¶¶ 2, 3. (Alprazolam is a benzodiazepine).
102. Schedule II controlled substances may not be refilled, but 16.19.4.16(E)(1)(a) NMAC refers to early refills of opioids as an indicator of abuse; however, the Court of Appeals did not “understand the issue in this case to turn on the difference between a ‘refill’ and a request to fill a new prescription ‘early,’ i.e., prior to the time the previously prescribed amount should have lasted if taken as directed.” Id. n. 4.
103. Id. ¶ 5.
104. Id.
105. Id. ¶ 6.
106. Id. ¶ 7.
107. Id.
108. Id. ¶ 8.
109. Id. ¶¶ 8, 32.
110. Id. ¶¶ 11, 12.
111. Id. ¶ 1.
potential for abuse and addiction[.]

In its explanation of the legal framework to be applied to negligence claims, the court indicated that pharmacists are medical professionals, and were to be held to a professional standard of care. The court noted that the professional standard of care is established by experts, and whether one has met that standard is generally reserved for the fact-finder. However, “statutes, regulations, and court rules imposing requirements on professionals are relevant to the determination of the standard of care required by the circumstances and whether it has been met, even if they do not necessarily suffice to establish a standard of care or provide a cause of action for their violation.” Thus, the professional standard of care required by pharmacists is a factual inquiry established by experts and informed by “statutes and regulations governing the practice of pharmacy and dispensing physician-prescribed controlled substances.”

The court ultimately reversed the district court’s summary judgment motion for three reasons. First, the pharmacy did not establish as a matter of law the proper standard of care, or the pharmacy’s compliance with that standard. Second, even if the pharmacy established a standard of care and adherence to that standard, the plaintiff’s expert affidavit established a genuine issue of material fact as to the issues. Third, the pharmacy’s motion did not demonstrate entitlement to summary judgment on the claim of negligence per se, and the district court did not consider the claim. The Court also stated the facts and law were insufficiently developed, and precluded review.

Curiously, the court made an effort to compile cases that supported an expanded standard of care for pharmacists that neither party presented to the district court. The court’s language also seems to be an implicit recognition of strong state policy considerations that weigh against a clerical accuracy standard, at least in the circumstances presented in the case. Specifically, the court devoted a portion of

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112. *Id.* ¶ 19.
113. *Id.*
114. See *id.* ¶ 25 (“Where the defendant is a professional, the duty imposed by law is not the requirement to exercise ‘ordinary care’ under the same or similar circumstances but ‘to apply the knowledge, care, and skill of reasonably well-qualified professionals practicing under similar circumstances.’”).
115. *Id.* ¶¶ 25, 26.
116. *Id.* ¶ 26.
117. *Id.* ¶ 28.
118. *Id.* ¶ 18.
119. *Id.*
120. *Id.*
121. *Id.* ¶ 20.
123. *Id.* ¶ 38 (“[A] standard of care that requires nothing more of pharmacists in the circumstances presented here . . . than that they accurately fill an apparently valid prescription raises other policy concerns related to the potential harm to patients and the public at large. These concerns are reflected in
the opinion to detailing New Mexico’s Administrative Code regulations, outlined above, regarding the practice of pharmacy that prescribes conduct in certain circumstances beyond simply filling a prescription. The court also briefly mentioned the corresponding responsibility doctrine as stated in state regulations and federal statute.

After *Oakey* was decided, the New Mexico Supreme Court let the Court of Appeals’ opinion stand. Although the denial of certiorari does not express approval for either side, it hints that the Supreme Court found no error with the Court of Appeals’ analysis.

**C. COMMENT**

A detailed reading of the case indicates that the court signaled disapproval of the clerical accuracy standard. The immediate impact of the opinion is that practitioners in New Mexico are now on notice that the state has most likely rejected the traditional clerical accuracy standard and is counting itself among the minority of progressive jurisdictions that fully recognize the pharmacist’s role as a health care provider, undiminished by the role of the physician. Such an implication is strong, considering that the court devoted a paragraph to mentioning a jury instruction describing a health care provider’s duty, and other jurisdictions applying the “health care provider” designation to pharmacists. The “health care provider” designation is important, because it recognizes a pharmacist as a professional whose primary responsibility is patient health. Implicitly, this means that in fulfilling his or her responsibility, the pharmacist may have to second guess a physician’s prescription, rendering the physician-patient relationship subordinate to the heightened responsibility.

In addition, there are several sources that suggest that the pharmacist now has an expanded role as a health care provider and vital team player in a patient’s overall healthcare. The Center for Disease Control (“CDC”) describes the pharmacist as “an essential part of the health care team” that is “on the front lines of dispensing opioid pain medications and providing medication-related services,” and in an

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federal and state statutes and regulations[.]” This language followed directly after citations to other jurisdictions supporting a clerical accuracy standard).

124. *Id. ¶¶ 34–36.*

125. *Id. ¶ 34 (citing 16.19.20.41(A) NMAC and 21 C.F.R. § 1306.04(a) (2005)).*

126. *Id., cert. denied, No. S-1-SC-36470 (June 12, 2017).*

127. Kowalski v. Rose Drugs of Dardanelle, 378 S.W.3d 109, 119 (Ark. 2011) (recognizing that a minority of jurisdictions “have recognized that a pharmacist has a duty beyond merely filling a prescription accurately.”).

128. UJI 13-1101 NM. R. ANN. states “In [treating] [operating upon] [making a diagnosis of] [caring for] a patient, [defendant] is under the duty to possess and apply the knowledge and to use the skill and care ordinarily used by reasonably well-qualified [health care providers] practicing under similar circumstances . . . .”

ideal position to help prevent opioid abuse and overdose.\textsuperscript{130} The CDC describes the pharmacist's role as “multiple and complex,” reflecting professional responsibility and expertise, and lists ways in which a pharmacist must critically evaluate prescriptions.\textsuperscript{131} Such critical evaluation echoes the corresponding responsibility doctrine, in which a pharmacist should assess the prescriptions and the presence of “red flags” to make sure they are prescribed for a “legitimate medical purpose in the usual course of professional practice.”\textsuperscript{132} In essence, the CDC states that there are certainly occasions when a pharmacist is permitted, and even expected, to second guess the physician, diminishing the significance of the policy concern regarding the pharmacist interfering with the doctor/patient relationship. Despite this second guessing, pharmacists and physicians are not adversaries, but team players with the important mutual responsibility of ensuring patient safety and improving outcomes.\textsuperscript{133} The recognition of being part of the health care team reinforces how important pharmacists are, and how critical of a role they play in helping to prevent overdoses.

\textit{Oakey} briefly mentioned the corresponding responsibility doctrine present in 16.19.20.41(A) NMAC and 21 C.F.R. § 1306.04(a).\textsuperscript{134} Reference to this doctrine is surprisingly rare in state court opinions involving pharmacist malpractice.\textsuperscript{135} The DEA’s “red flag test” that helps it determine whether a pharmacist has violated his or her corresponding responsibility has significant overlap with the actions or inactions that form the basis of many plaintiffs’ pharmacy malpractice arguments. Furthermore, as previously stated, New Mexico’s own pharmacy regulations have incorporated these red flags—and their required resolution—into a pharmacist’s mandated responsibility. The result would seem to be that the corresponding responsibility doctrine may be applied to pharmacists in lawsuits, at least in New Mexico, and help form the basis for a heightened standard. 16.19.4.16 NMAC does not specifically create a cause of action, or prescribe specific conduct to resolve red flags, but as the court in \textit{Oakey} stated, the regulation should help inform the standard of care.\textsuperscript{136} It may also be that the DEA’s application of corresponding responsibility and the requirement of resolving red flags should inform the standard of care. If this is the case, the upshot would be that a pharmacist confronted with the facts in \textit{Oakey} would need to resolve the cash payments, high dosages, and prescribed medication combinations of opioids and benzodiazepines, or refuse to dispense the prescriptions to avoid liability.

\begin{itemize}
\item \textsuperscript{131} \textit{Id.} (“evaluating new prescription orders with concurrent treatments, \textit{determining whether medication is improperly prescribed}, and assessing prescription orders for forgery/alteration.”) (emphasis added).
\item \textsuperscript{132} \textit{Id.}; E. Main St. Pharmacy, 75 Fed. Reg. at 66163, 66164 (Oct. 17, 2010).
\item \textsuperscript{133} CDC, Pharmacists, supra note 130.
\item \textsuperscript{134} Oakey v. May Maple Pharmacy, Inc., 2017-NMCA-054, ¶ 34, 399 P.3d 939.
\item \textsuperscript{135} Kowalski v. Rose Drugs of Dardanelle, 378 S.W.3d 116 (Ark. 2011), briefly discussed and dismissed 21 C.F.R. § 1306.04: “looking at the entirety of the regulation, it is clear that a pharmacist has an obligation to ensure that any prescription for a controlled substance is legitimate according to the law. It does not unequivocally [impose a greater duty on pharmacists].”
\item \textsuperscript{136} \textit{Oakey}, 2017-NMCA-054, ¶ 28.
\end{itemize}
Finally, there are strong policy considerations supporting a heightened standard of care that may override the concern over interference in the doctor-patient relationship, a few of which are outlined here. First, a heightened standard of care reflects the pharmacist’s extensive training and role in providing healthcare. Take, for instance, the depth and rigor of Doctor of Pharmacy programs such as the one at the University of New Mexico’s College of Pharmacy, which requires four years of full-time study, with a 230-hour requirement. Pharmacy programs in general often include “more medication-related schooling than any other professional.” A clerical accuracy standard that requires nothing more of the pharmacist than robotic compliance does not reflect the level of training and expertise that a pharmacist wields. Such a standard would, as the court in Horner stated, “denigrate the expertise which a pharmacist’s education provides concerning drugs and their therapeutic use.”

Second, pharmacists may be in a better position to observe and analyze a patient’s behavior, due to the frequency of contact. There have been reports of predicted “doctor shortages” in the United States, and as of 2012 the average primary care physician had around 2,300 patients under his or her care, averaging 93.2 “patient encounters” each week. Furthermore, New Mexico averages approximately 2.11 doctors per 1,000 people. These numbers alone seem to indicate that the physician-patient relationship is not as personalized as it used to be. Pharmacists may encounter patients on a more frequent basis, and may be better able to judge a patient’s demeanor and any red flags that the physician is unaware of.

Third, doctors cannot be entirely relied upon to prevent prescription drug abuse and diversion. A review of DEA orders and case law indicates doctors who function as so-called “pill-mills” exist and present a very real threat to the containment of the opioid epidemic. Additionally, as mentioned above, doctors in the modern era may be overloaded with patients, resulting in oversight and missed cues regarding their patients’ behavior or addictive tendencies. Pharmacists are a valuable component of the health-care team, fully capable of engaging with the patient and primary care physician. It seems odd that given the chance to correct a clear error of judgment or to help prevent abuse, we should require a pharmacist to turn a “blind eye.” A proper solutions-oriented view will utilize every professional in the healthcare team to ensure the ultimate goal: patient health and well-being.

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138. Gardipee, supra note 32.
140. Lenny Bernstein, How many patients should your doctor see each day?, WASH. POST (May 22, 2014), https://www.washingtonpost.com/news/to-your-health/wp/2014/05/22/how-many-patients-should-your-doctor-see-each-day/?utm_term=.0c4a17912048.
includes affirmative action on the pharmacist’s part to ensure resolution of any red flags.

This article does not advocate a wholesale practice of routinely turning patients away when the pharmacist has the slightest inkling of abuse. Refusing to fill a facially valid prescription should be a last resort in order to maintain a patient’s health and well-being. Pain management is a necessary part of health care. Pain medication, including opioids, may be vital to managing a patient’s severe pain. However, we cannot avoid the reality that the United States is in the midst of an opioid overdose crisis. To ignore the situation and ask less of health providers than what they are fully capable of would be disastrous for patient health.

CONCLUSION

The effect of Oakey’s holding is that pharmacists are now potentially exposed to greater liability. The court’s language in Oakey will also provide a clear stimulus to both parties to lay out a stronger foundation for a proposed standard, so that on another appeal from the trial court’s decision, a definitive ruling on the pharmacist’s professional standard of care may be established.143 This professional standard will be established by experts, informed by New Mexico’s pharmacy regulations,144 and potentially federal regulations. It is a unique opportunity, as all matters of first impression are. One thing is clear, however: regardless of the nuances of the pharmacist’s professional standard of care that is ultimately adopted, New Mexico will almost certainly count itself among the minority of jurisdictions applying a heightened standard. How effective this heightened standard will be in combating opioid overdoses will remain to be seen.

143. See Oakey v. May Maple Pharmacy, Inc., 2017-NM CA-054, ¶ 20, 399 P.3d 939 (“[T]he factual record and the law potentially relevant to this determination were not adequately developed below . . . leaving us with an insufficient basis for appellate review.”).

144. Pharmacists may also benefit from the Board of Pharmacy promulgating an amendment to 16.19.4.16 NMAC that specifically releases pharmacists from civil or criminal liability for refusing to dispense medications, similar to Indiana’s immunity provision, IND. CODE ANN. § 25-26-13-16 (2010). The provision states that “The pharmacist is immune from criminal prosecution or civil liability if he, in good faith, refuses to honor a prescription because, in his professional judgment, the honoring of the prescription would . . . aid or abet an addiction or habit. . . .” Id.