

THE ROLE OF THE PHARMACIST IN ADDRESSING THE OPIOID CRISIS

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INTRODUCTION

During the last century, numerous chronic diseases have become manageable with medication therapy. Reliance on medication for diseases like diabetes, high blood pressure, and chronic pain, though effective when taken correctly, has become extremely complicated. Because of this, patients have difficulty self-managing to the point that they are able to take medication correctly a mere fifty-percent of the time.¹ Treatment of acute and chronic pain with opioids, is clearly an area that is prone to medication mismanagement and abuse. As a result, the role of the pharmacist is evolving from that of a medicine provider to a patient care provider, providing health services, in addition to products.

The opioid crisis has emerged as an extremely vexing public health problem, in which pharmacists are directly involved on the supply side, but are underutilized when it comes to mitigating the demand side due to a variety of legal constraints. This article will describe the traditional role of the pharmacist in limiting the supply of opioids, an emerging role directed at mitigating demand, and will offer the proposition of greater direct involvement by the pharmacist in the treatment of patients suffering from addiction.

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¹ See Marie T. Brown & Jennifer K. Bussell, *Medication Adherence: Who Cares?*, 86 MAYO CLINIC PROC. 304, 304 (2011).

BACKGROUND

Opioids are “controlled substances” under the law.² The controlled substance laws provide a variety of roles for pharmacists; essentially they are both subject to the law *and* enforce the law.³ The prescription drug aspects of this law establishes a system requiring accountability for every dose of controlled substance medication from the time of acquisition to the time of dispensing.⁴ In addition, pharmacists are the de facto partners of law enforcement and prescribers in preventing improper diversion of controlled substances from legitimate treatment due to phony prescriptions, theft, and other inappropriate means.⁵ Recent changes to the prescription process help enhance the ability of pharmacists to function in this role, but vigilance will continue to be necessary.

Congress styled a regulatory control framework for abuse-prone medications in 1970 in the Controlled Substances Act.⁶ Based on the Uniform Controlled Substances Act (a guide published by an independent legislative think-tank), the law homogenized an array of federal laws dealing with certain (but not *all*) psychoactive substances under one umbrella.⁷ New York, along with forty-six other states, adopted a slightly modified version of the Uniform law.⁸ New York law and federal controlled substance provisions are similar, with similarities outweighing the differences.⁹

The federal government, through the Drug Enforcement

² See *Which Opiates are Listed as Controlled Substances?*, AM. ADDICTION CTRS., <https://americanaddictioncenters.org/opiates/controlled-substances/> (last visited Jan. 26, 2018).

³ KG WILLIAMS, *NEW YORK PHARMACY PRACTICE REGULATION 2017* (St. John Fisher College 2017).

⁴ See BRIAN T. YEH, *THE CONTROLLED SUBSTANCES ACT: REGULATORY REQUIREMENTS 1, 4, 5* (2012), <https://fas.org/sgp/crs/misc/RL34635.pdf>.

⁵ See 21 C.F.R. § 1301.71(a) (2014); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.65 (1973).

⁶ See Controlled Substances Act, 21 U.S.C. §§ 801–904 (2012).

⁷ See Virgil Van Dusen & Alan R. Spies, *An Overview and Update of the Controlled Substances Act of 1970*, PHARMACY TIMES (Feb. 1, 2007), <http://www.pharmacytimes.com/publications/issue/2007/2007-02/2007-02-6309>.

⁸ See N.Y. PUB. HEALTH LAW §§ 3300–3397 (2017); N.Y. State Controlled Substances Act, ch. 878, 1972 N.Y. Laws 3296. Extensive regulations are catalogued at 10 NYCRR Part 80. See also THE NAT’L CONFERENCE OF COMM’RS ON UNIFORM STATE LAWS, UNIFORM LAW COMMISSION, CONTROLLED SUBSTANCES ACT SUMMARY, <http://www.uniformlaws.org/ActSummary.aspx?title=Controlled%20Substances%20Act> (last visited Jan. 26, 2018).

⁹ Personal Observation.

Administration (“DEA”) within the Department of Justice, has concurrent jurisdiction over controlled substances with a counterpart agency in New York: the Bureau of Narcotic Enforcement (“BNE”), part of the state Department of Health.¹⁰ That is, in the context of diversion of controlled substances from legitimate clinical uses to improper utilization (“abuse”), the DEA and the BNE are empowered to do essentially the same thing. The DEA’s scope of responsibility, as a law enforcement agency, is broader in that it also has a mandate to interdict large-scale trafficking in substances such as methamphetamine, heroin, and marijuana.¹¹ Small-scale transgressions, such as diversion from legitimate sources, are in large part within the scope of the BNE who, therefore, is more likely to be interested in the prescription process than is the DEA. Still, the DEA has concurrent jurisdiction over prescribing and dispensing, but is perhaps more likely to allow BNE to take the lead in this area. Pharmacists play an important role in the process established by these agencies.¹²

TRADITIONAL ROLE: SUPPLY MANAGEMENT

This regulatory process requires an accounting for the physical inventory of medication present at any given instant.¹³ The process regulates by creating a discrete legal status of medication (i.e., “scheduling”), controlling people and institutions through registration, and documenting the flow of medication through mandatory record creation and maintenance.¹⁴ Collectively, these elements create an auditable process for which pharmacists are accountable.

Scheduling

Defining the legal status of medication is central to the regulatory process. Medication is assigned to one of five schedules based on the presence of recognized medical value, relative potential for abuse, relative propensity to cause dependence, and

¹⁰ See *Bureau of Narcotic Enforcement*, N.Y. STATE DEP’T OF HEALTH, <https://www.health.ny.gov/professionals/narcotic/> (last visited Nov. 13, 2017).

¹¹ See *DEA Fact Sheet*, DRUG ENF’T ADMIN. (June 2016), https://www.dea.gov/docs/DEA_Factsheet_june2016.pdf.

¹² See *infra* “Traditional Role.”

¹³ YEH, *supra* note 4, at 5.

¹⁴ *Id.* at 1.

inherent danger.¹⁵ Despite the existence of both a federal list of schedules and another at the state level, there is little conflict or variability between the two.¹⁶ It is interesting that in New York the scheduling decisions are retained by the legislature, while the overwhelming majority of states and the federal government delegate this process to an agency composed of health professionals having specific training necessary to evaluate the propriety of choosing one schedule over another.¹⁷ New York's Commissioner of Health may *reclassify* C-II substances to other schedules under certain circumstances, but does not have the authority to add to a schedule.¹⁸ Congress delegated scheduling authority in the Attorney General, guided by the Commissioner of FDA.¹⁹ New York's complete list of controlled substances is in New York Public Health Law at §3306.²⁰ Criteria, with numerous examples, follow:²¹

SCHEDULE I

(A) The drug or other substance has a *high potential for abuse*.

(B) The drug or other substance has *no currently accepted medical use* in treatment in the United States.

(C) There is a *lack of accepted safety* for use of the drug or other substance under medical supervision.

Examples: marijuana²² (in NY's code "marihuana"), LSD, heroin, peyote, MDMA ("ecstasy"), precursor substances used in synthesis of controlled substances, and many more. Note that many of the substances implicated for increasing overdose mortality are fentanyl derivatives having no known medical value.

SCHEDULE II

(A) The drug or other substance has a *high potential for abuse*.

(B) The drug or other substance has a *currently accepted*

¹⁵ See *Drug Scheduling*, DRUG ENF'T ADMIN., <https://www.dea.gov/druginfo/ds.shtml> (last visited Nov. 13, 2017).

¹⁶ Personal comparison of the two schedules.

¹⁷ Personal Observation.

¹⁸ N.Y. PUB. HEALTH LAW § 3307 (2013).

¹⁹ 21 U.S.C. §§ 811–812 (2012).

²⁰ Under the federal scheme these may be viewed at 21 C.F.R. § 1308.01 (2017).

²¹ This information annotates 21 U.S.C. § 812 (2012).

²² 21 U.S.C. § 812(b)(1)(A)–(C) (It is somewhat counter intuitive to place marijuana in Schedule I; to suggest there is "no known medical use" seems contrary to the medical marijuana programs in a majority of states. Undoubtedly the states and federal government will reckon with this traditional scheduling eventually.)

medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to *severe* psychological or physical *dependence*.²³

Examples: include pharmaceutical-grade cocaine, codeine, fentanyl, morphine, meperidine, oxycodone (e.g., Oxycontin™ and Percocet™), amphetamine derivatives, methylphenidate (Ritalin™), and most oral and injectable barbiturates. Hydrocodone products moved from schedule III on February 23, 2013, all products containing hydrocodone. Also, note that fentanyl does indeed have an established medical value, despite its connection to the increased rates of overdose deaths in recent years.

SCHEDULE III

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.²⁴

Examples: acetaminophen w/codeine, aspirin w/codeine, barbiturate-containing suppositories, dronabinol (Marinol™), buprenorphine, and paregoric. (NY: Chorionic gonadotropin)

SCHEDULE IV

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.²⁵

Examples: benzodiazepines (e.g., Valium™, Ativan™, Xanax™), phenobarbital (a barbiturate), chloral hydrate, pemoline, butorphanol, carisoprodol/meprobamate, all tramadol-containing products.

SCHEDULE V

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted

²³ 21 U.S.C. § 812(b)(2)(A)–(C) (2012).

²⁴ 21 U.S.C. § 812(b)(3)(A)–(C) (2012).

²⁵ 21 U.S.C. § 812(b)(4)(A)–(C) (2012).

medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.²⁶

Examples: Codeine-containing cough suppressants²⁷, anti-diarrheals, diphenoxylate combinations, and mixtures containing paregoric, lacosamide (VimpatTM), ezogabine (PotigaTM), and pregabalin (LyricaTM).

Practical effects of the assigned schedule include the restrictions placed on access to the medication. Note that there is no access to Schedule I drugs, owing to the absence of known medical use and inherent danger. Generally, access restrictions are greater in Schedule II, and ease somewhat as you progress through to Schedule V. Also, the assigned schedule will dictate internal accounting and paperwork controls required over the inventory.

Registration

Federal and NYS controlled substance law includes a system of registration of individuals and organizations based on the activities they engage in that require them to possess or prescribe controlled substances.²⁸ Legally, authorization to purchase, possess, prescribe and/or dispense these substances requires proper registration.²⁹ From a regulatory point of view, registration identifies a responsible party to whom the agency can look for an accounting of activities. For the pharmacist, he or she must be able to demonstrate that the physical quantity of medication in inventory is correct based on records of acquisition and distribution.³⁰ Under the federal definition, the registration category “dispense” includes individual professionals and organizations that have some therapeutic connection to patients involving opioids and other controlled substances.³¹ This broad definition includes professionals with authority to prescribe,

²⁶ 21 U.S.C. § 812(b)(5)(A)–(C) (2012).

²⁷ 21 U.S.C. § 812 (2012) (in Schedule V, codeine-containing products are formulated in much lower concentration than those in Schedule III).

²⁸ 21 U.S.C. § 823 (2012); N.Y. PUB. HEALTH LAW § 3310 (1989).

²⁹ See N.Y. PUB. HEALTH LAW § 3305 (1998) (there are some specific exemptions for temporary possession by law enforcement and common carriers but only in the normal course of official duties).

³⁰ Personal Observation.

³¹ 21 U.S.C. § 802(10) (2012).

community pharmacies, and institutions that store and administer controlled substances.³² There is no direct parallel in NYS, likely because NYS regulates individuals as professionals,³³ and the added layer of registration is unnecessary in addition to being duplicative with federal registration. However, “Institutional dispensers” *are* a distinct category under NYS.³⁴ Institutions with onsite pharmacies obtain a “Class 3” license that permits ordering and maintaining stock of controlled substances in Schedules II-V.³⁵ As noted above, these are also registered with DEA as dispensers. Institutions such as nursing homes and other health-related facilities that do *not* have a pharmacy obtain a “Class 3a” license permitting the organization to obtain, store, and administer controlled substances filled by an outside vendor pharmacy.³⁶ Note that nursing homes would not register with DEA unless they have an in-house pharmacy, and few do.

Record production and maintenance

A third crucial element of controlled substance regulation involves the ability of the DEA or the BNE to conduct an audit of any registrant, for any particular controlled substance, at any time. All records of receipt, inventory, distribution, and theft of controlled substances are required to be maintained in such a fashion that they are “*readily retrievable*”³⁷ on the request of a properly qualified investigator. In essence, an investigator should be able to reconcile records of receipt of controlled substances with records of dispensing such that the ‘paper’ records must match the physical inventory on the shelf.³⁸ Though most states follow the federal rule requiring maintenance of records for at least two years,³⁹ in New York all controlled substance records are maintained for five years.⁴⁰

Pharmacists must make every effort to be meticulous in

³² 21 U.S.C. § 812(b)(3)(A)–(C) (2012).

³³ N.Y. EDUC. LAW § 6505-b (2008) (note that the medical profession is jointly regulated by the Department of Health).

³⁴ N.Y. PUB. HEALTH LAW § 3302(18) (2014); N.Y. COMP. CODES R. & REGS. tit. 10, §§ 80.45–80.51 (2008).

³⁵ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.45 (1973).

³⁶ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.47 (2008).

³⁷ See 21 C.F.R. § 1304.04(h)(1) (2014); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.106(c) (2013).

³⁸ See 21 U.S.C. § 880 (2012); 21 C.F.R. § 1316.03 (2012).

³⁹ 21 C.F.R. § 1304.04(a) (2014).

⁴⁰ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.100 (2008).

compliance with the record-keeping requirements. The agencies, particularly DEA, are known to assign severe penalties for seemingly minor and technical infractions, even in the absence of any suggestion of diversion or bad faith.⁴¹

Records of *receipt* of medication

The front end of the audit trail involves records of receipt, or purchase, of controlled substances. The law requires distinguishing Schedule II acquisition records, which include the overwhelming majority of opioids, from those in other schedules.⁴² The official order blank, DEA 222, is required for purchasing in this schedule.⁴³ The formal procedure for using this form is set out in the regulations and on the back of the 222 form.⁴⁴ In recent years a majority of pharmacies have adopted the electronic “Controlled Substance Ordering System” (“CSOS”)—an electronic process devised by DEA as an alternative to the Form 222 process.⁴⁵ The system adopts a technology that provides the same level of integrity as the paper-based DEA 222 process.⁴⁶ In either case, the pharmacist documents order fulfillment, and the record maintained separately from all other records. Only designated individuals may place an order.⁴⁷

In contrast, documentation of receipt medication in Schedules III, IV, and V is the *invoice* accompanying the medication.⁴⁸ Note that a wider variety of individuals may place the order in these schedules. Legally, these may be filed with invoices for non-controlled substances as long as they are distinguishable and *readily retrievable*.⁴⁹

⁴¹ RICHARD R. ABOOD & KIMBERLY A. BURNS, PHARMACY PRACTICE AND THE LAW 276 (8th ed. 2017).

⁴² See 21 C.F.R. § 1305.13 (2005).

⁴³ 21 U.S.C. § 828 (2012).

⁴⁴ See 21 C.F.R. § 1305.12 (2005).

⁴⁵ 21 C.F.R. § 1305.21 (2005); DRUG ENF'T ADMIN., CSOS OVERVIEW 1, <https://www.deaecom.gov/overview.pdf>.

⁴⁶ See 21 C.F.R. § 1305.21 (2005).

⁴⁷ Additional individuals may be permitted to order in Schedule II when granted a power of attorney on a form specified in DEA regulation. 21 C.F.R. § 1305.05 (2005); 21 C.F.R. § 1305.06 (2005).

⁴⁸ See 21 C.F.R. § 1304.22(c) (2014).

⁴⁹ See 21 C.F.R. § 1304.04(h)(1) (2014); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.106(c) (2013).

Records of distribution of medication

Prescriptions

In the regulatory accounting system, prescriptions constitute the highest volume of distribution of controlled substances for pharmacies and careful maintenance of records is required.⁵⁰ In addition to retaining routine dispensing records, all controlled substance prescriptions dispensed by a practitioner is filed electronically with the BNE database within twenty-four hours.⁵¹ This information populates New York's Prescription Monitoring Program ("PMP") Registry, which intends to minimize the inappropriate prescribing, dispensing, and use of controlled substances⁵² by granting practitioners and pharmacists with "direct, secure access to view their patients' recent controlled substance prescription history."⁵³ The PMP Registry is further discussed in greater detail below.

According to state and federal regulations, inpatient medication orders are not prescriptions⁵⁴ because the medication order is dispensed for "immediate administration to the ultimate user"⁵⁵ In this context, records of administration are included in the patient's medical records.⁵⁶ Additionally, institutional dispensers keep a separate running inventory of all dispensed and prescribed controlled substances.⁵⁷ These records of distribution and administration satisfy the audit trail requirement.⁵⁸

THE PHARMACIST'S "CORRESPONDING RESPONSIBILITY"

Title 10, section 80.65 of the New York Code ⁵⁹ states that "a

⁵⁰ See 21 C.F.R. § 1304.04 (2014); PHARMACEUTICAL CARE MGMT. ASS'N, PHARMACY DISTRIBUTION CHANNELS FOR NARCOTICS AND OTHER CONTROLLED SUBSTANCES 3, <https://www.pcmanet.org/wp-content/uploads/2016/08/visante-report-on-controlled-substances-mar-2012.pdf>.

⁵¹ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.68(d)(2) (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.71(e) (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.73(f)(1) (2013).

⁵² N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(1) (2013).

⁵³ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(1) (2013).

⁵⁴ 21 C.F.R. § 1300.01 (2005) ("Prescription means an order for medication which is dispensed to or for an ultimate user.").

⁵⁵ 21 C.F.R. § 1300.01 (2017).

⁵⁶ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.48(a)(3) (1973).

⁵⁷ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.48(a)(2) (1973).

⁵⁸ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.46(d)-(f)(2) (2008)

⁵⁹ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.65 (1973).

prescription for a controlled substance must be issued for a *legitimate medical purpose* by a practitioner acting within the usual course of his professional practice” and assigns “responsibility for the proper prescribing and dispensing of controlled substances upon the prescribing practitioner,” and further declares that a “corresponding responsibility shall rest with the pharmacist who fills the prescription” to assure its legitimacy.⁶⁰ Federal regulations also places a corresponding responsibility upon pharmacists using the same language.⁶¹ That said, the ambiguous language has at times been problematic since the proscribed conduct is not self-explanatory. On many occasions, courts have provided clarification to the notion of “legitimate medical purpose”⁶² through criminal and civil litigation.⁶³

In fact, there is an overwhelming body of case law finding the regulations constitutional⁶⁴ and a valid exercise of regulatory authority.⁶⁵ While most case law looks at the actions of the prescriber,⁶⁶ the pharmacist’s corresponding responsibility has been construed as well⁶⁷ Recent case law has also determined that an organization is accountable for ignoring lack of legitimacy for filling prescriptions that are without an appropriate therapeutic purpose.⁶⁸

The cases generally have provided that pharmacists who fill prescriptions that they know, or *should know*, are not for a legitimate medical purpose, are subject to criminal and civil liability corresponding to that of the prescriber.⁶⁹ Most often the

⁶⁰ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.65 (1973).

⁶¹ 21 C.F.R. § 1306.04(a) (2005).

⁶² See *United States v. Birbragher*, 576 F. Supp. 2d 1000, 1011 (N.D. Iowa 2008).

⁶³ *Birbragher*, 576 F. Supp. 2d at 1011 (finding that the regulations provided adequate notice of this corresponding responsibility and has not lend itself to arbitrary enforcement).

⁶⁴ *Id.*

⁶⁵ See *Ryan v. Dan’s Food Stores, Inc.*, 972 P.2d 395, 406 (Utah 1998) (Section 1306.04 of the C.F.R. does contain a clear and substantial public policy, but it is a narrow one, one which only prohibits pharmacists from *knowingly* filling an improper prescription).

⁶⁶ *Birbragher*, 576 F. Supp. 2d at 1012 (citing *U.S. v. Moore*, 423 US 122 (1975) (holding that a physician could be charged with criminal conduct for dispensing methadone outside the usual course of professional practice)).

⁶⁷ See *United States v. Hayes*, 595 F.2d 258, 258 (5th Cir. 1979). See also *United States v. Lawson*, 682 F.2d. 480, 482 (4th Cir. 1982).

⁶⁸ See *United States v. Appalachian Reg’l Healthcare, Inc.*, 246 F. Supp. 3d 1184, 1189–90 (E.D. Ky. 2017).

⁶⁹ *Hayes*, 595 F.2d at 258.

facts involve prescriptions filled under circumstances that should have made the pharmacist suspicious. In *United States v. Hayes*, the defendant pharmacist was charged with knowingly dispensing an opioid, hydromorphone, on “purported” prescriptions that he knew had false patient names or “were not issued in the usual course of professional practice.”⁷⁰ The court illustrated that the pharmacist, in one month, dispensed 3,400 hydromorphone tablets from thirty-four prescriptions, *for a single patient*, and the next month 101 prescriptions.⁷¹ The relative volume of prescriptions, large quantities, obviously fictitious names, suspicious conduct of the prescriber, and other qualities that depart from normal trends experienced in practice, are all, logically, relevant factors. Stated another way, the dispensing pharmacist may not ignore circumstances that should alert to the need for additional investigation.

The ambiguous nature of “legitimate medical purpose” is not self-defining, and logically, problematic in guiding conduct. That is, how far should the pharmacist’s judgment go in connection with any individual prescription? Since the pharmacist’s training and scope of practice does not include diagnosis of disease or prescribing authority, then intuitively, the corresponding responsibility does not include second-guessing the judgement of the prescriber with regard to choice of therapy.

New York’s Official Prescription

Of course, the prescription is the central to the distribution of, and accounting for opioids, with the pharmacist figuring prominently in quality assurance, process integrity, and record-keeping for audit purposes. A little background is useful.

In 1972, as part of the Controlled Substances Act,⁷² the state legislature required that a three-page (“triplicate”) prescription utilized, for each Schedule II dispensed.⁷³ The prescriber would retain copy 3, and after filling, the pharmacist would retain and file the top copy, and send copy 2 to the Health Department.⁷⁴ This process enabled surveillance of prescribing and dispensing by the Bureau of Controlled Substances (or “BCS,” predecessor to the

⁷⁰ *Id.* at 259.

⁷¹ *Id.* at 261.

⁷² N.Y. PUB. HEALTH LAW § 3331 (2016).

⁷³ N.Y. PUB. HEALTH LAW § 3319 (1973).

⁷⁴ N.Y. PUB. HEALTH LAW § 3320 (2014).

BNE). Physicians and patients immediately challenged the statute as an invasion of privacy.⁷⁵ The Federal Court for the Southern District of New York initially issued an injunction.⁷⁶ However, in *Whalen v. Roe*,⁷⁷ the United States Supreme Court, noting the oft-repudiated holding in *Lochner v. New York*,⁷⁸ reversed the lower court in holding that the triplicate prescription law was a reasonable exercise of the state's broad police power.⁷⁹ The confidentiality required of the agency did not pose a threat of public disclosure or the patient's private health information, or to the interest of making decisions independently.⁸⁰

In 1986, reacting to the perception of widespread abuse, the Department of Health (hereinafter "DoH") added Schedule IV benzodiazepine drugs (e.g., Valium®, Ativan®, etc.) to the triplicate prescription requirement⁸¹ and the prescribing and dispensing restrictions associated with medication in Schedule II.⁸² The Appellate Division upheld a preliminary injunction against implementation.⁸³ The New York Court of Appeals reversed the Appellate Division, removing the injunction because the regulations were not "outside of the authority constitutionally delegated to [the Commissioner] under the Public Health Law."⁸⁴ These two cases had the combined effect of cementing the broad authority of the legislature and the DoH in determining the prescribing and dispensing processes.

With validation of the substance and process of regulation by the courts, New York State has been innovative, expanding its prescription program in significant ways. Since then, the triplicate prescription has been retired in favor of a one-page document, the "Official" prescription.⁸⁵ The "Forge Proof" prescription amendments changed the format of the prescription document adding Section 21 (now Section 281) to the Public Health Law

⁷⁵ *Roe v. Ingraham*, 403 F. Supp. 931 (S.D.N.Y. 1975).

⁷⁶ *Id.*

⁷⁷ *Whalen v. Roe*, 429 U.S. 589 (1977).

⁷⁸ *Id.* at 597. *See* *Lochner v. New York*, 198 U.S. 45 (1905).

⁷⁹ *Whalen*, 429 U.S. at 598.

⁸⁰ *Id.* at 599.

⁸¹ Michael Norman, *State to Stiffen Sedative Rules*, N.Y. TIMES (Oct. 1, 1986), <http://www.nytimes.com/1986/10/01/nyregion/state-to-stiffen-sedative-rules.html>.

⁸² *Id.* *See* N.Y. COMP CODES R. & REGS. tit. 10, § 80.68 (2013).

⁸³ *Doe v. Axelrod*, 527 N.Y.S.2d 385 (App. Div. 1988) (later reversed in part).

⁸⁴ *Doe v. Axelrod*, 532 N.E.2d 1272 (N.Y. 1988).

⁸⁵ N.Y. PUB. HEALTH LAW § 21 (2012).

which requires the use of official forms for “*all prescriptions written in this state.*”⁸⁶ The BNE established regulatory machinery to distribute non-reproducible and non-transferable prescriptions, containing a unique serial number, to practitioners and facilities.⁸⁷

In 2012, the Internet System for Tracking Over-Prescribing (I-STOP)⁸⁸ went a step further. With the stated intent to “establish a prescription monitoring program registry that is designed to utilize real time data, integrate electronic prescribing, combat over-prescribing and doctor-shopping, and curtail abuse and illegal diversion without compromising access to controlled substances for legitimate health care purposes,” the legislature required an electronic prescribing process for all medication.⁸⁹ Effective on March 27, 2016,⁹⁰ New York became the first state to make the electronic process mandatory.

There are exceptions to the requirement of an official, or electronic, prescription prior to dispensing. In the event of an emergency, a quantity of a schedule II medication sufficient to cover the emergency period, to a maximum five-day supply, may be dispensed pursuant to an “oral” or telephone order.⁹¹ The criteria for an emergency situation are essentially the same as the federal regulation,⁹² as follows:

For the purposes of authorizing an oral prescription of a controlled substance listed in Schedule II of the Federal Controlled Substances Act, the term “emergency situation” means those situations in which the prescribing practitioner determines:

- (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;
- (b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II of the Act; and
- (c) That it is not reasonably possible for the prescribing practitioner

⁸⁶ See N.Y. PUB. HEALTH LAW § 281 (2017).

⁸⁷ N.Y. PUB. HEALTH LAW § 281 (2017); N.Y. PUB. HEALTH LAW § 3338 (2004). In regulation, N.Y. COMP CODES R. & REGS. tit. 10, §§ 80.67 (2013), 80.77 (2013), 910.1 (2008), 910.2 (2013), 910.3 (2008), 910.4 (2008), and 910.5 (2008), that cover definition, prescribing, registration, issuing, safeguarding, and dispensing on official prescriptions.

⁸⁸ S.B. 7637, 2012 Leg., 2011–2012 Sess. (N.Y. 2012).

⁸⁹ *Id.*

⁹⁰ See N.Y. State Bureau of Narcotic Enf't, *Frequently Asked Questions for Electronic Prescribing*, N.Y. STATE DEP'T OF HEALTH (revised Nov. 2016), https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/docs/epcs_faqs.pdf.

⁹¹ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.67 (2013).

⁹² 21 C.F.R. § 1306.11(d) (2010).

to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.⁹³

The NYS regulations permit a maximum five-day supply for emergency oral orders.⁹⁴ A follow-up prescription corresponding to the emergency order must be delivered to the pharmacy with the phrase “Authorization for Emergency Dispensing” (“AFED”) written on its face within seventy-two hours.⁹⁵ The quantity of dosage units on the follow up may not be more than what was initially ordered. Additional quantities, if desired, require a separate prescription. If there is no follow-up delivered, the pharmacy is required to write follow-up not received on the back of the emergency order and notify the BNE in writing within seven days from the date of dispensing.⁹⁶ The follow-up is attached to the emergency order, endorsed as an original with the date of dispensing, prescription number, DEA number of the pharmacy, and signature.⁹⁷

In 2016, Section 3331(5)(b) and (c) were amended to limit prescribing opioids for acute pain to a seven-day supply.⁹⁸ Acute pain is pain that the practitioner “reasonably expects to last only a short period of time,” and may be extended to greater quantities on “subsequent consultations.”⁹⁹ The Commissioner of Health clarified that pharmacists are NOT required to verify with the prescriber whether an opioid prescription written for greater than a 7-day supply is in accordance with the prescriber’s mandate under the statute.¹⁰⁰

⁹³ See 21 C.F.R. § 290.10 (1975).

⁹⁴ N.Y. COMP CODES R. & REGS. tit. 10, § 80.68(b) (2013). The federal law is more ambiguous allowing provision of enough medication to cover the emergency period, however long that may be. See 21 C.F.R. § 1306.11(d)(1) (2010).

⁹⁵ N.Y. COMP CODES R. & REGS. tit. 10, § 80.68(c) (2013). The DEA allows 7 days. See U.S. DEP’T OF JUSTICE, DRUG ENFORCEMENT ADMIN., DIVERSION CONTROL DIV., PHARMACIST’S MANUAL – SECTION IX – VALID PRESCRIPTION REQUIREMENTS (revised 2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

⁹⁶ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.68 (2013). The DEA also requires notification if follow-up is not received, but the time frame is not specified.

⁹⁷ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.68 (2013).

⁹⁸ N.Y. PUB. HEALTH LAW § 3331(5)(b)–(c) (2016).

⁹⁹ N.Y. PUB. HEALTH LAW § 3331(5)(b)–(c) (2016).

¹⁰⁰ *Electronic Prescribing Exceptions – Dispensing Clarification for Pharmacists*, N.Y. STATE DEPT OF HEALTH, (revised Apr. 2016), https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/elec_pres_except_disp_clar_4_pharm.htm.

Reporting and Surveillance

Beginning with the triplicate prescription for Schedule II medication in 1972, the pharmacist has been required to supply dispensing data to the Department of Health.¹⁰¹ After dispensing the medication and endorsing the prescription, the pharmacist reported all dispensing activity on a monthly basis. Containing the identities of the prescriber, patient, pharmacist, medication and date, the state was enabled to track patterns of distribution that might be indicative of misuse or abuse.¹⁰² In 2006, this was expanded to all controlled substances and required an electronic format of communication.¹⁰³

In 2013, pharmacists were required to provide real time reporting of delivery of medication to the patient.¹⁰⁴ That is, within twenty-four hours of delivery of controlled substance to the patient, associated data¹⁰⁵ is delivered electronically¹⁰⁶ to the registry and then available for review. This provides a data base of information for prescribers who are *required* to consult, and pharmacists who are *permitted* to consult.¹⁰⁷ This expansion of information formed the foundation for New York's "prescription monitoring program registry" (hereinafter "registry"), transforming the surveillance database into a clinical tool for prescribers and pharmacists.¹⁰⁸

Prescribers, or a designee, are required to review the registry prior to issuing a controlled substance prescription.¹⁰⁹ In contrast, pharmacists *may* access the database on receipt of a new prescription.¹¹⁰ That is, upon receipt of one or more controlled

¹⁰¹ N.Y. PUB. HEALTH LAW §§ 3331–3333; N.Y. PUB. HEALTH LAW § 3339 (2004). See *supra* text accompanying note 69.

¹⁰² N.Y. PUB. HEALTH LAW §§ 3331–3333; N.Y. PUB. HEALTH LAW § 3339 (2004). See *supra* text accompanying note 69.

¹⁰³ N.Y. PUB. HEALTH LAW § 3333(4) (2013).

¹⁰⁴ N.Y. PUB. HEALTH LAW § 3306 (2016).

¹⁰⁵ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.68(d)(2)(i)–(xvi) (2013).

¹⁰⁶ N.Y. PUB. HEALTH LAW § 3333(4) (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.73(f) (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.74(e) (2013).

¹⁰⁷ N.Y. PUB. HEALTH LAW § 3306 (2016).

¹⁰⁸ N.Y. PUB. HEALTH LAW § 3343-a (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63 (2013).

¹⁰⁹ N.Y. PUB. HEALTH LAW § 3343-a(2) (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(1) (2013). Certain professions, specialty areas, and clinical contexts are exempted from consulting the registry in N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(2) (2013).

¹¹⁰ N.Y. PUB. HEALTH LAW § 3343-a(3) (2013); N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(4) (emphasis added).

substance prescriptions, a pharmacist or designee¹¹¹ may review the “controlled substance history.” An individual Health Commerce System (HCS) account with the DoH is required to access the registry.¹¹² According to the regulations, a “designee” may be a pharmacist who does not have an HCS account, or a pharmacy intern.¹¹³ In either case, the designee must be located within the state when accessing the registry and be an employee or contractor of the same pharmacy. Also, the designating pharmacist must maintain a list of designees and notify the DoH “immediately” upon revocation of authority, or termination of employment.¹¹⁴

The regulations do not provide additional guidance concerning the circumstances or substance of the review. The information enables review of dispensing information on a patient-specific basis, as is already required of pharmacists as clinical counselors.¹¹⁵ That is, the registry becomes an extension of the required medication profile and includes not only medications, but prescribers, pharmacies, and date of medication delivery of each controlled substance to the patient.¹¹⁶ Indeed, clinical decisions become more informed as to the propriety of prescribing or dispensing an opioid or other controlled substance in a particular instance. This enables addressing clinical concerns, such as over or under-utilization. Reviewing the registry would also inform any concerns about potential diversion to improper uses.¹¹⁷

One additional note: New York has joined many states with PMPs having “interoperable” software permitting sharing of prescribing and dispensing information among states.¹¹⁸ Representatives of the Bureau of Narcotic Enforcement recently reported connection to a majority of states in the region, with

¹¹¹ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(4) (2013).

¹¹² *Instructions to Access the Prescription Monitoring Program (PMP) Registry*, N.Y. STATE DEP'T OF HEALTH (revised Oct. 2013), https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/online_notification_program/.

¹¹³ N.Y. EDUC. LAW § 6806 (1989).

¹¹⁴ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.63(c)(4)(i)–(ii) (2013).

¹¹⁵ See N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(a)(9)(7) (2014) (allowing for pharmacists and their interns to conduct a review without providing circumstances that would compel such review).

¹¹⁶ See N.Y. Pub. Health Law §3343-a(1)(b) (2012) (requiring a record of “patient specific information” surpassing just medication).

¹¹⁷ See N.Y. COMP. CODES R. REGS. tit. 10, § 80.65 (1973) (explaining the primary purpose of prescriptions and obligations of professionals who write prescriptions).

¹¹⁸ N.Y. PUB. HEALTH LAW §3343-a(1)(c) (2013).

intention to continue to make connections going forward.¹¹⁹

Enforcement has been identified at all levels as an ongoing priority, but there is little new to report on in this area. Unauthorized possession and sale are still criminal acts, and we will still continue to prevent diversion to inappropriate uses as addressed by the controlled substances laws.¹²⁰ One of the key process changes is a limit on the prescribed quantity of an opioid for initial treatment of acute pain to a seven-day supply; greater quantities in subsequent prescriptions based on the clinical judgement.¹²¹ Pharmacists are not required to enforce this.¹²² The idea is to limit the supply of opioids available for diversion, and to get professional reassessment for ongoing needs.

The Federal Controlled Substances Act provides that it is unlawful to transfer a controlled substance without the appropriate registration.¹²³ For the “ultimate user,” the patient, this has traditionally meant that it is unlawful to return unneeded opioids and other controlled substance medication obtained by way of prescription.¹²⁴ Indeed, regulations require the statement “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed” on medication in schedules II, III, and IV.¹²⁵ This put patients, pharmacists, and prescribers at legal risk when patients requested to return unwanted opioids for destruction, and created a pool of medication available for diversion and abuse. The Secure and Responsible Drug Disposal Act of 2010¹²⁶ required the DEA to

¹¹⁹ See *New York State Pharmacy Conference Minutes*, PHARMACISTS SOC'Y OF THE STATE OF N.Y. (Sept. 11, 2015), https://c.yomcdn.com/sites/pssny.site-ym.com/resource/resmgr/nys_pharm_conf_minutes/9-11-15_pharm_conf_minutes.pdf?hhSearchTerms=%22pmp%22 (noting the Bureau's efforts to make information accessible between states).

¹²⁰ See N.Y. COMP. CODES R. & REGS. tit. 10, § 80.106(c) (2013); 21 C.F.R. § 1304.04 (2014).

¹²¹ N.Y. PUB. HEALTH LAW § 3331(5)(b) – (c) (2016).

¹²² *Frequently Asked Questions: Limited Initial Opioid Prescribing*, N.Y. STATE DEPT OF HEALTH, https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/docs/combat_heroin_legislation_faq.pdf (last visited March 18, 2018).

¹²³ See 21 C.F.R. § 290.5 (1975) (requiring the appropriate labeling for controlled substances).

¹²⁴ See *Disposal of Controlled Substances*, 79 Fed. Reg. 53,520, 53520 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, & 1317) (explaining the history before The Disposal Act and its impact on ultimate users).

¹²⁵ 21 C.F.R. § 290.5 (1975).

¹²⁶ See *Secure and Responsible Drug Disposal Act of 2010*, Pub. L. No. 111–273, 124 Stat. 2858.

promulgate regulations that would allow a secure means of disposal by patients.

In September 2013, the state legislature amended the Public Health Law section 3343-b to permit pharmacies to voluntarily participate in disposal programs for unwanted controlled substances pharmacies.¹²⁷ Note that pharmacies must apply to BNE to participate in this program. The law permits return by “individual members of the public” without identification or fear of criminal charges associated with unlawful possession or trafficking for medication dispensed to someone else; remember, federal law prohibits transfer by the ultimate user.¹²⁸ On September 9, 2014, the DEA issued regulations of its own as required under the Secure and Responsible Disposal Act of 2010.¹²⁹ It complicated New York’s law by requiring drop off by the “ultimate user.”¹³⁰ Of course, the state is not obligated to enforce federal law.

In June 2017, legislation passing both the New York State Senate and the Assembly again amended Public Health Law 3343-b requiring “chain pharmacies” (ten or more) to provide “drug disposal options” through a “collection receptacle,” “mail-back program,” or other mechanism approved by DEA.¹³¹ In addition, pharmacies “shall not charge a consumer more than two dollars [for a] mail-back envelope.”¹³² As of November 1, 2017, the Governor has not acted on this bill.

In addition to voluntarily participating pharmacies, other drop off sites may include hospitals, long-term care facilities (program managed by vendor pharmacy), clinics with on-site pharmacy, and

¹²⁷ N.Y. PUB. HEALTH LAW § 3343-b (2015). Proposed DEA regulations were published in 2012. Disposal of Controlled Substances, 77 Fed. Reg. 75,784, 75,784 (Dec. 21, 2012) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, 1317, & 1321) (implementing Secure and Responsible Drug Disposal Act of 2010).

¹²⁸ N.Y. PUB. HEALTH LAW § 3343-b(1) (2015); 21 C.F.R. § 290.5 (1975) (noting that C.F.R. represents the federal law on transferring controlled substances, while N.Y. Public Health Law represents New York state’s laws on controlled substances).

¹²⁹ See Secure and Responsible Drug Disposal Act of 2010, S. Res. 3397, 111th Cong. (2010). See also Disposal of Controlled Substances, 79 Fed. Reg. 53,520, 53,520 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, & 1317).

¹³⁰ Disposal of Controlled Substances, 79 Fed. Reg. 53,520, 53,521 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, & 1317).

¹³¹ A.B. 387, 2017 Leg., 2017–2018 Sess. (N.Y. 2017); S.B. 6750, 2017 Leg., 2017–2018 Sess. (N.Y. 2017).

¹³² S.B. 6750, 2017 Leg., 2017–2018 Sess. (N.Y. 2017).

Narcotic Treatment Programs.¹³³ Similar to pharmacies, an individual may place medication in a designated receptacle, or mail in a pre-paid mailer.

EMERGING CLINICAL ROLE OF THE PHARMACIST:
MINIMIZING DEMAND

Prospective Drug Use Review and Patient Counseling

At the time of dispensing, pharmacists are in a unique position to educate the patient about opioids, including optimizing use, and managing risks. Indirectly, it was an act of Congress that prodded each individual state into requiring this basic pharmaceutical care. In 1990, a budget reconciliation provision in Congress called “OBRA-90”¹³⁴ conditioned continued receipt of federal Medicaid funds on demanding more patient care services from pharmacists.¹³⁵ The result was that all 50 states passed some form of mandate directing pharmacists to maintain a full database of medication-related information, make prospective reviews of medication regimens, and offer to counsel patients about their medication.¹³⁶ New York’s version is contained in §63.6(b)8 of the Regulations of the Commissioner of Education.¹³⁷ Also, maintenance of a database, “profiles,” with patient-specific information is required to support this process.¹³⁸ The information includes the age, gender, contact information (address, phone number), drug allergies and insensitivities, chronic diseases, and a comprehensive list of medications.¹³⁹

Prior to dispensing, the pharmacist or intern must conduct a prospective drug use review (“PDUR”).¹⁴⁰ The Regulations require that the PDUR include screening for:

- duplications

¹³³ Disposal of Controlled Substances, 79 Fed. Reg. 53,520, 53,521 (Sept. 9, 2014) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1305, 1307, & 1317).

¹³⁴ Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388. See also Jesse C. Vivian & Joseph L. Fink, *OBRA’90 at Sweet Sixteen: A Retrospective Review*, U.S. PHARMACIST (Mar. 20, 2008), <https://www.uspharmacist.com/article/obra-90-at-sweet-sixteen-a-retrospective-review> (describing the Omnibus Budget Reconciliation Act of 1990 as “OBRA ‘90.”).

¹³⁵ 42 U.S.C. §1396r-8(g)(2)(A) (2012).

¹³⁶ Vivian & Fink, *supra*, note 133, at tbl.1.

¹³⁷ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6 (b)(7)–(8)(a) (1999).

¹³⁸ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6 (b)(7) (1999).

¹³⁹ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6 (b)(7) (1999).

¹⁴⁰ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6 (b)(7) (1999).

- drug-drug interactions
- incorrect dosages and/or durations
- allergies
- clinical abuse or misuse.¹⁴¹

When a new prescription is dispensed, the pharmacist (or intern) is required to personally counsel the “patient or person authorized to act” for the patient.¹⁴² Note this is a change promulgated in 2003. Previously the law required the pharmacist (or intern) to personally *offer* to consult with the patient each time medication is dispensed.¹⁴³ Now with the “offer” element removed; counseling *shall* be provided.¹⁴⁴ Though perhaps subtle, this is an important distinction; the law does not call for an *offer* to counsel, but the *act* of counseling. So, in theory, the patient is less likely to refuse and more likely to be counseled. Note that this mandate includes new patients, new medications, and changes to existing therapy; increased dose, change in directions, and change in route.¹⁴⁵ For refills, an *offer* to counsel is still required, but this may come from staff members other than pharmacists or interns.¹⁴⁶

The Regulation is not prescriptive about the content of counseling, but does suggest that, based on professional judgment, topics may include:

- the name, description, and known indications
- dosage form, dosage, route, and duration of treatment
- special directions concerning preparation or administration
- common adverse effects, interactions, contraindications and how to avoid, recognize and manage if they occur
- self-monitoring
- storage and refill information
- action to take in the event of a missed dose.¹⁴⁷

Counseling is a professional function provided by a pharmacist or intern. The act of counseling is not delegable to unlicensed personnel.¹⁴⁸ Note that, if a patient refuses to provide the

¹⁴¹ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(7) (1999).

¹⁴² N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(i)(a) (2003).

¹⁴³ See N.Y. COMP. CODE R. & REGS. tit. 8, § 63.6(b)(8)(i)(a) (2003).

¹⁴⁴ N.Y. COMP. CODE R. & REGS. tit. 8, § 63.6(b)(8)(i)(a) (2003).

¹⁴⁵ See N.Y. COMP. CODE R. & REGS. tit. 8, § 63.6(b)(8)(i)(a) (2003).

¹⁴⁶ See N.Y. COMP. CODE R. & REGS. tit. 8, § 63.6(b)(8)(i)(d) (2003).

¹⁴⁷ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(i)(a)(1)–(8) (2003).

¹⁴⁸ N.Y. COMP. CODES R. & REGS. tit. 8, § 29.7(a)(21)(ii)(b)(6) (1984); N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(i)(b) (2003).

information necessary to constitute the patient profile or refuses counseling, the prescription may be filled, but the refusal to engage must be documented in the records of the pharmacy.¹⁴⁹ From a risk management perspective, records of refusal should be made systematically, easily identifiable, and readily retrievable.

A reasonable observation is that not all dispensed medication lends itself to the opportunity to counsel or offer to counsel. Mail order or other delivery services are obvious situations. In that situation, each time the prescription is dispensed a *written* offer to counsel must be made.¹⁵⁰ The telephone number must be provided with the notice and it must be toll-free for mail-order pharmacies.¹⁵¹ This bypasses the face-to-face counseling that is mandatory in the brick-and-mortar community pharmacy, and the opportunity to provide this opportunity for intervention is missed.

There are two situations in which the mail-order must give specific notice to the patient: obvious drug therapy problems and dispensing a prescriber-approved alternative.¹⁵² A “prescriber-approved alternative” is a medication that is a different generic medication than the one ordered.¹⁵³ This is often driven by the pharmacy benefit manager’s preferred medication. Personal notice by telephone is preferred if this option is reasonably available to the company. Attempts to contact must be documented and the offer to counsel “shall be provided personally” by a pharmacist or intern.¹⁵⁴ If there are “potential drug therapy problems” posed by the prescription, a pharmacist or intern “shall personally contact the patient.”¹⁵⁵ It would be relatively easy to include counseling anytime an opioid is dispensed.

EXPANDED SYRINGE ACCESS PROGRAM

Though typically requiring a prescription, in the interested of decreasing needle-sharing and the spread of blood-borne infections, such as hepatitis and HIV, New York has relaxed the prescription requirement for syringes under the Expanded Syringe

¹⁴⁹ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(i)(c) (2003).

¹⁵⁰ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii) (1999).

¹⁵¹ See N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii)(a) (1999).

¹⁵² See N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii)(d)(1) (1999); N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii)(c)(1) (1999).

¹⁵³ See N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii)(c) (1999).

¹⁵⁴ N.Y. COMP. CODE R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii)(c)(5) (1999); N.Y. COMP. CODE R. & REGS. tit. 8, § 63.6(b)(8)(e)(ii)(c)(4) (1999).

¹⁵⁵ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.6(b)(8)(ii)(d) (1999).

Access Program (“ESAP”).¹⁵⁶ Provided without a prescription by a pharmacy, health care facilities, and providers, syringes may sold in quantities of ten or less to patients at least eighteen years of age; organizations and providers must register with the Department of Health.¹⁵⁷ Accompanying each transaction is a leaflet that explains proper use, the risk of transmission of blood-borne pathogens (HIV, Hepatitis B and C), risks of injecting drugs, proper disposal, and how to access drug treatment.¹⁵⁸ Viewing this as an opportunity to reach a population of injecting drug users, in 2016 the NYS legislature amended this law to encourage pharmacists to provide direct counseling and referral services to purchasers under ESAP.¹⁵⁹ Counseling “for the purpose of”:

- Preventing injection drug use
- Provision of drug treatment
- Preventing and treating Hepatitis C
- Preventing drug overdose
- Testing for HIV
- Providing pre-exposure prophylaxis, and
- Non-occupational post-exposure prophylaxis.¹⁶⁰

The amendment makes that providing counseling, is at the “professional discretion” of the pharmacist, as is the actual subject matter.¹⁶¹ Obviously the legislature views this point of contact as a significant opportunity to try to influence the very risky behavior of the purchaser, and to highlight treatment options.¹⁶²

¹⁵⁶ N.Y. PUB. HEALTH LAW § 3381(1)(c) (2016); N.Y. PUB. HEALTH LAW § 3381(5) (2016) (with regulations at N.Y. COMP. CODES R. & REGS. tit. 10, § 80.137 (2017)). See also *Expanded Syringe Access Program (ESAP): Overview of the Law and Regulations*, N.Y. STATE DEPT OF HEALTH, https://www.health.ny.gov/diseases/aids/consumers/prevention/needles_syringes/esap/overview.htm (last visited Jan. 28, 2018).

¹⁵⁷ N.Y. PUB. HEALTH LAW § 3381(1)(c) (2016); N.Y. PUB. HEALTH LAW § 3381(5)(b) (2016).

¹⁵⁸ N.Y. PUB. HEALTH LAW § 3381(1)(c) (2016); N.Y. PUB. HEALTH LAW § 3381(5)(c) (2016).

¹⁵⁹ S.B. 8139, 2016 Leg., 2015–2016 Sess. (N.Y. 2016).

¹⁶⁰ S.B. 8139, 2016 Leg., 2015–2016 Sess. (N.Y. 2016); N.Y. PUB. HEALTH LAW § 3381(1)(e) (2016).

¹⁶¹ S.B. 8139, 2016 Leg., 2015–2016 Sess. (N.Y. 2016); N.Y. PUB. HEALTH LAW § 3381(1)(e) (2016).

¹⁶² Note also that the Session Laws of 2016 amended the Education Law permitting pharmacists to dispense post-exposure prophylaxis for HIV under protocol with a physician or nurse practitioner. See HIV—Sexually Transmitted Diseases—Tests and Testing, ch. 502, sec. 7, 2016 N.Y. Sess. Laws; N.Y. EDUC. LAW § 6801(5) (2016); N.Y. COMP. CODES R. & REGS. tit. 8, § 63.13 (2017).

COLLABORATION WITH PRESCRIBERS

In states with advanced practice laws pharmacists have been effective at improving therapeutic outcomes in patients with chronic diseases.¹⁶³ This level of practice involves legal authority to enter into collaborative agreements (or “protocols”) with prescribing practitioners (physicians, nurse practitioners, etc.) to provide more detailed medication therapy management in patients with chronic diseases.¹⁶⁴ Numerous peer-reviewed articles demonstrate significant improvement in treatment of patients with diabetes,¹⁶⁵ high blood pressure,¹⁶⁶ asthma,¹⁶⁷ blood clots,¹⁶⁸ and more. Results are obtained when patients receive additional education, detailed care planning, and counseling by a pharmacist working in concert with the patient.¹⁶⁹ Patients are more readily able to take their medication correctly, and minimize the secondary effects of poor medication management such as increased hospitalization, emergency room visits, etc. There seems to be no inherent reason why this process, well-established in so many disease states, would not work well for patients with chronic pain who are more prone to opioid dependence and overdose.

In utilizing collaborative care, one outpatient practice model showed that a pharmacist/physician team had improved pain scores and was associated with a lower overall cost of treatment with high levels of satisfaction reported by patients (0 = not satisfied at all; 10 = completely satisfied).¹⁷⁰ In this model the supervising physician made initial diagnosis and treatment and

¹⁶³ See *infra* notes 164–67.

¹⁶⁴ See *infra* notes 164–67.

¹⁶⁵ Carole W. Cranor et al., *The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program*, 43 J. AM. PHARMACEUTICAL ASS'N 173, 174, 182 (2003).

¹⁶⁶ Barry A. Bunting et al., *The Asheville Project: Clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia*, 48 J. AM. PHARMACISTS ASS'N 23, 31 (2008).

¹⁶⁷ Hanne Herborg et al., *Improving Drug Therapy for Patients with Asthma—Part I: Patient outcomes*, 41 J. AM. PHARMACEUTICAL ASS'N 539, 549 (2001).

¹⁶⁸ Nadia A. Amruso, *Ability of Clinical Pharmacists in a Community Pharmacy Setting to Manage Anticoagulation Therapy*, 44 J. AM. PHARMACISTS ASS'N 467, 471 (2004).

¹⁶⁹ See *supra* notes 164–67.

¹⁷⁰ Marlene Slipp & Robert Burnham, *Medication management of chronic pain: A comparison of 2 care delivery models*, 150 CANADIAN PHARMACISTS J. 112, 113–16 (2017).

the pharmacist completed follow-up visits.¹⁷¹ The supervising physician would intermittently see the patient and receive updates from the pharmacist.¹⁷² Once the pharmacist felt the patient's medications were optimized, they were discharged back to the supervising physician.¹⁷³ In another model, a pharmacy team was created specifically to focus on patients with chronic pain and adjuvant therapy.¹⁷⁴ Another goal of the team was screening patient for opioid aberrant behavior and monitoring the state's controlled substance database.¹⁷⁵ Interestingly, this pharmacy team not only optimized medication therapy, but also educated patient on non-pharmacologic interventions and offered referrals as appropriate (e.g. avoidance of pain trigger, biofeedback, meditation, yoga).¹⁷⁶ In addition to pain control and patient satisfaction, this study also examined if opioid use and side effects are reduced by referral to the pharmacist-led clinic.¹⁷⁷

Hospitals have utilized pharmacists in a variety of roles to aid in pain control. Many hospitals have interdisciplinary teams that include pharmacists and have been shown to be highly successful relative to more traditional care.¹⁷⁸ For example, when patients are not able to be seen promptly due to demand of the hospital's routine acute pain consult services, providers were able to engage the pharmacy pain consult service led by a pharmacist with specialized advanced training in pain management.¹⁷⁹

Currently New York law provides for a very narrow "collaborative drug therapy management."¹⁸⁰ Collaborative drug therapy management ("CDTM") relates to "clinical services"¹⁸¹ provided in a hospital for a patient in the care of a physician for a

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ Jessica L. Norman et al., *Implementation of a pharmacist-managed clinic for patients with chronic nonmalignant pain*, 74 AM. J. HEALTH-SYS. PHARMACISTS 1229, 1231 (2017).

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 1233.

¹⁷⁸ Stacy Mathew et al., *Impact of a Pharmacy-Led Pain Management Team on Adults in an Academic Medical Center*, 51 HOSP. PHARMACY 639, 639-40 (2016).

¹⁷⁹ *Id.* at 640.

¹⁸⁰ N.Y. EDUC. LAW § 6801 (2016); N.Y. EDUC. LAW § 6801-a (2015).

¹⁸¹ N.Y. EDUC. LAW § 6801-a(1)(b) (2015) ("Clinical services' shall mean the collection and interpretation of patient data for the purpose of initiating, modifying and monitoring drug therapy.").

“specific disease state, or associated disease states”, under a written agreement protocol.¹⁸² The protocol, or agreement, is between a physician and a pharmacist concerning the patients of that physician. The agreement/protocol sets the parameters of the service provided by the pharmacist within the boundaries of the law. Among other things, the protocol may allow the pharmacist to adjust the strength, frequency, or route of administration of a specific medication, or change to another medication when specified in the protocol.¹⁸³ The protocol is between voluntarily participating pharmacist and physician, who are affiliated with, or employed by, the same facility. The protocol must:

- Describe the nature and scope of the collaboration including the particular disease state, or associated disease states
- Identify the medications involved, the changes that may be made, and the circumstances under which they may be made
- Identify the specific functions permitted, for example: managing therapy, adjusting medication regimens, routine monitoring (histories, vital signs, etc.), ordering relevant lab tests
- Contain a process for reporting any changes.¹⁸⁴

The collaborating physician and pharmacist both sign the protocol. Finally, the law requires the written consent of the participating patient (or the representative), and this consent may be withdrawn at any time.¹⁸⁵

The statute also limits the clinical context of CDTM to those employed by a “facility,” which includes teaching hospitals and general hospitals including “any diagnostic center, treatment center, or hospital-based outpatient department.”¹⁸⁶ The statute also includes nursing homes that have an on-site pharmacy and engage the services of licensed pharmacists. While this may include diagnostic centers, treatment centers, and outpatient departments of the hospitals, the following are specifically excluded:

- Dental clinics and dispensaries
- Residential health care facilities

¹⁸² N.Y. EDUC. LAW § 6801-a(1)(c) (2015).

¹⁸³ The statute reads: “Adjusting the drug regimen shall not include substituting or selecting a different drug which differs from that initially prescribed by the patient’s physician unless such substitution is expressly authorized in the written order or protocol.” N.Y. EDUC. LAW § 6801-a(1)(c)(i) (2015).

¹⁸⁴ N.Y. EDUC. LAW § 6801-a (2015).

¹⁸⁵ N.Y. EDUC. LAW § 6801-a(4) (2015).

¹⁸⁶ N.Y. EDUC. LAW § 6801-a(1)(d) (2015).

- Rehabilitation centers
- Implicitly, by exclusion, community pharmacies.

Section 6801-a also provides for the qualifications pharmacists must satisfy to engage in CDTM.¹⁸⁷ Minimum experience of two to three years is required depending on the entry-level degree, doctorate or baccalaureate, respectively.¹⁸⁸ Also, the Department of Education was empowered to make additional “education, experience, or other requirements . . . in consultation with the board” of Pharmacy. The additional requirements, established in the Regulations of the Commissioner of Education, are extensive going well beyond the statutory requirements.¹⁸⁹ A pharmacist seeking to engage in this practice must apply by submitting qualifying credentials to the Board of Pharmacy for its approval.¹⁹⁰ Additional qualifications, beyond the experience required by statute include:

- (a) have residency training in a program accredited or accreditation-pending by a nationally recognized accreditation body acceptable to the department; [or]
- (b) have board certification awarded by a certification body acceptable to the department and shall include baseline and ongoing competency assessments.¹⁹¹

Requiring acquisition of experience in hospitals, where there is

¹⁸⁷ N.Y. EDUC. LAW § 6801-a(2)(b)(i)–(ii) (2015).

(i)(A) have been awarded either a master of science in clinical pharmacy or a doctor of pharmacy degree; (B) maintain a current unrestricted license; and (C) have a minimum of two years experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation; or (ii)(A) have been awarded a bachelor of science in pharmacy; (B) maintain a current unrestricted license; and (C) within the last seven years, have a minimum of three years experience, of which at least one year of such experience shall include clinical experience in a health facility, which involves consultation with physicians with respect to drug therapy and may include a residency at a facility involving such consultation.

N.Y. EDUC. LAW § 6801-a(2)(b)(i)–(ii) (2015).

¹⁸⁸ N.Y. EDUC. LAW § 6801-a(2)(b)(i)–(ii) (2015).

¹⁸⁹ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.10 (2016). The Board has recently updated its website to explain this in both a Frequently Asked Questions format and a tabular summary. See Office of the Professions, *Collaborative Drug Therapy Management*, NYSED.GOV, <http://www.op.nysed.gov/prof/pharm/pharmcdtm.htm> (last visited Jan. 24, 2018).

¹⁹⁰ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.10 (2016).

¹⁹¹ N.Y. COMP. CODES R. & REGS. tit. 8, § 63.10(c)(3)(iii) (2016).

little opportunity for the vast majority of pharmacists to obtain that experience, along with the additional education requirements associated with residency and board certification has the practical effect of excluding the vast majority of New York's licensed pharmacists from qualifying to engage in CDTM practice. As of July 17, 2017 there were 20,179 licensed pharmacists residing in New York State, with 131 certified to practice CDTM.¹⁹² Translating for the layperson, this means that ninety-nine point five percent of pharmacists are not permitted to practice CDTM practice in New York. This exclusive practice environment also excludes the vast majority of patients from obtaining the therapeutic benefit of the collaborative care process discussed above. From the patient's perspective, this translates into unnecessary morbidity and mortality.

Because the New York State law does not explicitly permit pharmacists to prescribe controlled substances, the DEA will not issue the registration to support this.¹⁹³ North Carolina, New Mexico, and California all allow pharmacists to prescribe controlled substances.¹⁹⁴ California, Massachusetts, Montana, North Carolina, Ohio, New Mexico and Washington characterize pharmacists as "mid-level practitioners" and may prescribe any controlled substance as long as it is part of the protocol between the pharmacist and a supervising practitioner.¹⁹⁵

"FACTS ABOUT CONTROLLED SUBSTANCE PRESCRIPTION MEDICATION"

In 2016, as part of the opioid legislation, an amendment to the Mental Hygiene Law¹⁹⁶ required the Commissioner of Mental Hygiene, in consultation with the Commissioner of Health, to create "educational materials regarding the dangers of misuse and the potential for addiction to prescription-controlled substances, treatment resources available, and the proper way to dispose of

¹⁹² Personal e-mail communication with the Board of Pharmacy, July 17, 2017. See also Office of the Professions, *License Statistics*, NYSED.GOV, <http://www.op.nysed.gov/prof/pharm/pharmcounts.htm> (last visited Jan. 24, 2018).

¹⁹³ See 21 C.F.R. § 1306.03(a) (1997).

¹⁹⁴ See DRUG ENF'T AGENCY, U.S. DEP'T OF JUSTICE, MID-LEVEL PRACTITIONERS AUTHORIZATION BY STATE 1, 2, 7 tbls. (2017), https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf.

¹⁹⁵ *Id.* at 1, 5–7 tbls.

¹⁹⁶ 2016 N.Y. Sess. Laws ch. 71, pt. D, sec. 1, at 409 (McKinney).

unused prescription controlled substances.”¹⁹⁷ Specifically, the law requires the material to include information about:

- Risks of consuming controlled substances;
- Physical, behavioral and advanced warning signs of addiction;
- The “Hopeline” telephone number (1-877-8-HOPE-NY) or text HOPENY;
- Procedures for safe disposal; and
- Other information the Commissioner of Mental Hygiene determines to be necessary.¹⁹⁸

The materials were published in December 2016, and entitled “Important Facts About Controlled Substance Prescription Medication,”¹⁹⁹ available on both websites of the Office of Alcoholism and Substance Abuse Services as well as the Department of Health. Each time a controlled substance prescription, including an opioid, is dispensed, the pharmacist distributes the materials;²⁰⁰ electronic distribution is permissible if the patient prefers. Also, the pharmacist may distribute additional information “regarding the safe disposal of controlled substances.”

TREATMENT

Naloxone

An opioid overdose features a dramatic decrease in the respiratory drive; the victim stops breathing resulting in the death of the subject in the absence of some intervention.²⁰¹ Naloxone works by competitively displacing the opioid from its site of action in the brain and reversing all of its life-threatening effects.²⁰² The Food and Drug Administration originally approved the drug naloxone for the purpose of reversing the effects of opioids,

¹⁹⁷ N.Y. MENTAL HYG. LAW § 19.09(j)(1) (2016).

¹⁹⁸ N.Y. MENTAL HYG. LAW § 19.09(j)(2)–(3) (2016).

¹⁹⁹ N.Y. STATE OFFICE OF ALCOHOLISM & SUBSTANCE ABUSE, N.Y. STATE DEPT OF HEALTH, IMPORTANT FACTS ABOUT CONTROLLED SUBSTANCE PRESCRIPTION MEDICATION (2016), <https://www.health.ny.gov/publications/12022.pdf>.

²⁰⁰ N.Y. MENTAL HYG. LAW § 19.09(j)(1) (2016).

²⁰¹ See Rukma Parthvi et al., *Acute Opiate Overdose: An Update on Management Strategies in Emergency Department and Critical Care Unit*, AM. J. THERAPEUTICS, Sept. 13, 2017, at 1.

²⁰² See *Information Sheet on Opioid Overdose*, WORLD HEALTH ORG. (Nov. 2014), http://www.who.int/substance_abuse/information-sheet/en/.

typically, in controlled environments like surgical suites where opioids are extensively utilized.²⁰³ With the alarming increase in opioid overdose deaths, one public health strategy is to place naloxone in an easily administered form, usually intra-nasal, that will enable even an inexperienced person to give the requisite dose. When administered in a timely manner, the victim will begin breathing again, regain consciousness (usually very upset), and hopefully receive follow-up care.

In terms of treating overdoses, the state has exerted significant effort to increase the public availability of the opioid antagonist naloxone without a prescription. First enacted in 2005, Public Health Law section 3309 “Opioid overdose prevention” has been amended numerous times since.²⁰⁴ The law encourages first responders to act, expands the availability of naloxone, and requires dissemination of public information.²⁰⁵ Significantly, the law permits pharmacists to distribute naloxone without a prescription.²⁰⁶ Under a “non-patient-specific order” or protocol, pharmacists may provide this medication to virtually anyone who may encounter an overdose,²⁰⁷ and may administer this medication without fear of legal reprisal.

Indeed, pharmacies in chains of twenty or more are required to participate in some way.²⁰⁸ As of September 2017, the state reports that over 2,000 pharmacies across the state participate.²⁰⁹ Under a “non-patient-specific prescription”, pharmacists may provide this medication to virtually anyone who may encounter an overdose.²¹⁰ At the time of distribution an “informational card or sheet” is

²⁰³ Adapt Pharma, Inc., *Full Prescribing Information for Narcan Nasal Spray*, NARCAN.COM, <https://www.narcan.com/pdf/NARCAN-Prescribing-Information.pdf> (last updated Feb. 2017).

²⁰⁴ N.Y. PUB. HEALTH LAW § 3309 (2016) (summarizing the statute’s history since it was enacted in 2005 (2005 N.Y. Sess. Laws ch. 413, sec. 1 (McKinney)), amended twice in 2014 (2014 N.Y. Sess. Laws chs. 34, sec. 1 (McKinney); 2014 N.Y. Sess. Laws ch. 42, sec. 1 (McKinney)), once in 2015 (2015 N.Y. Sess. Laws ch. 57, pt. V, secs. 1-3 (McKinney)) and four times in 2016 (2016 N.Y. Sess. Laws ch. 65, sec. 1 (McKinney); 2016 N.Y. Sess. Laws ch. 66, sec. 1 (McKinney); 2016 N.Y. Sess. Laws ch. 68, secs. 1, 2 (McKinney); 2016 N.Y. Sess. Laws ch. 70, pt. B, sec. 1 (McKinney)).

²⁰⁵ See N.Y. PUB. HEALTH LAW § 3309(3)(b)–(3-a) (2016).

²⁰⁶ N.Y. PUB. HEALTH LAW § 3309(3)(b)–(3-a) (2016).

²⁰⁷ N.Y. PUB. HEALTH LAW § 3309(3)(b)–(3-a) (2016).

²⁰⁸ N.Y. PUB. HEALTH LAW § 3309(3)(b)(v) (2016).

²⁰⁹ *New York State’s Opioid Overdose Prevention Program*, N.Y. STATE DEP’T OF HEALTH, https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/index.htm (last updated Oct. 2017).

²¹⁰ See N.Y. PUB. HEALTH LAW § 3309(3)(b)(i) (2016).

required, including the following:

- (a) how to recognize symptoms of an opioid overdose;
- (b) steps to take prior to and after an opioid antagonist is administered, including calling first responders;
- (c) the number for the toll free office of alcoholism and substance abuse services HOPE line;
- (d) how to access the office of alcoholism and substance abuse services' website; and
- (e) any other information deemed relevant by the commissioner.²¹¹

The law also contains an immunity statement providing that anyone acting in good faith and in compliance with the law “shall not be subject to criminal, civil or administrative liability solely by reason of such action.”²¹² For health care professions, this is further underlined in the Education Law limiting professional misconduct treatment for those “who would otherwise be prohibited from prescribing or administering drugs.”²¹³ Taken together, the law has evolved to encourage affirmative, assertive action by pharmacists to equip first responders and personally act when called for. In that same vein, witnesses of overdoses who call “911” will not be prosecuted for possession of controlled substances or paraphernalia.²¹⁴ This “Good Samaritan 911” also applies to the victim.²¹⁵

BUPRENORPHINE

A novel practice model in the state of Maryland illustrated that pharmacists can increase access to buprenorphine/naloxone (i.e., Suboxone) maintenance programs.²¹⁶ This model incorporated an internal medicine physician and a pharmacist with a board certification in psychiatry.²¹⁷ The pharmacist gathered a detailed medical, psychiatric, and substance abuse history in addition to other relative data (e.g. urine drug screen), then provides the

²¹¹ N.Y. PUB. HEALTH LAW § 3309(3-a) (2016).

²¹² N.Y. PUB. HEALTH LAW § 3309(4) (2016).

²¹³ N.Y. EDUC. LAW § 6509-d (2016).

²¹⁴ N.Y. PENAL LAW § 220.78(1) (2011). See N.Y. PENAL LAW § 220.03 (2015).

²¹⁵ N.Y. PENAL LAW § 220.78(2) (2011). See N.Y. PENAL LAW § 220.03 (2015).

²¹⁶ See Bethany A. DiPaula & Elizabeth Menachery, *Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients*, 55 J. AM. PHARMACISTS ASS'N 187, 187, 189 (2015).

²¹⁷ *Id.*

information to the physician. In this model, the pharmacist also established a working relationship with a community pharmacy to serve as the sole provider for patients referred to the program serving as additionally monitoring opportunity for program adherence. At the conclusion of this pilot study, twelve patients were cared for with an estimated \$22,000 cost savings relative to more traditional care.²¹⁸ The completion and retention rate was higher than reported in the literature at the time but difficult to make firm conclusions regarding this data with no control group.

Until 2016, the law permitted only qualified physicians to prescribe buprenorphine for the treatment of opioid dependence. The Comprehensive Addiction and Recovery Act²¹⁹ extended this privilege to nurse practitioners and physician assistants.²²⁰ Also in 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) increased the limit on the number of patients the practitioner may treat with buprenorphine to a limit of 275 patients.²²¹ Practitioners may accept up to thirty patients in the first year after qualification, then after petitioning SAMHSA up to 100, and then 275 in succeeding years.²²² Recently New York followed suit, amending Public Health Regulations by replacing the word “physician” with the word “practitioner” (thus including nurse practitioners and physician assistants), and adopting “the limit established by . . . (SAMHSA)” with regard to the number of patients.²²³ As discussed above, in a few states pharmacists have received “mid-level practitioner” authority to prescribe controlled substances under protocol. It would take an act of Congress²²⁴ to give pharmacists the authority to prescribe buprenorphine for detoxification and maintenance of patients suffering from opioid dependence.²²⁵ Given that this disease is a “Public Health

²¹⁸ *Id.* at 189–90.

²¹⁹ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695, 721.

²²⁰ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695, 721.

²²¹ Medication Assisted Treatment for Opioid use Disorders, 81 Fed. Reg., 44,712, 44712 (July 8, 2016) (to be codified at 42 C.F.R. pt. 8).

²²² *Id.*

²²³ N.Y. COMP. CODES R. & REGS. tit. 10, § 80.84(b)(1) (2017).

²²⁴ *See, e.g.*, Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695, 720–21 (allowing nurse practitioners and physician assistants to provide approved drugs “for the treatment of opioid use disorder.”).

²²⁵ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695, 720–21 (similar to the authority gained by nurse practitioners and physician assistants).

Emergency,” as declared by the White House,²²⁶ perhaps the time has come for this step.

Finally, in the context of recovery from dependence, the 2016 Opioid legislation provided that the use of buprenorphine shall be covered by insurance when an emergency condition exists, up to a five-day supply.²²⁷ Also, amendment to the Public Health Law enhanced access in the preferred drug program by Medicaid patients by prohibiting prior authorization for buprenorphine and naltrexone; “shall not be required.”²²⁸

SUMMARY

Pharmacists contribute to overcoming the opioid crisis in a variety of ways. These include the traditional role of carefully managing an inventory of controlled substances and a corresponding responsibility to ensure that distribution is based on a legitimate medical purpose, and that the prescriber is acting in the usual course of practice. Emerging areas include counseling at the time of dispensing, and other educational resources at the time of dispensing. In addition, in New York, like virtually every other state, pharmacists are engaging in distribution of emergency rescue medication, naloxone, without a prescription. Finally, direct patient care of patients suffering from dependence due to both prescription medication and illicit opiates such as heroin, is an untapped opportunity. Achieving this would require nothing less than an act of Congress, like the CARA law, and also amendment of professional practice laws and regulations at the state level. Perhaps we have reached that point, given that a tremendous amount of time, attention, and resources have been committed to overcoming the opioid menace, and it seems to be getting worse.

²²⁶ *President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis*, THE WHITE HOUSE: HEALTHCARE (Oct. 26, 2017), <https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis>.

²²⁷ 2016 N.Y. Laws ch. 69 (amending N.Y. INS. LAW §§ 3216(31-a)(A), 3221, and 4303).

²²⁸ 2016 N.Y. Laws ch. 69 (amending N.Y. PUB. HEALTH LAW § 273(10)).