DEVELOPMENTS IN DELAWARE HEALTH LAW: ADDRESSING PRESCRIPTION DRUG ABUSE

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In 2012, developments impacting Delaware health care providers, patients, and the delivery of health care in the state have highlighted the efforts to address prescription drug abuse. This article summarizes the principal health law developments aimed at curbing the growing prescription drug abuse problem: the launch of the Delaware Prescription Monitoring Program and the Board of Medical Licensure and Discipline's Regulation 18, addressing the standards for prescribing controlled substances for the treatment of pain.

Prescription drug abuse, specifically of opioids and other controlled substances, in Delaware has been covered widely in news media,[1] and the growing epidemic continues to have a devastating impact on the entire country.[2] Second only to marijuana, prescription painkillers are now considered the most abused drugs by youth in the United States.[3] And there is no denying that prescriptions for opioids have increased dramatically; between 1997 and 2007 the use of prescription opioids increased more than four times,[4] and "[t]he rate of death from drug overdose in the United States has more than doubled since 1999 impelled largely by an increase in overdoses involving prescribed substances, especially opioid analgesics."[5] Yet, "[p]aradoxically, there are simultaneous pressures to increase opioid prescribing for the benefit of individual patients and to reduce it for the sake of public health."[6]

Delaware health care providers sit at the center of these debates over detecting drug abuse and diversion and promoting sound prescribing. In providing controlled substances therapy to patients, providers must become cognizant of new requirements of the Delaware Prescription Monitoring Program and Board of Medical Licensure and Discipline Regulation 18.

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1. Chris Barrish & Daniel Sato, *Prescription Drug Abuse: An Epidemic of Painkillers*, Delaware News Journal (2011), *available at* http://www.delawareonline.com/section/NEWS1111/Pill-Abuse.

2. Jeanmarie Perrone & Lewis S. Nelson, *Medication Reconciliation for Controlled Substances—An "Ideal" Prescription-Drug Monitoring Program*, 366 N Eng. J. Med. 2341, 2341 (2012).

3. Shoshana Walter, *Meager Participation Hobbles Drug Oversight*, N.Y. Times (April 8, 2012) at A23A, *available at* http://www.nytimes.com/2012/04/08/us/poor-participation-hobbles-californias-drug-oversight.html?pagewanted=all&_r=0.

4. Centers for Disease Control and Prevention, *CDC Grand Rounds: Prescription Drug Overdoses—A U.S. Epidemic*, Morbidity & Mortality Wkly. Rep., Jan. 13, 2012, at 10. Some have reported that the Joint Commission's pain management standards, which went into effect for accredited facilities in 2001 and recognized patients' rights to the appropriate assessment and management of pain, among other factors, has led to a "liberalization" of opioid prescribing for pain management. Perrone & Nelson, *supra* note 2 at 2341. "In this new model, physicians, dentists, and nurse practitioners – rather than drug cartels and street dealers – play prominent roles in escalating drug use." *Id.*

5. Leonard J. Paulozzi et al., *A History of Being Prescribed Controlled Substances and Risk of Drug Overdose Death*, 13 Pain Med. 87, 88 (2012).

6. Perrone & Nelson, *supra* note 2 at 2341.

I. THE DELAWARE PRESCRIPTION MONITORING PROGRAM

The Prescription Monitoring Program ("PMP") is a product of the Delaware Prescription Monitoring Act (the "Act"), signed by Governor Markell in 2010.[7] The PMP was launched in August 2012 "as a means to promote public health and welfare and to detect the illegal use of controlled substances" and to address the dual purposes of "reducing misuse and diversion of controlled substances in the State while promoting improved professional practice and patient care."[8] The PMP allows key stakeholders to monitor the prescribing and dispensing of all Schedule II, III, IV and V controlled substances and to research the prescribing and dispensing of drugs of concern.[9] Importantly, the "PMP shall not interfere with the legal use of a controlled substance or drug of concern."[10]

The core of the PMP is a database, accessed via a public website.[11] The Act authorizes the Office of Controlled Substances ("OCS"), within the Department of State's Division of Professional Regulation, to establish and maintain the PMP. The PMP serves to trace the path of a controlled substance, wherein dispensers and prescribers are required to access the PMP website to report and monitor information about the prescribing and dispensing of controlled substances. Members of law enforcement are permitted to access the PMP website to investigate illegal activity.

A. Stakeholder Requirements

The first key stakeholder in the program is the "prescriber" of controlled substances. A "prescriber" is defined by the Act as "a licensed health care professional with the authority to write and issue prescriptions" with certain exceptions.[12] Exempted from the Act's requirements, however, is a prescriber—or other authorized person—who "administers" a controlled substance or drug upon the lawful order of a prescriber. "Administer" is defined as "the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means."[13] Also exempt from the Act's requirements is a prescriber—or other authorized person—who *causes* the administration of such a substance for immediate relief from an

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7. 77 Del. Laws 396 (2010). As of October 2012, forty-two states had operational prescription monitoring programs, and eight states had enacted legislation establishing a prescription monitoring program. *Status of Prescription Drug Monitoring Programs*, Alliance of States with Prescription Monitoring Programs (Oct. 17, 2012), *at* http://www.pmpalliance.org/pdf/pmp_status_map_2012.pdf. Research regarding the effectiveness of such programs is still limited, but a recent Canadian study of prescription monitoring programs reported a sizable decrease in the number of inappropriate prescriptions for opioids and benzodiazepines in British Columbia. Pamela Lewis Dolan, *Study Quantifies Drug Monitoring Database's Effect on Opioid Prescriptions*, Am. Med.ical News (Sept. 20, 2012), *at* http://www.ama-assn.org/amednews/2012/09/17/bisf0920.htm.

8. Del. Code Ann. tit. 16, § 4798(a) (2011).

9. *Id.* § 4798(c). This article focuses on the prescribing of controlled substances in medical treatment. "Drugs of concern" are defined as those other than controlled substances to be defined by the Delaware Office of Controlled Substances by rule that "demonstrate a potential for abuse or diversion." *Id.* § 4798(b)(7). At the time of publication, no rules have been promulgated defining such drugs.

10. *Id.* §4798(c).

11. The PMP Web address is pmp.delaware.gov.

12. *Id.* § 4798(b)(9).

13. *Id.* § 4798(b)(1).

acute condition in the provision of emergency care. Thus, an emergency department prescriber who provides a controlled substance to a patient for immediate self-administration in providing emergency care is not subject to the requirements of the Act. Similarly, a prescriber "who prescribes up to a 72-hour supply of a controlled substance for on call services or emergency care" is exempt from the Act's requirements. Finally, a veterinarian who prescribes for veterinary services is not subject to the requirements of the Act.[14]

If a prescriber is subject to the Act, he or she is required, under certain circumstances, to take certain actions before writing and issuing a prescription for a controlled substance.[15] If the prescriber has a "reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition," the prescriber—or another person authorized by the prescriber—must obtain a utilization report regarding that patient from the PMP database.[16] The utilization report, a collection of the data submitted by dispensers to the PMP, will provide the patient's prescription history for the preceding twelve months. The prescriber must review the utilization report and, based upon the information contained therein assess whether the prescription sought is "necessary" for the treatment of the patient.[17]

In the event that a prescriber is unable to access the database to obtain the prescription information by electronic means—perhaps because the prescriber does not utilize a computer or internet connection in his or her office—the OCS may grant a waiver to the prescriber, relieving him or her from the Act's requirements.[18] Any such prescriber must obtain a waiver from the OCS on an annual basis until such prescriber is able to access the prescription information by electronic means. Once the prescriber writes and issues a prescription to a patient, the dispenser must enter the prescription information into the PMP when the patient seeks to fill the prescription.

The Act defines "dispenser" as a person authorized by the State to dispense or distribute controlled substances or drugs of concern to the ultimate user, with certain exceptions.[19] To "dispense" means to interpret, evaluate, and implement a prescription, including the preparation and delivery of the drug to a patient or his or her agent for administration to, or use by, the patient.[20] "Distribute" is defined as the delivery of a drug other than by administering or dispensing.[21] A health care facility pharmacy is not subject to the Act's requirements when it dispenses or distributes controlled substances for inpatient care or for immediate use by an emergency department , or when dispensing up to a seventy-two-hour supply at the time of discharge.[22]

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14. *Id.* § 4798(b)(9).

15. Certain prescribers are also subject to the Board of Medical Licensure and Discipline Regulation 18, which describes the standards of prescribing controlled substances for the treatment of pain. For a discussion of the requirements of Regulation 18, see *infra* Section II.

16. Del. Code Ann. tit. 16, § 4798(e).

17. *Id.*

18. *Id.* § 4798(f).

19. *Id.* § 4798(b)(4).

20. *Id.* § 4798(b)(3).

21. *Id.* § 4798(b)(5).

22. Basically, "dispensers" under the Act include retail pharmacies, non-resident pharmacies who operate in other states but ship, mail, or deliver a controlled substance to a patient in Delaware, and controlled substance registrants who dispense controlled substances, including samples.

For every controlled substance prescription dispensed or otherwise distributed, the dispenser shall submit certain information into the electronic PMP database.[23] The information required to be submitted includes: (1) the pharmacy name; (2) the dispenser's DEA registration number; (3) the date the drug was dispensed; (4) the prescription number from the prescriber; (5) whether the prescription is new or a refill; (6) the national drug code for the drug dispensed; (7) the quantity dispensed; (8) the approximate number of days supplied; (9) the patient's name and date of birth; (10) the patient's address; (11) the prescriber's DEA registration number and name; and (12) the date the prescription was issued by the prescriber.[24] The data is submitted pursuant to the Dispenser's Implementation Guide.[25] Waivers similar to those granted to prescribers are not available to dispensers.

For those with a basic familiarity with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")—which by most accounts is everyone who has ever been to a health care provider and signed a medical record privacy policy—it is evident that the information described above includes protected health information.[26] The Act makes clear that this prescription information is not subject to open records laws or otherwise subject to disclosure, unless provided for by the Act.[27] The OCS is responsible for ensuring that privacy and confidentiality is maintained in the collection, transmission, and maintenance of the information in the PMP.[28]

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23. *Id.* § 4798(d). Where a controlled substance is needed for bona fide research, the OCS may not require dispensers to submit information any more frequently than that required for controlled substance prescriptions. *Id.*

24. *Id.*

25. *Dispenser's Implementation Guide*, Del. Div. of Prof'l Regulation Prescription Monitoring Program (March 2012), http://dpr.delaware.gov/boards/controlledsubstances/pmp/documents/DE%20PDMP_Dispensers%20Implementation%20Guide.pdf.

26. Protected health information is "individually identifiable health information" that is transmitted and/or maintained in electronic media or in any other form or medium, with certain exceptions not relevant to this article. 45 C.F.R. § 160.103 (2007). "Individually identifiable health information" includes demographic information collected from an individual created or received by a health care provider (and other covered entities) that "[r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual" and that identifies the individual or may where there is a reasonable basis to believe it may be used to identify the individual. *Id.*

27. Del. Code Ann. tit. 16, § 4798(h). While this is not an article discussing the intricacies of HIPAA, it is worth briefly mentioning the interplay of the PMP and HIPAA's Privacy Rule. Prescribers and dispensers are covered entities under HIPAA, and the Act may require these individuals to transmit protected health information to the PMP. This may appear to conflict with HIPAA regulations, which generally limit the circumstances in which, and to what extent, such information can be disclosed. *See* 45 C.F.R. § 164.502. HIPAA expressly preempts contrary state law, unless an exception applies. 45 C.F.R. § 160.203. For example, the Secretary of the United States Department of Health and Human Services may find that the state law is necessary to prevent health care fraud and abuse or for purposes of "serving a compelling need related to public health, safety, or welfare." *Id.* § 160.203(a)(1). Most importantly, perhaps, the Secretary may find that the state law's principal purpose is "the regulation of the … distribution, dispensing, or other control of any controlled substances." *Id.* § 160.203(a)(2). Exceptions also exist that do not require a prior determination of the Secretary, including where a state law provides for "the conduct of public health surveillance, investigation, or intervention." *Id.* § 160.203(c). If an exception does not apply, the HIPAA privacy rules apply, though it is likely that disclosures under the Act will comply with HIPAA requirements.

28. Del. Code Ann. tit. 16, § 4798(i).

B. The Use And Disclosure Of Prescription Information

In exercising its authority to ensure the integrity of the program and to further its stated goals, the OCS is required to make certain disclosures and is authorized to make others. For example, the OCS has an affirmative duty to notify appropriate law enforcement officials or professional licensure, certification, or regulatory agencies whenever it has reasonable cause to believe that a dispenser or prescriber has breached professional standards, or knows of a violation of law—be it patient abuse or diversion of controlled substances or otherwise.[29] The professional standards of every health care profession are either established by statute or promulgated by that profession's licensing or certification authority. Presumably, the OCS must have a basic familiarity with those standards in order to refer dispensers or prescribers to the appropriate regulatory agency.[30] For example, it is considered unprofessional conduct for a physician to use, distribute, or issue a prescription for a dangerous or narcotic drug, other than for therapeutic or diagnostic purposes.[31] In addition to the required reports to professional regulators, the OCS may also provide data at the request of a designated representative of any professional regulating board or commission who is involved "in a bona fide specific investigation involving a designated person,"[32] or at the request of the Division of Professional regulation for purposes of administering and enforcing the Act.[33]

The OCS may also honor other requests to provide PMP data. For example, the OCS may honor requests by prescribers or dispensers who request such reports pursuant to their own obligations under the Act, as long as the prescriber or dispenser requesting information first certifies that the information is requested for the purpose of providing medical or pharmaceutical treatment to a bona fide patient.[34] Naturally, the OCS may provide data to an individual who requests his or her own PMP information.[35] Certain qualified personnel can also obtain PMP data reports for bona fide research or educational purposes, but the OCS must delete or redact any information that would reasonably identify a specific recipient of a substance, and the information may only be released pursuant to a written agreement.[36] The OCS may also provide data reports regarding Medicaid recipients to the Delaware Department of Health and Social Services ("HSS").[37] There are no stated limits regarding an HHS request for such information.

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29. *Id.* § 4798(i)(1).

30. For example, physicians' professional standards are found at Chapter 17 of Title 24 of the Delaware Code and are further defined by regulations promulgated by the Board of Medical Licensure and Discipline at Chapter 17 of Title 24 of the Delaware Administrative Code. Pharmacists' professional standards are found at Chapter 25 of Title 24 of the Delaware Code and are further defined by regulations promulgated by the Board of Pharmacy at Chapter 25 of Title 24 of the Delaware Administrative Code.

31. Del. Code Ann. tit. 24, § 1731(b)(6) (2011).

32. Del. Code Ann. tit. 16, § 4798(i)(2)(c). It is interesting to note here, that the professional boards cannot go on fishing expeditions by utilizing PMP data. They must first initiate a bona fide and specific investigation.

33. *Id.* § 4798(i)(2)(g).

34. *Id.* § 4798(i)(2)(a).

35. *Id.* § 4798(i)(2)(b). Prescribers and dispensers, however, are not permitted to release PMP data to patients because the reports that a prescriber or dispenser can obtain will contain confidential information about the prescriber and dispenser.

36. *Id.* § 4798(i)(2)(h).

37. *Id.* § 4798(i)(2)(e).

Finally, the OCS may release information to a local, state, or federal law enforcement or prosecutorial office administering, investigating, or enforcing controlled substances laws.[38] The requester, however, must be involved in a "bona fide specific drug-related investigation in which a report of suspected criminal activity involving controlled substances by an identified suspect has been made."[39] Furthermore, the information must be "relevant and material" to the investigation and limited to the "extent reasonably practicable in light of the purpose for which the information is sought."[40] The OCS shall include identifying information only if non-identifying information cannot be used.

C. Penalties And Immunity

The Act provides penalties for failure to comply with its requirements and for the misuse of the program. A dispenser who fails to submit the information required under the Act is subject to discipline by the Board of Pharmacy pursuant to Chapter 25 of Title 24 of the Delaware Code.[41] The same is true if a dispenser knowingly submits incorrect prescription information. A dispenser alleged to have violated the Act is entitled to a hearing, and if found to have violated this provision, is subject to disciplinary sanctions ranging from a letter of reprimand to a revocation of his or her license.[42]

Any person authorized to have prescription information pursuant to the Act—including dispensers, prescribers, licensing Board personnel, patients, and State personnel—who knowingly discloses the information without authorization under the Act is guilty of a class G felony and, upon conviction, shall be fined not more than $10,000, imprisoned not more than two years, or both.[43] Any person authorized to have prescription information pursuant to the Act who intentionally uses the information in furtherance of a crime is guilty of a class E felony and, upon conviction, is subject to a fine not more than $10,000, imprisonment for not more than five years, or both.[44] Finally, any person not authorized to have prescription information pursuant to the Act and who obtains such information fraudulently is guilty of a class E felony.[45] Such person shall be fined not more than $10,000, imprisoned not more than five years, or both.[46]

There is no express penalty in the Act for a prescriber's failure to obtain a utilization report. However, a physician prescriber commits unprofessional conduct if he or she engages in any "dishonorable, unethical, or other conduct likely to deceive, defraud, or harm the public."[47] Likewise, a dentist prescriber is subject to disciplinary sanctions if he or she has

38. The OCS may also provide a report to a properly convened grand jury pursuant to a subpoena. *Id.* § 4798(2)(f).

39. *Id.* § 4798(i)(2)(d). Like professional boards and commissions, law enforcement cannot use the PMP to fish for illegal activity.

40. *Id.*

41. *Id.* § 4798(m).

42. Del. Code Ann. tit. 24, § 2516 (2007).

43. Del. Code Ann. tit. 16, § 4798(n).

44. *Id.* § 4798(o).

45. *Id.* § 4798(p).

46. *Id.*

47. *Id.* § 1731(b)(3).

"practiced dentistry … in an incompetent or grossly negligent manner."[48] Thus, an argument can be made that if such prescribers fail to request a utilization report where there is a *reasonable belief* that the patient may be seeking controlled substances for reasons other than the treatment of a medical condition, the prescribers may be subject to professional disciplinary action. For a physician, the argument would be that in failing to request a utilization report, he or she engaged in conduct that is likely to harm the public. For a dentist, the argument would be that in failing to request a utilization report, he or she engaged in the practice of dentistry in an incompetent or grossly negligent manner. While there are immunity provisions contained in the Act, they would not apply to such circumstances.

The Act's immunity provisions address distinct acts or omissions. Under section 4798(g), a court of competent jurisdiction must first make a finding of gross negligence, malice or criminal intent before any prescriber, dispenser, or other person or entity in proper possession of information pursuant to the Act, can be subject to civil liability, administrative action or other legal or equitable relief for any of the following: (1) furnishing information pursuant to the Act; (2) receiving, using or relying on, or not using or relying on, information received pursuant to the Act; (3) failing to furnish information to the OCS; (4) providing factually incorrect information to the OCS; and (5) circumstances where the OCS released information to the wrong person or entity. Note that these immunity provisions would not seem to apply to the prescribers described in the above hypotheticals regarding the prescribers' failure to obtain a utilization report where there is a reasonable belief of abuse or diversion of controlled substances because receiving and being in possession of the information is a prerequisite to immunity. Whether this result was intended by the drafters of the statute is unclear. Nevertheless, it appears that a prescriber's professional board potentially could take disciplinary action if the prescriber failed to obtain a report in violation of the Act, without any court first having made a finding of gross negligence, malice or criminal intent.

D. Implications For Health Care Providers

The Act has many implications for health care providers, especially as the PMP's requirements relate to providers' other legal and ethical duties.

First, as described above, a prescriber must request a utilization report prior to prescribing a controlled substance where the prescriber has a reasonable belief that the patient may be seeking the controlled substance for any reason other than valid treatment purposes. For some prescribers, particularly those familiar with prescribing controlled substances for the treatment of pain and physicians subject to Board of Medical Licensure and Discipline Regulation 18,[49] there are a number of mechanisms to assist the prescriber in detecting any potential abuse or diversion of controlled substances. For those who do not prescribe such substances with any regularity, however, it may not be clear whether their belief of abuse or diversion is reasonable. If this becomes a difficult question for providers, will the default position be to request the utilization report? Is it "gross negligence" to request a utilization report as a default, even if there is no reasonable belief of abuse or diversion? While controlled substances have a recognized benefit in the treatment of pain, as acknowledged by the General Assembly and the Federation of State Medical Boards,[50] will providers wary of the process simply refuse to

48. *Id.* § 1128(2).

49. For a discussion on the standards set forth in Regulation 18, see *infra* Section I.B.

50. Federation of State Medical Boards of the United States, Inc., *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004), *at* http://www.fsmb.org/pdf/2004_grpol_controlled_substances.pdf.

issue such prescriptions? And how would such a refusal implicate health care providers' ethical obligations? These questions may remain unanswered for some time.

Second, prescribers are directed to review the utilization report, if requested, to assess whether the prescription for the controlled substance is "necessary." Presumably, this allows some degree of flexibility in the provider's medical decision-making. Can a controlled substance prescription still be "necessary" even if the utilization report indicates drug abuse by showing that the patient received controlled substances from another prescriber at the same time? Simply stopping prescriptions of controlled substances may be inappropriate and at odds with the standard of care, which may require the patient to be slowly tapered from the drugs.[51] Furthermore, every physician is ethically prohibited from abandoning his or her patient, and patient abandonment may give rise to a claim for malpractice. Abandonment generally occurs where the provider unilaterally severs the treatment relationship with the patient, without providing reasonable notice, at a time when the patient still requires medical attention. Care should be taken in ending a treatment relationship with a patient believed to be abusing controlled substances.

Third, most health care professionals in Delaware have legal obligations—imposed by statute or regulation—that require the reporting of other health care professionals who may be engaging in unprofessional conduct. All health care providers and health care facilities must report physicians—any person certified and registered to practice medicine—when the reporting provider reasonably believes that the physician is or may be guilty of unprofessional conduct.[52] In practice this means a dentist prescriber and any dispenser who, upon obtaining and reviewing prescription information under the Act, believes a physician prescriber has engaged in unprofessional conduct[53] must report that prescriber to the Division of Professional Regulation. However, a physician prescriber has no duty to report a dentist prescriber or a dispenser. Dentist prescribers have an affirmative duty to report, in addition to physician prescribers, other dental prescribers and dispensers when the reporter reasonably believes that the person engaged in conduct that would constitute grounds for disciplinary action.[54] The recognition of these duties is important for one reason: if any of these key stakeholders fails to report when required, they are subject to substantial fines and potential disciplinary sanctions.[55] Thus, the required actions under the PMP may necessitate further action with regard to reporting unprofessional conduct.

Also of concern to providers may be the impact of the PMP where patients may "doctor shop" across state lines for controlled substances. In areas close to state borders, including much of Delaware, interstate collaboration may be essential to the program's effectiveness in these areas. An interstate network has been created to allow interstate sharing of PMP information, but it is currently operational in only ten states, excluding Delaware and its neighboring states.[56]

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51. "[A]t discharge, you must consider how the patient will tolerate discontinuation without harm, and, in cases involving such drugs as opioids, benzodiazepines, anticonvulsants, and antidepressants, and others, safe discontinuation may require a tapering schedule." Scott M. Fishman, Responsible Opioid Prescribing: A Physician's Guide 77 (2007).

52. Del. Code Ann. tit. 24, § 1731A (2010).

53. Again, it is unprofessional conduct for a physician prescriber to use, distribute, or issue a prescription for a dangerous or narcotic drug, other than for therapeutic or diagnostic purposes. *Id.* § 1731(b)(6).

54. *Id.* § 1131A(a).

55. The Board of Medical Licensure and Discipline has "the authority to impose a fine, not to exceed $10,000 for the first violation, and not to exceed $50,000 for any subsequent violation, on any person, any healthcare provider, any healthcare institution, and the Medical Society of Delaware for violation" of the duty to report. *Id.* § 1731A(i). Furthermore, it is unprofessional conduct for a physician who willfully fails to report under section 1731A, subjecting that physician to a range of disciplinary sanctions. Any dentist who fails to report pursuant to title 24, section 1131A of the Delaware Code is subject to disciplinary sanctions. *Id.* § 1128(15).

56. *NABP PMP InterConnect*, National Association of Boards of Pharmacy, *at* http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect.

II. BOARD OF MEDICAL LICENSURE AND DISCIPLINE REGULATION 18

The Delaware Board of Medical Licensure and Discipline ("BMLD") also took an important step to curb prescription drug abuse when it promulgated Regulation 18, Use of Controlled Substances for the Treatment of Pain, in February 2012.[57] While the regulation's primary focus is the treatment of chronic pain, it "may be applicable to prescribing controlled substances for the treatment of acute pain when clinically appropriate."[58] For purposes of this article, reference will only be made to the treatment of chronic pain. The regulation's stated purpose reinforces the State's recognition that "[t]he diagnosis and treatment of pain is integral to the practice of medicine" and that controlled substances may play an important role in pain treatment:

> The principles of quality medical practice dictate that citizens of Delaware have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.
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> …
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> The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins.[59]

With this in mind, the regulation was developed to define the specific requirements for the treatment of pain with controlled substances, in order "to alleviate licensed practitioners' uncertainty, to encourage better pain management, and to minimize practices that deviate from the appropriate standard of care and lead to abuse and diversion."[60] Thus, much like the legislative purpose behind the PMP, the regulation was promulgated with the hope of curbing inappropriate use of controlled substances while not burdening proper utilization of such drugs in medical treatment. In fact, the BMLD believes that the regulation will help ease licensed practitioners' fears of investigation or sanction by setting better standards

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57. 15 Del. Reg. Regs. 1184 (Feb. 01, 2012) *amended by* 16 Del. Reg. Regs. 651 (Dec. 01, 2012). The amendments to the regulation in December 2012 addressed concerns regarding the regulation's applicability to use of controlled substances for the treatment of acute pain. 16 Del. Reg. Regs. 651, at 651. The amendment clarified the focus of the regulation, which was the use of controlled substances for the treatment of chronic pain. *Id.* The amendments also allowed the BMLD discretion to utilize clinical practice guidelines and the use of expert review for disciplinary matters involving pain treatment with controlled substances. *Id.* The text of the final regulation is found at 24 Del. Admin. Code 1700 § 18.0 (2013). The BMLD's statutory authority to promulgate regulations is found at Del. Code Ann. tit. 24, § 1713(a)(12).

58. 24 Del. Admin. Code 1700 § 18.0. "Acute pain" is defined as "the normal, predicted physiological response to a noxious chemical thermal or mechanical stimulus and typically associated with invasive procedures, trauma and disease" and is generally limited in duration. *Id.* § 18.10.1. "Chronic pain" is defined as "a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years." *Id.* § 18.10.3.

59. *Id.* § 18.0. The BMLD adopted the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain," which can be found at http://www.fsmb.org/pdf/2004_grpol_controlled_substances.pdf.

60. 24 Del. Admin. Code 1700 § 18.0.

for such treatment.[61] To be clear, the BMLD will consider inappropriate treatment to be a departure of the standards of medical practice and will investigate complaints pursuant to its regulatory authority.

Regulation 18 provides both the standards practitioners must follow in the treatment of chronic pain with controlled substances and the standards to which the BMLD must adhere in reviewing the appropriateness of such treatment. Each will be addressed in turn. First, it is important to note that the BMLD exercises regulatory authority in this regard only over certain health care providers, or those subject to the Medical Practice Act, including physicians and physician assistants (hereinafter, "practitioner(s)").[62]

Turning to the standards of treatment, the BMLD first set forth some primary overarching requirements for practitioners. First, "[a]ppropriate pain management is the treating practitioner's responsibility," so practitioners must obtain education regarding assessing pain and the effective methods of pain treatment.[63] Most importantly, in regard to that education, practitioners should understand that "tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and alone are not the same as addiction."[64] Patient pain should be properly assessed, in accordance with current clinical practice guidelines, and practitioners should use both pharmacologic and non-pharmacologic treatment modalities according to his or her judgment in accordance with current knowledge and scientific research. The quantity and frequency of doses of controlled substances must be adjusted according to the intensity and duration of pain, as well as treatment outcomes.[65] In addition to these more general requirements, there are six main requirements for the treatment of chronic pain with controlled substances: (1) evaluation; (2) the treatment plan; (3) informed consent; (4) the treatment agreement; (5) periodic review; (6) and consultation. In addition, Regulation 18 addresses standards for medical record documentation.

When evaluating a chronic pain patient, the practitioner must obtain a medical history and conduct a physical examination, which should be documented in the medical records. The practitioner's evaluation must document the etiology, nature and intensity of pain, any current and past treatments for pain, and any underlying or coexisting diseases or conditions. In addition, the evaluation must document the effect the pain has had on the patient's physical and psychological function, including whether the patient has a history of substance abuse. Finally, there must be present one or more recognized medical indications for treatment with controlled substances.[66]

The treatment plan is a written document stating the goals and objectives that will be used to determine treatment success. Such goals may be complete or partial pain relief, or improved physical function. The plan shall indicate any planned diagnostic evaluations or treatments, as well as whether alternative treatment modalities or rehabilitation programs

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61. While the regulation is broad in its scope, it only applies to the licensed practitioners over whom it exercises licensing and regulatory authority. This includes physicians, but excludes other potential prescribers of controlled substances, such as dentists.

62. Del. Code Ann. tit. 24, ch. 17.

63. 24 Del. Admin. Code 1700 § 18.0.

64. *Id.* "Tolerance" is defined by the regulation as "a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time." *Id.* § 18.10.9. "Physical dependence" is defined as "a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist." *Id.* § 18.10.6.

65. *Id.* § 18.0.

66. *Id.* § 18.1.1.

are indicated and necessary. Most importantly, after treatment begins with controlled substances, the practitioner must review the effectiveness of treatment and adjust the drug therapy to suit the continuing medical needs of the patient.[67]

Informed consent is a basic tenet of medical practice and a well-settled risk area for health care providers.[68] Regulation 18 specifically requires the practitioner to explain the risks and benefits of the use of controlled substances to the patient, or to someone with decision-making capacity for the patient if the patient lacks such capacity.[69]

The treatment agreement often stands at the center of these treatment relationships. Like any effective treatment, it requires a plan agreed upon by patient and practitioner. Regulation 18 imposes additional safeguards that must be included in agreements for the treatment of chronic pain with controlled substances, but *only if* the patient is "at high risk for medication abuse or has a history of substance abuse." As a matter of course, however, it is not always easy to detect a history of substance abuse, unless the patient is forthcoming with such information. If an agreement is required, it must include certain patient responsibilities. First, the patient must agree to random urine/serum medication level screening.[70] The patient must also agree to receive prescriptions only from the individual practitioner and only from one pharmacy when possible. The agreement shall also list the number and frequency of prescription refills and the reasons for which the treatment with controlled substances may be discontinued by the practitioner, such as violation of the agreement.[71]

Practitioners treating chronic pain patients with controlled substances must periodically review the course of the treatment, documenting any new information regarding the cause and source of the pain and any changes in the patient's health. At a minimum, the review must include an evaluation of whether controlled substances therapy should continue or be modified based on the practitioner's evaluation of the patient's progress toward the goals and objectives contained in the original treatment plan. Further, the periodic review must document an evaluation of whether the patient is having a satisfactory response to the treatment, as perhaps indicated by decreased pain, increased levels of function, or an improvement in quality of life. The hallmark of such evaluations is objective evidence of patient function, but the regulation notes that information from family members or caregivers should be considered in determining how the patient has been responding to controlled substances treatment. Finally, if the patient's progress is unsatisfactory, the periodic review must document the practitioner's assessment of the appropriateness of continuing the course of treatment and the consideration of alternative therapeutic modalities.[72]

The final of the six core standards is consultation. At any point during treatment, the practitioner must be prepared to refer the patient for additional evaluation and treatment to other health care providers in order to meet the treatment objectives contained in the treatment plan. The regulation states that "[s]pecial attention must be given to those patients with pain who are at risk for medication misuse, abuse or diversion." In addition to patients with a history of substance abuse, patients with co-morbid psychiatric disorders require extra care and may require consultation with or referral to

67. *Id.* § 18.2.

68. *See, e.g.*, Spencer v. Goodill, 17 A.3d 552 (Del. 2011).

69. 24 Del. Admin. Code 1700 § 18.3.

70. "Some physicians may feel uncomfortable with the mistrust implied by such confrontational approaches and may find that a highly functional [PMP] readily alerts its users to signs of aberrant drug-procurement behavior." Perrone & Nelson, *supra* note 2, at 2341. Still, when a treatment agreement is required under the regulation, urine drug screens are a mandated component of that agreement. 24 Del. Admin. Code 1700 § 18.4.

71. *Id.* Again, as stated *supra*, practitioners should be cognizant of patient abandonment.

72. *Id.* § 18.5.

experts familiar with treating such patients. The regulation affirmatively requires practitioners who "regularly treat" such patients to educate themselves about the current standards of care in the treatment of such patients.[73]

As stated above, in addition to the six core standards, Regulation 18 requires the practitioner to keep accurate and complete medical records. The medical records of a chronic pain patient being treated with controlled substances must include: (1) a history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) documentation of etiology of pain; (5) treatment goals; (6) a documented discussion of the risks and benefits of the use of controlled substances; (7) informed consent; (8) all treatments; (9) all medications, include the date, type, dosage and quantity prescribed; (10) patient instructions and agreements; and (11) documented results of periodic review.[74] All medical records must be current and maintained in an accessible manner. Thus, for each visit, a practitioner should include documentation appropriate for the level of care, including: (1) an interim history and physical examination; (2) a record of the patient's vital signs, as clinically appropriate; (3) an assessment of patient progress; and (4) the medication plan.

Turning to the standards under which the BMLD shall review the care provided by practitioners in the treatment of chronic pain patients, "practitioners should not fear disciplinary action from the [BMLD] for ordering, prescribing, dispensing or administering controlled substances … for a legitimate medical purpose and in the course of professional practice."[75] Such treatment must be based on sound clinical judgment, and the documentation addressed above is crucial to demonstrating that clinical judgment.

In reviewing treatment for pain with controlled substances, the BMLD may refer to current clinical practice guidelines and may utilize experts in the field. The validity of the treatment will be judged based upon the practitioner's documentation, and not solely on the quantity and duration of medication prescribed.[76] Every allegation of inappropriate treatment will be evaluated on an individual basis. A practitioner will be subject to discipline for violating Regulation 18 unless the contemporaneous medical records "document reasonable cause for deviation" from the regulations. Finally, the practitioner's treatment with controlled substances "will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life."[77]

The effectiveness of the rule in decreasing controlled substances abuse and diversion, its application in disciplinary proceedings, and its relationship with the operation of the PMP will be revealed over time. In the meantime, providers and their attorneys should view these developments as safeguards in safely prescribing to a sensitive patient population, and should work to ease any administrative hurdles encountered when attempting to comply with the new legal requirements.

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73. *Id.* § 18.6.

74. *Id.* § 18.7.

75. *Id.* § 18.0.

76. The quantity and duration of medication prescribed is exactly the type of information contained in the PMP. Such information may garner attention from regulators, but only medical record documentation will tell the whole story.

77. *Id.*