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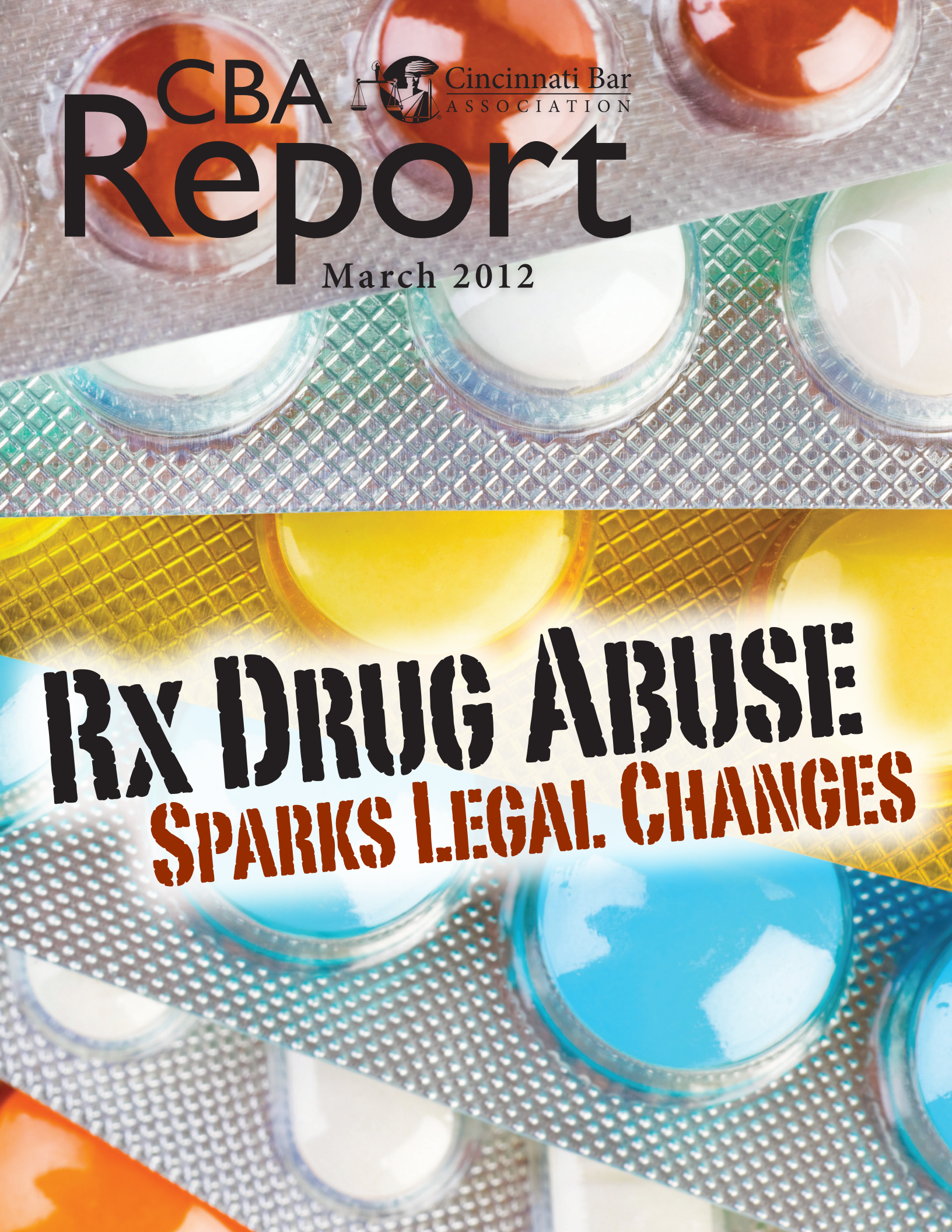

Rx Drug Abuse
Sparks Legal Changes

Ohio's New Law Combats Prescription Drug Abuse

By Rosemary D. Welsh

Ohio is engulfed by an epidemic of prescription drug abuse, and lawmakers have taken aim at rogue medical practices that operate as "pill mills."[1] H.B. 93 took effect on May 20, 2011, and imposed strict new controls that impact both individual physicians and pain management clinics. The new law was based, in part, on findings from the report of the Ohio Prescription Drug Abuse Task Force issued in 2010.[2] The Task Force reported that the death rate from unintentional drug overdoses increased by more than 300 percent from 1999 to 2008. Prescription pain medications such as methadone, oxycodone, hydrocodone and fentanyl are largely responsible for this alarming increase. In fact, prescription opioids are associated with more overdoses than any other prescription or illegal drug, including cocaine and heroin. Based on the significant increase in unintentional drug poisoning, the General Assembly declared the Act to be an emergency measure necessary for the immediate preservation of the public peace, health, and safety.[3]

Representative Terry Johnson, a physician that co-sponsored the bill, stated that in addition to the loss of life, the trade in diverted prescription drugs in Southern Ohio has created a shadow economy involving huge quantities and exorbitant profits.[4] In Scioto County, where Dr. Johnson practices, oxycodone sells for $80 a pill. "No one should suffer in pain needlessly, and legitimate sufferers must continue to receive needed medication, but the abuse has to stop," Johnson stated.

Multiple factors have combined to exacerbate the epidemic. Beginning in the 1990s, medical professionals recognized that pain was under-treated in clinical settings, and new practice parameters were developed at both the national and state levels. In 1998, the State Medical Board of Ohio adopted standards of care for the treatment of intractable pain that were directed primarily to end of life care.[5] A physician that treated intractable pain with prescription drugs was subject to disciplinary action by the Medical Board only if the prescription drugs were not utilized in accordance with the rules.[6] Such changes in medical practice, coupled with aggressive marketing strategies by pharmaceutical companies and direct marketing to consumers, resulted in a growing use of prescription pain killers throughout Ohio. The unlawful diversion of these regulated drugs has flooded illicit markets with controlled substances, fueling the epidemic.

H.B. 93 provides a multi-pronged approach to curtailing the epidemic that includes licensing and regulation of pain management clinics, limits on controlled substances, changes to the automated prescription reporting system, and revision of the legal basis for pain treatment with dangerous drugs.

Regulating Pain Clinics

The bill defines a pain management clinic as a facility for which the primary component of practice is treatment of pain or chronic pain and which includes the use of controlled substances, tramadol, or carisoprodol for the majority of patients.[7] Even a family practice, an internal medicine practice, or other type of practice that is not limited to pain management is classified as a pain management clinic if these two criteria are met. However, the administrative rules for pain management clinics adopted by the State Medical Board of Ohio provide an exclusion. Patients who are being treated with controlled substances for an injury or illness that lasts or is expected to last 30 days or less are not considered in the calculation of the majority.[8]

Existing Ohio law has long required a terminal distributor of dangerous drugs to be licensed by the Ohio State Board of Pharmacy.[9] The bill establishes "pain management clinic" as a classification of terminal distributor.[10] In addition to the requirements applicable to all terminal distributors, licensees with a pain management clinic classification must also demonstrate that the facility is owned and operated by one or more physicians licensed to practice medicine or osteopathic medicine, ensure that employees comply with requirements for the operation of pain management clinics, submit criminal records checks of any owner of the facility to the Pharmacy Board, ensure no employees have been convicted of or pleaded guilty to a felony, and maintain a list of persons with ownership of the facility.[11]

An applicant that meets the requirements for operation of a pain management clinic will be licensed as a category III terminal distributor of dangerous drugs.[12] A category III license authorizes the holder to possess, have custody or control of, or distribute

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any controlled substance contained in schedule I, II, III, IV, or V.[13] The General Assembly charged the Medical Board with adopting standards and procedures for the operation of pain management clinics, and these rules became effective August 31, 2011.[14]

The new rules require a pain management clinic to have proper equipment, materials, and personnel on the premises to provide appropriate medical treatment as required by the minimal standards of care.[15] The clinic must comply with the Drug Prevention and Control Act, 21 U.S.C. 801, *et seq.*, and Chapters 3719, 4730 and 4731 of the Revised Code and conduct a quality assurance program to monitor and evaluate the quality and appropriateness of patient care. A daily log of patients, personally signed by each patient, must be maintained for seven years. Each patient must give informed consent prior to the start of treatment, with full disclosure as to the nature and purpose of the treatment and its risks and benefits. The background, training, certification and licensure of all clinical staff must be documented, and licensure and certification must be verified annually. Adequate billing records must be maintained, and patient records must be kept for seven years from the last date of treatment.

New Limits on Prescribers

Individual physicians, podiatrists, and dentists that prescribe controlled substances are also subject to new requirements. The bill limits the amount of controlled substances that prescribers may personally furnish each month and in any 72-hour period.[16] "Personally furnish" refers to a provider's providing a whole or partial supply of drugs to a patient for the patient's personal use, but not the direct administration of a drug to a patient. In any 30-day period, the combined amount of controlled substances personally furnished by a prescriber may not exceed 2,500 dosage units. In any 72-hour period, the amount of a controlled substance provided to or for a patient may not exceed the amount necessary for the patient's use in a 72-hour period. Methadone is an exception. When personally furnished to a patient to treat drug addiction, methadone does not count toward the limits.[17]

Ohio's Automated Reporting

In 2006, the Ohio State Board of Pharmacy established the Ohio Automated Rx Reporting System, a drug database known as "OARRS," to monitor the misuse and diversion of controlled substances and other dangerous drugs.[18] OARRS can be used to generate a report regarding a specified patient's prescription history of schedule II through V controlled substances, carisprodol, or tramadol ("reported drugs").[19] Wholesale distributors and certain terminal distributors are required to report information to OARRS regarding the delivery and dispensing of dangerous drugs.[20] Prescribers must register on-line to gain access to OARRS, both to submit reports and to review a patient's prescription history.

The bill provides a new reporting requirement for prescribers who personally furnish controlled substances or other dangerous drugs specified by the Pharmacy Board.[21] For purposes of OARRS, the Ohio Administrative Code defines "personally furnish" as "the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting."[22] A licensed health care professional that personally furnishes a controlled substance, carisprodol, or tramadol to a patient must report the following information to OARRS:

- Prescriber identification;
- Patient identification;
- The date the prescriber furnished the drug;
- Whether the drug is new or a refill;
- Name, strength and national drug code of the drug;
- Quantity of the drug furnished;
- The number of days' supply furnished; and
- Source of payment for the drug furnished.[23]

Besides complying with reporting requirements, in certain cases health care practitioners must also access and review the OARRS prescription history for their patients. Each licensing entity, *i.e.,* the boards for physicians, pharmacists, dentists, nurses, optometrists, and physician assistants, must adopt rules implementing the new OARRS review requirements. The Medical Board's new rules became effective on November 10, 2011, and direct physicians to consult OARRS for guidance in determining whether a reported drug should be prescribed or personally furnished to a patient. If a physician believes or suspects that a patient may be abusing or diverting drugs, the new rule directs the physician to "use sound clinical judgment" in determining whether to use a reported drug.[24] If the patient exhibits the following warning signs of drug abuse or diversion, however, an OARRS report is mandatory:

(a) Selling prescription drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;

(f) Having been arrested, convicted or received diversion or intervention in lieu of conviction for a drug related offense while under the physician's care;

(g) Receiving reported drugs from multiple prescribers, without clinical basis; or

(h) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs.[25]

Other signs of possible abuse or diversion include:

(a) A known history of chemical abuse or dependency;

(b) Appearing impaired or overly sedated during an office visit or exam;

(c) Requesting reported drugs by specific name, street name, color, or identifying marks;

(d) Frequently requesting early refills of reported drugs;

(e) Frequently losing prescriptions for reported drugs;

(f) A history of illegal drug use;

(g) Sharing reported drugs with another person; or

(h) Recurring emergency department visits to obtain reported drugs.[26]

Under the rule, a physician that detects these signs of possible abuse or diversion may, but is not required, to request an OARRS report of the patient's prescription history. Even where a physician has no reason to believe that a patient may be abusing or diverting drugs, a physician who prescribes or personally furnishes reported drugs must obtain an OARRS report where treatment with dangerous drugs will continue for more than twelve continuous weeks and at least once annually thereafter.[27] The Ohio State Medical Association has strongly encouraged all physicians who currently or may potentially prescribe reported drugs to register with OARRS.[28] As a result, OARRS has experienced a high volume of applications. According to Danna Droz, administrator of the prescription monitoring program for the Oho State Board of Pharmacy, the time required to process registrations has stretched to nearly a month. Ohio does not have jurisdiction over federal facilities, however, and Droz stated that at present practitioners working at Veterans Administration hospitals and military bases do not participate in OARRS. The Pharmacy Board is working with the Ohio VA to enable practitioners to contribute to and receive information from OARRS.[29]

New Legal Standards

In 1997, the General Assembly directed the Medical Board to establish standards and procedures for diagnosing and treating what was termed "intractable pain."[30] Intractable pain was defined as "a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found."[31] The statute contemplated managing intractable pain by the use of "dangerous drugs in amounts or combinations that may not be appropriate when treating other conditions."[32] The rules promulgated by the Medical Board were codified in Chapter 4731-21 of the Ohio Administrative Code and set forth accepted and prevailing standards of care for the treatment of intractable pain.[33]

H.B. 93 changed the legal basis for the treatment of pain. The bill replaced the term "intractable pain" with "chronic pain," which is defined as "pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months."[34] While recognizing that pain may extend beyond the normally expected healing period, the addition of a specific duration for pain to qualify as "chronic," *i.e.*, three continuous months, sharpens the definition. Pain associated with a terminal condition or with a progressive disease that may reasonably be expected to result in a terminal condition is specifically excluded from the definition of "chronic pain."[35]

The bill left intact the requirement for a physician to maintain a record of the following information:

1. Medical history and physical examination of the individual;
2. The diagnosis of chronic pain, including signs, symptoms, and causes;
3. The plan of treatment proposed, the patient's response to treatment, and any modification of the plan of treatment;
4. The dates on which dangerous drugs were prescribed, furnished, or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed, or administered, and the amounts and dosage forms for the dangerous drugs prescribed, furnished, or administered; and
5. A copy of the report made by the physician or the physician to whom referral for evaluation was made.[36]

With the new definition in place, the Medical Board must adopt new rules regarding the standards and procedures to be followed in the diagnosis and treatment of "chronic pain" and develop new continuing medical education courses.[37] According to Michael Miller, the Medical Board's program administrator for policy and governmental affairs, the Board will begin work on the new rules in February. A multidisciplinary advisory panel including pharmacists, nurses, and medical specialists will make recommendations and prepare a draft of the new rules for the Board's consideration.

Although H.B. 93 changed the terminology from "intractable pain" to "chronic pain," the guidelines for clinical practice to be adopted by the Medical Board are likely to retain the essential elements of the existing rules and to increase the emphasis on informed consent. Rule 4731-21-02 of the Ohio Administrative Code currently requires an initial evaluation that includes complete medical, pain, alcohol and substance abuse histories, assessment of the impact of pain on physical and psychological function, review of previous diagnostic studies and therapies, an assessment of co-existing illnesses, diseases or conditions, and a physical examination.[38] The medical diagnosis must be documented along with the signs, symptoms, and causes of pain. An individual treatment plan is also documented with the medical justification for treatment of pain with prescription drugs on a protracted basis, the intended role of prescription drug therapy within the overall plan, and noting other medically reasonable pain treatments that have been tried. The patient must be counseled as to the risks and benefits of receiving prescription drug therapy and of available treatment alternatives, and the patient's informed consent must be retained in the patient's medical record.

After establishing the treatment plan, the practitioner must see the patient at appropriate intervals to assess the efficacy of treatment, to assure that prescription drug therapy remains indicated, to evaluate progress, and to note

any adverse drug effects. The practitioner must also assess functional status, the intensity of pain, and any interference with activities of daily living, quality of life, and social activities. The practitioner may obtain a drug screen if warranted, and the results should be documented. If the practitioner believes that the patient is suffering from addiction or drug abuse, the rule requires immediate consultation with an addiction medicine or substance abuse specialist.

"Lock-In" Program Established

Drug-seeking patients have become adept at increasing their access to prescription medication by requesting treatment from multiple practitioners simultaneously. A dentist prescribing a pain killer following a tooth extraction, for example, may not be aware that the patient is already receiving narcotics for a disc herniation. Where Medicaid recipients have over-utilized Medicaid services, federal law allows states to restrict Medicaid recipients to designated providers. Consistent with federal law, H.B. 93 requires each Medicaid managed care organization and the fee-for-service component of the Medicaid program to implement a coordinated services program for Medicaid recipients who are found to have obtained prescription drugs at a frequency or in an amount that is not medically necessary.[39] Also referred to as a "lock-in," a coordinated services program generally requires a Medicaid recipient to choose a single pharmacy as the provider for prescription medication, thereby minimizing the likelihood that a recipient will overuse prescription pain medication. Before dispensing any prescription, a pharmacist must review the patient profile to identify over-utilization, therapeutic duplication, and evidence of abuse/misuse, among other things.[40]

The bill also requires the Administrator of the Ohio Bureau of Workers' Compensation (BWC) to implement a similar coordinated services program for claimants that have obtained prescription drugs at a frequency or in an amount that is not medically necessary.[41] The Bureau already evaluates claims to ensure that injured workers are receiving appropriate medical services, which should facilitate implementation of a coordinated services program for workers' compensation claimants.

Workers' Comp Pain Treatment

The Ohio Administrative Code provides that medical supplies and services will be considered for payment under the Workers' Compensation Act "when they are medically necessary for the diagnosis and treatment of conditions allowed in the claim, are causally related to the conditions allowed in the claim, and are rendered by a health care provider."[42] In *State ex rel. Miller v. Industrial Commission*, 71 Ohio St.3d 229, 231 (1994), the Ohio Supreme Court set forth a three-pronged test for authorizing medical services under the Workers' Compensation Act:

1. Are the medical services reasonably related to the conditions allowed in the claim?
2. Are the medical services reasonably necessary for treatment of the industrial injury?
3. Is the cost of these services medically reasonable?

In a 2004 Position Paper regarding the use of prescription medication for the treatment of intractable pain, the Bureau acknowledged both the three-pronged test set forth in *Miller* and the administrative rules governing prescriptions of controlled substances.[43] "Since these rules provide the legal authorization and criteria for use of prescription drugs for treatment of intractable pain, they must also be followed by physicians providing opinions for authorization of payment for such medications in claims in either file reviews or independent medical evaluations for BWC." As long as a treating physician complies with these rules, the Bureau stated that "the use of prescription medication for the treatment of chronic intractable pain is acceptable in Ohio on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions." The Bureau has contacted the Medical Board regarding its new rules, and it is likely that the Bureau will approve the extended use of prescription medication for the treatment of chronic pain prescribed in accordance with the new standards and procedures to be adopted by the Medical Board.

Unintended Consequences

The General Assembly, the Medical Board, and the Pharmacy Board are united in opposing improper prescription, dispensing, and use of dangerous drugs while at the same time assuring that medically necessary treatment for pain continues to be provided. Physicians that practice in the area of pain management, however, have expressed concern that the broad definition of "pain management clinic" contained in H.B. 93 will inevitably curtail the availability of legitimate pain treatment. Under the bill, any medical practice for which the primary component of practice is treatment of pain or chronic pain and which includes the use of controlled substances, tramadol, or carisoprodol for the majority of patients is a "pain management clinic" and subject to significant additional regulations. [44]

Some practitioners believe that the impact of this section of the bill has been significantly misjudged. A family practice that includes a high percentage of geriatric patients treated for osteoarthritis or degenerative disc disease, for example, could result in more than 50 percent of patients receiving pain treatment with controlled substances. Even though a family physician who is very familiar with the patient's entire medical history is often in the best position to manage chronically painful conditions, the physician may be deterred by the regulatory burdens that accompany a "pain management clinic" classification and simply abandon the use of controlled substances to treat pain. Such a result is not likely to be in the patient's best interest, particularly where the patient has a dual diagnosis of chronic pain coupled with bi-polar disorder or schizophrenia. According to a pain management physician who practices in Cincinnati, adequate treatment of the underlying mental health issue is essential to forestall overconsumption of pain medication triggered by anxiety or other mental illness, and most pain management clinics are not in the best position to provide mental health treatment. In addition, persons that have become ad-

dicted to narcotic medication may simply turn to street drugs such as heroin and cocaine if their access to pain pills is cut off – essentially trading one problem for another. Such unintended consequences may come to light as H.B. 93 is fully implemented.

Conclusion

The American College of Surgeons has lauded Ohio's success in passing laws to combat the epidemic of prescription drug abuse – one of only two states to stymie pill mills legislatively.[45] In light of the abuse of prescription opioids continuing to rise more than 400 percent in ten years, more states must act to protect both patients and physicians. In 2001, the American Pain Society issued a joint statement with twenty other health organizations and the Drug Enforcement Administration entitled "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act."[46] The consensus statement recognized that prevention of drug abuse "should not hinder patients' ability to receive the care they need and deserve." That balancing act will be critical as Ohio's policy makers adopt the rules to implement H.B. 93.

Welsh is of counsel with Vorys, Sater, Seymour and Pease LLP. Her practice encompasses a broad range of workplace issues, including workers' compensation, retaliatory discharge, intentional torts and toxic exposures.

1 In August 2011, for example, a Scioto County physician, John S. Temponeras, M.D., lost his medical license after authorizing thousands of prescriptions for controlled substances without individualized treatment plans for each patient, knowing that the prescriptions would likely be filled by an unregistered dispensary owned by his daughter, Margy Temponeras, M.D., and failing to maintain adequate records of inventory. The State Medical Board of Ohio indefinitely suspended Dr. Margy Temponeras's medical license by order dated January 11, 2012. It has been appealed in the Franklin County Court of Common Pleas.

2 Ohio Prescription Drug Abuse Task Force Final Report and Task Force Recommendations, October 1, 2010.

3 H.B. 93, Section 3.

4 Capitol Connection Bill History for H.B. 93, 129th General Assembly.

5 OAC Chapter 4731-21.

6 OAC 4731-21-06(B).

7 R.C. 4731.054(A)(4)(a). While not narcotics, tramadol and carisprodol have been identified as having a high potential for abuse.

8 OAC 4731-29-01(A)(5)(c)(ii).

9 R.C. 4729.01(Q) defines terminal distributor of dangerous drugs as "a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs."

10 R.C. 4729.552.

11 R.C. 4729.552(B)(1)-(5).

12 R.C. 4729.552.

13 R.C. 4729.54(E)(5); R.C. 4729.54(A)(3); R.C. 3719.41.

14 R.C. 4731.054(C); OAC 4731-29-01.

15 OAC 4731-29-01(B)(6).

16 R.C. 4729.291(C)(1).

17 R.C. 4729.291(C)(2)(b).

18 R.C. 4729.75. Currently, Ohio is one of 48 states that either have operating prescription monitoring programs or have passed legislation to implement monitoring programs. The Alliance of States with Prescription Monitoring Programs, http://pmpalliance.org/content/state-pmp-websites, accessed January 27, 2012.

19 R.C. 4729.80(A); OAC 4731-11-11(A)(5).

20 R.C. 4729.77 and R.C. 4729.78.

21 R.C. 4729.79.

22 OAC 4731-11-11.

23 R.C. 4729.79(A).

24 OAC 4731-11-11(B).

25 OAC 4731-11-11(B)(1).

26 OAC 4731-11-11(B)(2).

27 OAC 4731-11-11(C).

28 Medical Board OARRS Rule Finalized, OSMA, September 23, 2011.

29 Danna Droz, Administrator, Prescription Management Program, Ohio Board of Pharmacy, personal communication, January 27, 2012.

30 R.C. 4731.052.

31 R.C. 4731.052(A)(2).

32 R.C. 4731.052(B).

33 OAC 4731-21-02(A).

34 R.C. 4731.052(A)(2).

35 R.C. 4731.052(A)(2).

36 R.C. 4731.052(C). H.B. 4731.052(C)(2) to refer to "chronic pain" rather than "intractable pain."

37 R.C. 4731.052(B); R.C. 4731.283.

38 OAC 4731-21-02(1).

39 R.C. 5111.085.

40 OAC 4729-5-20.

41 R.C. 4121.50.

42 OAC 4123-6-25.

43 Ohio Bureau of Workers' Compensation, Position Paper on Utilizing Prescription Medications for the Treatment of Intractable Pain, January 2004; OAC Chapter 4731-21.

44 R.C. 4731.054; OAC Chapter 4731-29.

45 Macias, A., "State legislatures attempt to shut down the pill mills," Bulletin of the American College of Surgeons, Vol. 96, No. 11, November 2011, 38-39.

46 "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act," a Joint Statement from 21 Health Organizations and the Drug Enforcement Administration (October 2001).