Introduction

Medical regulators are obliged to evaluate physicians suspected of diverting controlled substances for personal use and thus decrease or prevent risks to patient health, safety and welfare, as well as the health and well-being of the physicians themselves. This type of diversion places patients at risk for infectious disease transmission, substandard patient care, and/or denial of medication. State medical boards (SMBs) have an obligation to ensure that the highest quality of care is provided to all patients, which includes a multifaceted role in investigating, monitoring and disciplining physicians and a responsibility to make concerted efforts to prevent harm to patients. Thus, SMBs are an integral part of the process when a physician is suspected of being impaired. Implementation of both preventive and responsive measures is crucial in attempting to not only avoid physician drug diversion, but to effectively address drug diversion when it occurs. In April 2011, the House of Delegates of the Federation of State Medical Boards (FSMB) adopted its Policy on Physician Impairment. The policy provides guidance for state medical and osteopathic boards on the inclusion of physician health programs (PHPs) to facilitate evaluation, recovery and rehabilitation and monitoring of physicians, as well as to protect the public from impaired physicians. This article reviews the problem of controlled-substances diversion by physicians and its adverse effect on public and personal safety, and it demonstrates how SMBs or other parties can use the FSMB Policy on Physician Impairment as a guide to develop their own professional assistance programs to ensure public safety.

Abstract: Diversion of opioids and other controlled substances for personal use by physicians poses a risk to patient health, safety and welfare, as well as the health and well-being of the physicians themselves. This type of diversion places patients at risk for infectious disease transmission, substandard patient care, and/or denial of medication. State medical boards (SMBs) have an obligation to ensure that the highest quality of care is provided to all patients, which includes a multifaceted role in investigating, monitoring and disciplining physicians and a responsibility to make concerted efforts to prevent harm to patients. Thus, SMBs are an integral part of the process when a physician is suspected of being impaired. Implementation of both preventive and responsive measures is crucial in attempting to not only avoid physician drug diversion, but to effectively address drug diversion when it occurs. In April 2011, the House of Delegates of the Federation of State Medical Boards (FSMB) adopted its Policy on Physician Impairment. The policy provides guidance for state medical and osteopathic boards on the inclusion of physician health programs (PHPs) to facilitate evaluation, recovery and rehabilitation and monitoring of physicians, as well as to protect the public from impaired physicians. This article reviews the problem of controlled-substances diversion by physicians and its adverse effect on public and personal safety, and it demonstrates how SMBs or other parties can use the FSMB Policy on Physician Impairment as a guide to develop their own professional assistance programs to ensure public safety.

The outbreaks described in Table 1, which represent the injectable drug diversion outbreaks investigated in the United States from 1983 to 2013, demonstrate gaps in monitoring systems to detect diversion.

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In addition to the clear patient harm documented in Table 1, the diversion of opioids and other controlled substances by physicians also raises the problem of harm to the physicians themselves.

The dual goal of protecting patients from potential harm caused when physicians divert medications for personal use and, at the same time, preventing physicians from becoming impaired, requires a multidisciplinary approach to detect and investigate diversion. In this environment, state medical boards (SMBs) are positioned to play a significant role.

This article describes the role of medical regulation in preventing diversion, ensuring the quality of care and responding to physician impairment.

Table 1 summarizes several actual outbreaks and other possible serious blood-borne pathogens that can be transmitted (including both viral and bacterial) with association to healthcare workers in various scopes of practice. From 1983 to 2013, a total of 225 cases of patients who have been infected by contaminated vials related to health care provider drug-diversions have been documented.¹

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References

Physician Impairment

Physicians, like the general population, are at risk for substance-abuse disorders. Physicians have higher rates of opioid and benzodiazepine abuse than the general population, and the highest among health care providers. Estimates of physicians’ chemical dependency to drugs or alcohol during their careers vary from 10 to 15%, which is similar to the general population. A survey in 2005 reported that anesthesiologists are overrepresented with substance use disorders in PHPs and are more likely to abuse fentanyl and sufentanil. They are more likely to enroll in PHPs, due to opioid abuse and higher rates of intravenous drug use. Over a five-year period, anesthesiologists were less likely to fail a drug test during administrative substance abuse monitoring and had no statistically significant differences in their rate of PHP completion, disciplinary actions, return to work, or death than other physicians. In addition, the overall relapse rate for physicians enrolled in a PHP is significantly less than the 40% to 60% relapse rate in the general population. A retrospective cohort study found that the physician relapse rate increased with use of a major opioid, co-existing psychiatric illness or a family history of substance use disorder.

Preventing Drug Diversion

Prevention of drug diversion requires an interdisciplinary approach. It is essential to the safety of the patients in a health care facility and is the individual responsibility of every employee. Drug diversion is difficult to completely prevent; however, due to its adverse consequences, many health care facilities have incorporated systems to deter controlled substance diversion and promptly identify it and intervene when it occurs. Such systems are multifaceted and require close cooperation between multiple stakeholders, such as departments of pharmacy, safety and security, nursing, legal counsel and human resources.

Beyond effective reporting and investigation, education and policy implementation are keys to the prevention of drug diversion. Some examples of preventive strategies include pre-employment criminal background checks, as well as education and training of all employees at orientation and throughout the duration of their employment—especially for those directly handling controlled substances. The implementation of policies that adhere to federal, state and local laws, together with regulations such as controlled substance tracking, handling and surveillance, all contribute to the prevention of drug diversion.

Ultimately, when a physician diverts controlled substances, mandatory reporting to various agencies—such as a professional licensing board—becomes an important part of ongoing drug diversion prevention.

The Role of Medical Regulation in the Quality of Care

SMBs have an obligation to ensure that the highest quality of care is offered to patients. Over the years there have been many ways of achieving this goal—from physician self-reporting of errors to
The Role of Medical Regulation in Physician Impairment

In addition to potential disciplinary actions to protect the public, SMBs also must consider potential actions to address physician impairment if the diversion is for self-administration. They play an integral role in the process of addressing physician impairment.

Incidences of health care providers becoming dependent on controlled substances have existed since their discovery. One prominent case involved 19th century American surgeon William Halstead, who early in his medical career developed a substance use disorder when he experimented with cocaine and morphine — both of which were being used in surgical treatments at the time. Halstead, who went on to a historically significant surgical career at Johns Hopkins, continued to use the drugs throughout his professional life.26

Historically, SMBs have viewed physician impairment as a disciplinary matter. To a degree, they still are. Impairment and narcotic actions made up the majority of SMB disciplinary actions from 1963 to 1972. The focus started to change to recovery and rehabilitation with passage of the Florida “Sick Doctor Law” in 1969. Since then, the policy on physician impairment has evolved.27 As the physician shortage grew and rehabilitation became more successful, regulators developed processes to facilitate physician rehabilitation and reentry to practice.

In April 2011, the FSMB’s House of Delegates adopted its Policy on Physician Impairment. The policy gives guidance to state medical and osteopathic boards for inclusion of PHPs to help protect the public from impaired physicians. SMBs, such as the New Jersey Board of Medical Examiners (NJBME), may be empowered through regulations to mandate physician participation in PHPs, to communicate with and coordinate with PHPs regarding participation and fitness to practice, and to have a legal agreement with PHPs regarding licensee participation. Individual SMBs can integrate the FSMB’s policy into their routine practice, as illustrated in Table 2, which uses mandatory testing and even public notices and action taken against a physician’s license.22 The need for intervention is never more evident than when a physician is impaired due to drug diversion. SMBs have a multifaceted role in the investigation of impaired physicians, ensuring that any potential patient harm is limited, while addressing the physician’s rehabilitation.

The first aspect in determining physician impairment involves the investigation of the quality of care provided by the physician. This may include obtaining the medical records of patients, an on-site inspection, staff interviews and/or a hearing. The matter may also require a “look-back” investigation to determine the number of exposed patients that should be contacted for recommended follow-up testing to determine if disease transmission occurred and whether there is a need for subsequent treatment. The “look-back” is usually conducted as a collaborative effort between local and state public health departments and the CDC. CDC support includes technical guidance, consultation by epidemiologists, on-site assistance with field investigations, and laboratory assistance. The CDC has developed a four-section tool kit that can be used during these investigations. The toolkit includes information on risk communication and sample patient notification and patient test result letters, media planning and communication strategies (including sample press releases and fact sheets), communication resources to support patient notification (including frequently asked questions for call center utilization) and strategies to coordinate with the media when releasing patient notification letters.23, 24 In one of the examples of drug diversion noted in Table 1, an anesthesiologist with chronic hepatitis C used the same needle to anesthetize his patients that he had used to administer fentanyl to himself. He also gave patients anesthetics from an ampule contaminated with his own blood. More than 1,200 patients were tested for hepatitis C, 33 of whom were confirmed by molecular analysis to have been infected with hepatitis C by the anesthesiologist and needed treatment with antiviral medications. The anesthesiologist was arrested and convicted of spreading hepatitis C.4

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the Professional Assistance Program of New Jersey (PAPNJ) as an example.²⁸

Currently PHPs are available in all states except California, Georgia, Nebraska and Wisconsin.¹⁷ The role of PHPs is to guide physician rehabilitation while protecting public safety via early identification, evaluation, treatment, monitoring and advocacy.²⁸

The relationship between SMBs and PHPs varies from state to state. PHPs can be independent, non-profit entities, affiliated with a state medical society, or operated by the SMB. The relationship between an SMB and a PHP is usually defined in a legal agreement.²⁸

Physicians can be referred to a PHP by an employer or colleague, independent of action by an SMB. However, SMBs can compel a physician to enroll in a PHP and comply with its recommendations.²⁹

PHPs, including the PAPNJ, have knowledge and expertise in evaluating, diagnosing, monitoring, and treating impaired physicians, as well as physicians with a potentially impairing illness. PHPs approach substance use disorder as a treatable chronic disease. They treat both the disorder and any mental health co-morbidity with early treatment referral, long-term treatment and intensive management.

U.S. PHPs have been very successful, with only 22% of physicians testing positive within five years of PHP admission.¹⁹ An estimated 72% to 85% of physicians enrolled in a PHP for substance use disorder maintain their license and continue to practice within this timeframe.²⁵, ³⁰

The PAPNJ is used as an example of implementation of the FSMB policy by an SMB. The mission of PAPNJ is to provide services to protect the public safety and welfare of the citizens of New Jersey through education, identification, evaluation, treatment planning, and advocacy for licensed health care and other professionals in recovery from impairing medical conditions and illnesses, including substance use/abuse, psychiatric disorders, psychosexual disorders, disruptive disorders, metabolic disorders, cognitive disorders, and physical disorders.³¹ Table 2 shows the areas in which the NJBME, through its PAPNJ, is consistent with the details of the FSMB policy, as well as areas in which they differ.²⁸

Conclusion

Medical regulation of physicians not only plays an important role in protecting the health, safety and welfare of patients, but also acts to protect physicians through various measures to prevent drug diversion. Medical licensing and disciplinary boards in the United States can conduct investigations; limit, suspend or revoke licenses; and require entry into a recovery and rehabilitation program, remedial education or training, to protect the public. Boards can also address physician impairment through their relationship with PHPs. It is through these mechanisms that boards can address the diversion of opioid and other controlled substances by physicians to prevent health care worker injury or ongoing adverse patient outcomes, such as substandard care, infections, and denial of medication. The FSMB’s Policy on Physician Impairment provides guidance to state medical boards and PHPs to effectively assist impaired licensees, or those with impairing illness, in coordinating intervention and treatment of the physician’s health.²⁸ States without PHPs should develop them according to the FSMB’s policy. States with a PHP should review their relationship with the PHP for consistency with the FSMB policy.

Physician rehabilitation is increasingly more important as the physician shortage grows. In this environment, PHPs have a primary commitment to uphold their state medical boards’ overall mission of protecting the public. In conjunction with the PHPs and with their goal of ensuring the overall safety of the public and the practitioner, the SMBs can determine if and when — and if necessary, under what limitations — the physician can regain his or her license and resume practice, based on fitness to practice.

In drug diversion, physicians provide a substandard level of care and also put themselves at significant risk of losing their medical licenses — possibly for a lifetime. Through education, monitoring and advocacy, programs such as the PAPNJ — which are developed following the FSMB’s Policy on Physician Impairment — provide a means to identify, evaluate and treat physicians who may have diseases of impairment in order to ultimately protect the public safety.
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<tr>
<th>Federation of State Medical Boards (FSMB) Policy</th>
<th>Professional Assistance Program of New Jersey (PAPNJ)</th>
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<tr>
<td>The PHP should have a clearly defined mission</td>
<td>To provide services and to protect the public safety and welfare of the citizens of New Jersey through education, identification, evaluation, treatment planning and advocacy for licensed health care and other professionals in recovery from impairing medical conditions and illnesses</td>
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<td>The PHP should have an independent organizational structure. The PHP should employ a full-time medical director with qualifications in addressing addictive, mental and behavioral illness</td>
<td>Independent from the NJBME, the PAPNJ Board of Directors Executive Medical Director is Louis E. Baxter, MD, DFASAM, DABAM, who is past president of the American Society of Addiction Medicine and past director of the National Association of Drug Court Professionals</td>
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<td>A formal contract should be executed between the SMB and PHP setting forth accountability, collaboration and communication</td>
<td>The NJBME entered into an agreement with PAPNJ to administer their anonymous program, the Alternative Resolution Program (ARP) which is a special committee of the Board known as the Impairment Review Committee (IRC)</td>
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<td>The PHP should be empowered to conduct an intervention based on clinical reasons suggestive of potential impairment</td>
<td>Each health care professional referred for an evaluation of an impairing condition will undergo a thorough and comprehensive interviewing process designed to elucidate the common impairing conditions that are causative. Treatment plans will be developed in accordance with evidenced based protocols and procedures individualized according to each person's need and severity of illness</td>
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<td>The PHP should include adequate support staff</td>
<td>The PAPNJ has five clinicians and adequate clinical and administrative support staff</td>
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<td>PHPs and SMBs should periodically review laws and regulations and recommend changes to ensure that the PHPs function effectively and are legally able to keep up with evolving best practices</td>
<td>New Jersey regulation sunset laws require periodic review and, if necessary, revision of all regulations including N.J.A.C. 13:35-1.1, which is the NJBME regulatory subchapter pertaining to the PAPNJ</td>
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<td>PHPs should seek organized medicine support and support of others</td>
<td>A major malpractice insurance carrier in New Jersey provides space for the PAPNJ. The IRC includes a designee of the Commissioner of the New Jersey Department of Health</td>
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<td>PHPs should have a process to intervene when information indicates a reasonable concern that a physician may have a potentially impairing illness</td>
<td>New Jersey regulation (N.J.A.C.13:35-11.3) requires the PAPNJ to promptly intervene and make an initial report to the IRC concerning every referral that suggests an impairment within 30 days of receipt of the referral</td>
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<td>PHPs should have the authority to conduct an initial screening assessment and coordinate a referral for professional evaluation to determine the nature and extent of functional impairment and underlying illness. The FSHP Guidelines for referral criteria should be followed</td>
<td>The PAPNJ, when appropriate, refers for professional evaluation and provides the results of that evaluation to the IRC. The IRC has regulatory authority to direct the PAPNJ to conduct a supplemental inquiry</td>
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<td>Treatment or secondary prevention strategies should be used to diagnose and treat an illness. The PHP should use the FSHP Guidelines to determine if a facility or provider is acceptable for referrals</td>
<td>The PAPNJ utilizes modalities such as inpatient hospitalization for detoxification, residential treatment, outpatient treatment, 12-step programs, professionally led individual counseling and/or group therapy and other types of treatment as appropriate</td>
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<td>The PHP must be able to develop and implement discharge planning, continuing care, and monitoring plans. The PHP should have the authority to ensure compliance with continuing care and to remove participants from practice who pose a risk to patient safety</td>
<td>This is part of the scope of practice of the PAPNJ. Regulations (N.J.A.C. 13:35-11.3) require an immediate report to the IRC and disclosure of the identity of the participant to the NJBME if the participant has not complied with the terms of their letter agreement with the PAPNJ or the plan; has a urine or blood test result that is positive for a substance that is not appropriately prescribed for a legitimate medical reason; demonstrated relapse or impairment; engaged in deceptive behavior; suffered an exacerbation rendering the licensee incapable of practicing with requisite skill and safety; or has changed status. The PAPNJ can request that licensee stop practicing if they pose a risk to public safety</td>
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<td>Methods should be designed for early recognition of relapse and the PHP should have the ability to respond in a timely, effective fashion. The response should include a report to the SMB with agreed upon reporting requirements. It is critical that the PHP Medical Director communicates with the SMB the identification of previously anonymous participants in the event of substantive non-compliance or relapse</td>
<td>Regulations (N.J.A.C. 13:35-11.3) require an immediate report to the IRC and disclosure of the identity of the participant to the NJBME if the participant has a relapse. The PAPNJ can request that the participant stop practicing if they are concerned about public safety</td>
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The PHP should have a voluntary track allowing the physician to maintain confidentiality. For voluntary participants, PHP records and identifying information should be accessible only by PHP staff and not divulged to other sources without proper legal consent and authorization. The PHP should maintain documentation of PHP participant records

PAPNJ participant confidentiality is defined in the regulations as maintaining a licensee’s identity as well as information from which a licensee’s identity could be deduced in a limited access file maintained by the IRC with disclosure provided only to those persons who need to know in order to perform their role in the review process.

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### Table 2
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<th>Federation of State Medical Boards (FSMB) Policy</th>
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<td>Recovery monitoring should provide documented evidence, such as reports from treatment providers, worksite monitors, PHP consultants, behavioral monitoring, and appropriate others, of participant ability or inability to practice safely</td>
<td>The reports listed in the FSMB policy are maintained in the PAPNU medical record with pertinent information provided to the IRC at its required periodic meetings (N.J.A.C. 13:35-11.2)</td>
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<td>Forensic monitoring with random routine utilization of appropriate frequency using biological specimens such as blood, urine, hair, nails and saliva should be done by certified laboratory facilities with certified Medical Review Officers used as necessary. The participant is typically responsible for the cost of forensic testing</td>
<td>The PAPNU uses forensic testing, most commonly random, witnessed urine drug screen testing by a licensed laboratory with the frequency determined by the PAPNU physician who interprets the result in addition to the interpretation provided by the laboratory. Forensic testing costs are the responsibility of the participant</td>
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<td>The PHP should advocate for participants with appropriate objective recovery documentation. The PHP can play a role in maintaining or regaining a license by assisting in the administrative process with the NJBME and appearing before the NJBME. The PHP should determine suitability to return to work from the standpoint of disease stability and limit or restrict work hours when appropriate. If indicated, the PHP can restrict workplace access to mind or mood-altering substances</td>
<td>The PAPNU advocates on behalf of participants by writing to the NJBME requesting regulatory relief from disciplinary action, provides the NJBME with a position statement and when necessary, forensic screening results. A physician from the PAPNU accompanies the participant in appearances before committees of the NJBME. The PAPNU, in its position statement or testimony before a committee of the NJBME, can indicate if the participant is able to return to work and, if work restrictions are necessary, what those restrictions should be</td>
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<td>The PHP should educate physicians and medical students through presentations</td>
<td>PAPNU and NJBME staff educate the stakeholders, health care professionals, the teaching institutions, and the regulatory agencies about health care professional impairment. This education occurs through lectures and continuing medical education presentations in their various venues</td>
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<td>The PHP should use both internal and external quality assurance measures reflecting PHP activities and performance and participant results</td>
<td>After appropriate selection of level of care and referrals, the PAPNU selects the level of care and referrals for each participant encounter, which is then provided to the IRC members in a report along with the forensic testing results and participant treatment progress note for review and quality assurance purposes</td>
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<tr>
<td>Funding sources can include, but are not limited to, medical boards, health care organizations, professional societies, hospitals, malpractice carriers, and participant fees. Conflicts of interest should be avoided in acceptance of funds from all sources</td>
<td>The PAPNU receives funding and in-kind contributions from multiple sources including, but not limited to, participants, malpractice carriers, and fundraising activities</td>
</tr>
<tr>
<td>PHP participant contracts should be consistent with FSMB Guidelines. The contract should clearly state the conditions in which anonymity is maintained and when it must be broken. PHP participants should execute an informed consent in the monitoring contract which includes an appropriate statement of confidentiality and limitations and reporting of substantive non-compliance. In the event of participant relocation the PHP record should be portable</td>
<td>By regulation (N.J.A.C. 13:35-11.2) the PAPNU is required to have a letter agreement, including a plan for recovery relating to each referral, setting forth the participant’s obligations and memorializing his or her consent to the release of all pertinent medical, psychiatric or personnel records to the IRC should such documents become necessary as part of its review. The letter agreement also includes the licensee’s consent to provide notice to the IRC of all events and notice to comparable PHPs or licensing boards. The reasons for immediate report to the IRC and disclosure of the participant identity are included in regulations (N.J.A.C. 13:35-11.3a.5 thru 6)</td>
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### References


