PUBLIC HEALTH VULNERABILITY REVIEW:

DRUG DIVERSION, INFECTION RISK, AND DAVID KWIATKOWSKI'S EMPLOYMENT AS A HEALTHCARE WORKER IN MARYLAND

Maryland Department of Health and Mental Hygiene

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EXECUTIVE SUMMARY

Background

In July 2012, a healthcare worker, David Kwiatkowski, was arrested on suspicion of unlawful drug diversion activity that transmitted the hepatitis C infection to 32 patients at Exeter Hospital in New Hampshire. Mr. Kwiatkowski had been employed as a radiographer by multiple temporary agencies and had worked in several states, including Maryland, where he is now suspected of narcotic drug diversion and resultant hepatitis C transmission.

In Maryland, Mr. Kwiatkowski was temporarily employed from 2008 through 2010 at four hospitals. Over 1700 patients at these hospitals have been notified of potential exposure to the hepatitis C virus via Mr. Kwiatkowski. To date, there have been five documented cases of hepatitis C infection among those notified; the five cases involve patients at two of the four Maryland hospitals where Mr. Kwiatkowski worked.

The Department of Health and Mental Hygiene (the Department) has undertaken a comprehensive review of Mr. Kwiatkowski's employment as a healthcare worker in Maryland from 2008 to 2010. The Department has reviewed Mr. Kwiatkowski's interaction with public and private systems designed to identify and prevent drug diversion by healthcare workers and to protect patients against the transmission of infection and disease by healthcare workers. The review has identified weaknesses and vulnerabilities in a number of these systems. This report sets forth the results of the Department's review and makes recommendations for systemic improvement, including recommendations for strengthening legislative and regulatory protections in the areas of safe healthcare delivery, drug diversion and infection control. It was not the purpose of the investigation, nor is it the purpose of this report, to assign fault to individual facilities or agencies for the transmissions that occurred; and it is the conclusion of this report that weaknesses in laws, regulations and widely-shared practices contributed significantly to a system-wide failure to stop Mr. Kwiatkowski's dangerous actions and prevent the transmissions.

Methods

The Secretary of Health and Mental Hygiene requested this review in September 2012. The review was conducted by: Renee Webster, R.E.H.S., Assistant Director of the Department's Office of Health Care Quality; Lucy Wilson, M.D., Sc.M.,

Chief of the Department's Center for Surveillance, Infection Prevention and Outbreak Response (Chair); and Patricia O'Connor, J.D., Assistant Attorney General. The Secretary directed the review team to gain a comprehensive understanding of Mr. Kwiatkowski's employment as a healthcare worker in Maryland from 2008 to 2010, and his interaction with public and private systems designed to identify and prevent drug diversion by healthcare workers and to protect patients against the transmission of infection and disease by healthcare workers. The Secretary further directed the review team to identify any weaknesses in these systems, including systems relating to human resources, risk management, drug diversion and blood borne pathogen transmission, and to make recommendations for improvement. The team investigated credentialing, licensing and hiring of healthcare workers; licensing and hiring practices of staffing agencies; and narcotics delivery systems within regulated facilities. The team's focus was on preventing blood borne pathogen transmission resulting from healthcare worker diversion of injectable narcotics. The team's report is based on publicly available information, records produced in response to subpoenas issued by the Department, and discussions with stakeholders.

Findings

The review team found that the hepatitis C outbreak at issue did not result from a single critical gap or deficiency, but was, instead, the result of multiple gaps in regulations, allied health professional credentialing and licensing procedures, and human resources and risk management practices at staffing agencies and facilities. The team found the systemic weaknesses in the following areas:

1. Licensing and Regulatory Oversight of Staffing Agencies

Interstate staffing agencies that place allied health professionals, like those that found employment for Mr. Kwiatkowski, are largely unregulated nationwide, creating risks for patients.

Before placement, agencies do not ask past employers specifically about drug abuse and diversion, or about other patient safety violations and risks. In the case of Mr. Kwiatkowski, agencies did not disclose negative employment references to new employers, possibly because the agencies are only paid by the healthcare provider for successful placements. At the end of a contract, agencies do not require a written evaluation of whether the licensee committed a patient safety violation or showed signs of drug abuse and diversion. Even when workers are given negative evaluations, it appears that agencies often do not report information contained in

these evaluations to licensing boards and credentialing authorities, or make disclosures to prospective employers.

2. Licensing of Allied Health Professionals

Mr. Kwiatkowski falsely obtained and renewed his radiographer certification from the American Registry of Radiologic Technologists, and his license from the Maryland Board of Physicians, because both entities, in deciding whether to license or credential allied health professionals, rely primarily on self-reporting of criminal history and past adverse actions by employers and regulatory authorities, and, in Mr. Kwiatkowski's case at least, did not verify what he put in his applications.

In Mr. Kwiatkowski's case, neither licensing entity performed a national criminal background check or adequately validated past employment experience.

In addition, in terms of supervision of allied health professionals by licensed clinicians, laws governing allied health professionals can be unclear about the physician's supervisory responsibilities, particularly relating to medication administration and handling, enabling unsupervised and unauthorized access to injectable narcotics.

3. Employment References and Reporting of Patient Safety Violations and Risks

Maryland law confers immunity from liability on employers who, acting in good faith, disclose information about the job performance or reason for termination of an employee to a prospective employer or to a governmental or industry regulatory authority. *See* Md. Code Ann., Cts. & Jud. Proc. § 5-423. But healthcare employers remain reluctant to give negative references, either because they are unaware of the statute or they desire more protection than the statute affords.

Many healthcare co-workers, facilities and staffing agencies failed to report concerns about Mr. Kwiatkowski's conduct, including concerns about drug diversion, to licensing boards and to other employers during reference checks.

4. Prevention of and Response to Drug Diversion in Hospitals and Other Healthcare Facilities

The healthcare environment provides opportunities for a healthcare worker to steal and manipulate medications and devices resulting in patient infections with

blood borne pathogens. Multitasking by healthcare workers in emergency situations and imperfect environmental and supervisory controls can allow momentary lapses in medication security and patient safety. Many hospitals have drug diversion monitoring programs. Such programs, however, are not currently mandated or standardized, and the scope and efficacy of existing programs varies among facilities.

In general, hospitals and healthcare facilities do not effectively communicate to staff the critical nature of drug diversion and the patient safety and infection risks that are associated with it. Highly educated and well trained staff fail to recognize and/or overlook behaviors indicative of an addiction or, in some cases, fail to follow established policies concerning substance abuse and drug diversion among fellow staff members. There is inadequate education regarding legal obligations to report drug-related misconduct. Likewise, anonymous reporting mechanisms are not uniformly available for staff. The definition of "significant loss" of an injectable narcotic, triggering an obligation to make a report of the loss, has not been refined or standardized, making reporting of such a loss a matter of subjective judgment. Mechanisms do not exist to facilitate the reporting of injectable narcotic loss as an adverse event via "root cause analysis" to regulatory authorities. The development of such mechanisms would facilitate evaluation and remediation. Additionally, environmental controls, such as placement of medication storage containers and procedures for handling of unused medication, could be strengthened. Referral to substance abuse treatment is an important aspect of this response.

5. Interstate Information Sharing About Allied Health Professionals

The federal government has established a registry, called the Data Bank, to enable state licensing boards, hospitals, and professional societies to report unprofessional behavior, prevent incompetent providers from ongoing practice if they move between states, and decrease fraud and abuse.

However, there are limitations on the usefulness of the Data Bank for addressing ongoing misconduct by allied health professionals.

There are two main areas of reporting to the Data Bank that may be monitored by hiring entities and licensing bodies:

Licensure actions: Licensure actions have historically been reported to two separate entities, the National Practitioner Data Bank and the Healthcare Integrity & Protection Data Bank, which under the Affordable Care Act have been consolidated into one entity, the Data Bank. Before 2010, licensure actions against

allied health professionals were only accessible to health plans and to federal and state governments. Starting in 2010, these licensure actions became available to hospitals, other health care entities, and professional organizations.

Administrative actions: Reporting of administrative actions—such as termination for activity that compromises patient care or illegal activity—to the Data Bank is mandated for physicians and dentists. Such reporting is permitted (but not required) for some other health care practitioners with clinical privileges—for example, nurse practitioners or physician assistants. However, the Data Bank cannot receive reports of administrative actions against health care practitioners without clinical privileges, such as radiographers.

Recommendations

Based on the identified gaps, the review team makes the following recommendations:

1. Staffing agencies that place allied health professionals in Maryland facilities should be required by law to obtain a license.

Maryland law requires licensure for nurse staffing agencies. *See* Md. Code Ann., Health-Gen. §§ 19-2001 and 19-2002; COMAR 10.07.03. The review team recommends that the law be amended to provide for the regulation of staffing agency placement of allied health professionals.

In addition, § 19-2302 of the Health-General Article should be amended so staffing agencies can be "deemed" for licensure if certified by a Department-approved accreditation organization, such as The Joint Commission.

Should such a law be enacted, the Department should consider imposing specific requirements on staffing agencies to obtain from facilities information pre- and post- placement about drug diversion and other patient safety risks.

Because the details of these issues are complex, the review team recommends further discussion with interested parties on the best approach to regulation in this area.

2. The Board of Physicians should review and revise its procedures for licensing allied health professionals.

The Maryland Board of Physicians should undertake a thorough review of the processes by which allied health professionals are licensed, and the role, if any, a credentialing authority like the American Registry of Radiologic Technologists should play.

The Board and credentialing authorities should refine their initial and renewal application processes, based on a better understanding of the profiles of healthcare workers who engage in drug diversion. The Board and credentialing authorities should incorporate into their procedures a national criminal background check; should validate past employment experiences and thoroughly investigate any suspicions of drug abuse and diversion; and should have robust processes for complaint intake, investigation, resolution, and interstate reporting, when appropriate. In addition, in terms of scope of practice issues for allied health professionals, the Board should examine the statutes governing the licensure and practice of the allied health professions and clarify any ambiguity regarding supervisory responsibilities they may impose on physicians, particularly relating to medication administration and handling.

3. <u>There should be consideration of additional legislation related to disclosure of negative employment references.</u>

While there are existing statutes conferring immunity on those who report potential disciplinary violations to the health occupations boards, the review team recommends there be consideration of a single immunity statute that would apply to reports and references made to any licensing board and to other prospective employers.

Consideration should also be given to broadening the obligation to report to require that employers make concerns about patient safety known to prospective employers during reference checks.

Because the details of these issues are complex, the review team recommends further discussion with interested parties on the best approach to legislation in this area.

4. <u>Hospitals and other healthcare facilities should develop processes to prevent and respond to drug diversion.</u>

The review team recommends that hospitals and healthcare facilities regard drug diversion as a patient safety issue and standardize their prevention and response efforts. Such efforts should include:

- the formation of drug diversion and response teams at each facility;
- staff education regarding substance abuse, drug diversion and patient safety;
- the development of a standard definition of "significant loss" of controlled substances, with a special focus on injectable narcotics;
- staff empowerment to report suspected diversion, including education about applicable legal protections and immunities;
- placement of medication storage units in procedure areas, such as electronic medication dispensing systems;
- limiting staff witnessing of drug wasting to only those licensed to handle controlled dangerous substances;
- implementing injectable narcotics count "time outs" after procedures, in order to tally the amount dispensed and wasted before staff leave the procedure area;
- instituting a "stop work" or "lockdown" if there is any missing narcotic post-procedure;
- mandatory staff testing for the presence of narcotics immediately following a discrepancy occurrence;
- internal reporting protocols for diversion events;
- posting of an internal and external hotline for anonymous reporting of suspected drug diversion;
- clarification of supervisory responsibility over allied health professionals, including temporary employees;
- the development of a system to identify, refer for treatment, and assist employees with substance use disorders;
- requiring drug diversion to be a reportable adverse event; and
- discrepancy reporting via "root cause analysis" to regulatory authorities.

Facilities should explore new technologies that may improve products and protocols related to narcotic use. These technologies should include changes in drug administration, such as minimizing intravenous administration of narcotics or

improved dosing to negate the need for the risky practice of "drug wasting." Also, product changes could include single-use and/or tamper-proof syringes or the addition of inert dyes in all injectable narcotics that would make substitution by other substances evident.

To accomplish these objectives, the review team recommends that the Office of Health Care Quality, the Maryland Patient Safety Center, or similar organization convene hospitals and develop a best practices approach appropriate for statewide adoption.

5. <u>The federal government should expand the Data Bank to capture additional information about allied health professionals who may pose risks to patient safety.</u>

Medical licensing boards and health care employers should utilize the Data Bank's existing capabilities and run queries on licensure actions when licensing and hiring allied health practitioners.

The federal Data Bank should be configured to support reporting of adverse administrative actions against all health care practitioners and to allow for routine queries for all hiring and licensure of health care practitioners. This step may require federal regulatory action.

When such capacity is available, health care facilities should be required to report to the Data Bank administrative actions against all health care practitioners.

TIMELINE

(Mr. David Kwiatkowski is referred to as "DK" below)

Date	**Event**[1]
2000	According to his 2008 application for a Maryland license, DK "got a lenient sentence" for driving under the influence of alcohol in Michigan.
February 28, 2003	DK applies for certification by the American Registry of Radiologic Technologists. The application does not disclose his 2000 DUI.
June 25, 2003	DK graduates from the William Beaumont Hospital School of Radiologic Technology in Michigan.
July 1, 2003	DK is certified as a radiographer.
August 2003	DK works in radiology at William Beaumont Hospital.
September 2003 – June 2006	DK works in a cardiac catheter lab at Detroit Medical Center.
June 7, 2005	DK is sentenced to 6 months probation and fined $1075 after pleading guilty to a DWI charge in Michigan. He does not disclose the 2005 DWI conviction on his annual renewal applications to the American Registry of Radiologic Technologists.

[1] This timeline is based upon publicly available information, media reports, and other information obtained during this review.

June –December 2006	DK works in Interventional Radiology at the University of Michigan Hospital. He quits in December 2006 when the hospital suspends him pending investigation of drug diversion suspicions.
January – August 2007	DK works in a cardiac catheter lab at Oakwood Annapolis Hospital in Michigan.
August – October 2007	DK works as a laborer in Michigan before leaving the state to start working as a temporary traveler for interstate staffing agencies.
November 9, 2007	New York issues a license to DK.
November 2007	Advance Med, a staffing agency, places DK at St. Francis Hospital in Poughkeepsie, New York for a 13 week contract. He helps set up a new cardiac catheter lab under the supervision of a manager who provides a positive reference to several future employers.
February 15, 2008	Arizona issues a license to DK.
March 17, 2008	Maxim, a staffing agency, makes a "Quick Placement" of DK at University of Pittsburgh Medical Center - Presbyterian with an assignment end date of June 12, 2008.

May 8, 2008	Maxim terminates DK's contract following his termination by the Pittsburgh hospital "for cause, reason - misconduct". He was allegedly caught with fentanyl syringes in his scrub pants and allegedly tested positive for narcotics. Maxim's "Termination Notice" form states DK is able to work for Maxim again, and that Maxim is looking to place him again.
June 2008	Advance Med, a staffing agency, places DK at the Baltimore Veterans Affairs Medical Center in Baltimore to work in interventional radiology until November 2008.
September 25, 2008	DK applies to the Maryland Board of Physicians for a radiographer license and falsely gives a negative answer to a question about past suspensions and terminations. Because the Board requires its analysts only to contact past employers identified in affirmative answers to this question, and DK did not disclose the adverse actions taken by the University of Michigan Hospital and the University of Pittsburgh Medical Center-Presbyterian, the analyst does not contact them or other past employers. DK discloses the 2000 DUI but not the 2005 DWI. Board policy requires analysts to refer for staff investigation only DUIs and DWIs within 3 years of application, so the analyst does not refer the 2000 DUI for investigation. Board policy requires an analyst to obtain a letter of explanation from the applicant about older DWIs. DK writes an explanatory letter, and no further investigation is undertaken.
October 28, 2008	The Maryland Board of Physicians issues a license to DK with an expiration date of April 30, 2009.
November 9, 2008	Maxim places DK at Southern Maryland Hospital in Clinton to work in the cardiac catheterization lab.

Feb 16, 2009	Southern Maryland Hospital terminates DK after verifying an anonymous tip that he was falsifying time records and forging his supervisor's signature on timesheets.
March 2009	DK does not file an application to renew his Maryland license by the March deadline.
March 22, 2009	SpringBoard Healthcare Staffing and Search places DK at Maryvale Hospital in Phoenix, Arizona to work in the cardiac catheter lab.
April 30, 2009	DK's Maryland license expires.
June 17, 2009	DK applies to "renew" his Maryland license. He again falsely answers the question about suspensions and terminations, and does not disclose that he was recently terminated for cause by Southern Maryland Hospital.
July 8, 2009	Maryland re-issues a license to DK, effective July 9, 2009 through April 30, 2011.
July 9, 2009	Medical Solutions, a staffing agency, places DK at The Johns Hopkins Hospital in Baltimore to work in the cardiac catheterization lab.
October 2009	Johns Hopkins offers DK another 13 week contract and a permanent job starting after the second contract ends.
November 30, 2009	Johns Hopkins rescinds the permanent job offer.

January-March 2010	DK works as a permanent, full time employee in interventional radiology at Maryland General Hospital. He fails to give sufficient notice to the hospital before quitting the position, leading the hospital to classify him as not re-hirable.
March 2010	SpringBoard, a staffing agency, places DK at Arizona Heart Hospital in Phoenix. The hospital terminates DK's employment on 4/1/10 "due to a drug incident," after a co-worker finds him unresponsive next to a toilet containing a blue fentanyl-labeled syringe and needle. Later, DK admits to hospital staff and police that he had injected himself with fentanyl, claiming he found the syringe in the pocket of a lead apron. The hospital does not press criminal charges. SpringBoard reports DK to the American Registry of Radiologic Technologists and to the Arizona licensing board. The Arizona licensing board's investigation begins immediately and DK surrenders his license. The American Registry of Radiologic Technologists takes no adverse action against DK.
March-April 2010	Advantage, RN, a staffing agency, places DK at Temple University Hospital in Philadelphia, Pennsylvania.
May 2010	Medical Solutions places DK at Hays Medical Center in Hays, Kansas, despite SpringBoard's reference saying he is not re-hirable. At the end of his placement, the catheter lab manager gives DK a negative evaluation. (Six patients at Hays Medical Center have tested positive for DK's strain of hepatitis C.)
June 2010	DK tests positive for hepatitis C virus.
Jun 25, 2010	Kansas issues a license to DK with an expiration date of 9/30/11.

October 2010	DK works at Houston Medical Center in Warner Robins, Georgia
April 2011	Triage, a staffing agency, places DK at Exeter Hospital in New Hampshire to work in the cardiac catheter lab. The hospital subsequently hires him as a permanent, full time employee.
May-June 2012	Communicable disease authorities investigate the Exeter Hospital hepatitis C outbreak and identify DK as the source of hepatitis C infections in 32 Exeter patients.
June 20, 2012	New Hampshire's communicable disease authorities inform Maryland's Department of Health and Mental Hygiene about the Exeter Hospital outbreak and report that DK worked at four Maryland hospitals. The Department notifies the hospitals.
July 2012	DK is arrested by the FBI and charged with federal crimes. He remains in federal custody pending criminal trial.

INTRODUCTION

In July 2012, David Kwiatkowski, a hepatitis C-infected healthcare worker, was arrested on suspicion of unlawful drug diversion activity that transmitted the hepatitis C infection to 32 patients at Exeter Hospital in New Hampshire. In the preceding ten years, Mr. Kwiatkowski had worked as a radiographer for multiple temporary staffing agencies in hospitals across the country. To date, 43 cases of hepatitis C infection nationwide have been attributed to transmission by Mr. Kwiatkowski, including five cases in Maryland.

Mr. Kwiatkowski was temporarily employed in four Maryland hospitals from 2008 through 2010. Over 1700 patients at these hospitals have been identified as potentially exposed to Mr. Kwiatkowski and have been notified of the exposure. The five documented cases of hepatitis C infection linked to Mr. Kwiatkowski involve patients at two of the four Maryland hospitals where Mr. Kwiatkowski worked.

Media reports to date have noted:

- Co-workers suspecting Mr. Kwiatkowski of drug diversion may not have reported their suspicions. [2]
- Supervisors may not have accurately described Mr. Kwiatkowski's suspicious conduct to prospective employers when asked for references. [3]
- Co-workers reportedly observed Mr. Kwiatkowski behaving erratically, showing up at work when not scheduled to be there, and displaying symptoms of drug intoxication and withdrawal.[4]
- Co-workers reportedly observed Mr. Kwiatkowski in possession of narcotic syringes, stealing syringes, and leaving used syringes in toilet bowls.[5]

The Department of Health and Mental Hygiene (the Department) has undertaken a comprehensive review of Mr. Kwiatkowski's employment as a

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[2] Patricia Wen, Boston Globe, As risk grew, hospitals turned a blind eye, November 11, 2012.

[3] Patricia Wen, Boston Globe, As risk grew, hospitals turned a blind eye, November 11, 2012.

[4] Patricia Wen, Boston Globe, As risk grew, hospitals turned a blind eye, November 11, 2012.

[5] http://www.post-gazette.com/stories/news/us/hospital-techs-arrest-sets-off-hepatitis-scare-shows-flaws-in-system-649052/; Patricia Wen, Boston Globe, As risk grew, hospitals turned a blind eye, November 11, 2012.

healthcare worker in Maryland from 2008 to 2010. The Department has also reviewed his interaction with public and private systems designed to identify and prevent drug diversion by healthcare workers and to protect patients against the transmission of infection and disease by healthcare workers.

The review team sought to identify any weaknesses in these systems and to make recommendations for improvement. This report sets forth the results of the review and makes recommendations for systemic improvement, including recommendations for strengthening legislative and regulatory protections in the areas of safe healthcare delivery, drug diversion and infection control.

BACKGROUND

1. Blood Borne Pathogen Disease and Healthcare Transmission

Most commonly, clusters of new hepatitis C infections in the healthcare setting are caused by improper use of syringes, medical equipment contamination or sloppy sterilization techniques[6] - problems that have been linked to 26 documented hepatitis C outbreaks since 1998. From 2008 to 2011, 13 hepatitis C and 19 hepatitis B outbreaks were reported to CDC, resulting in 257 outbreak associated cases and over 90,000 persons notified for screening. Poor infection control is the most common cause of healthcare-associated blood borne pathogen exposure.[7]

Hepatitis C is the most common chronic blood borne pathogen in the United States, and transmission in the healthcare setting often results from a break down in

[6] Shepard CW, Finelli L, Alter MJ, Global epidemiology of hepatitis C infection, *Lancet Infectious Diseases*, 5 (9), 2005 Sept: 558-567.

[7] Healthcare-Associated Hepatitis B and C Outbreaks Reported to the Centers for Disease Control and Prevention (CDC) in 2008-2011: http://www.cdc.gov/hepatitis/Outbreaks/PDFs/HealthcareInvestigationTable.pdf,

sterile procedures[8]. Hepatitis C also has a higher prevalence among those with narcotic use disorders. This population includes healthcare workers who seek prescription drugs at the hospitals where they work.[9]

Injectable narcotics, which are highly potent, are commonly stolen by healthcare workers with substance abuse problems. There are multiple documented instances of diversion of injectable narcotics that occurred before the detection of Mr. Kwiatkowski's actions.[10] In a July 2012 article, the Concord Monitor described five previous outbreaks of hepatitis C infection caused by healthcare worker narcotic theft and tampering.[11] In 1991, a surgical technician admitted to stealing narcotic filled syringes in a Texas outpatient clinic, leading to the hepatitis C infection of dozens of patients seen at the clinic. The technician was noted to have inconsistent work performance, a "glowing" personality, and work habits suggesting narcotic addiction. He had committed petty crimes, and was anecdotally seen handling syringes. Ultimately, it was determined that the surgical technician may have exposed at least 3,300 patients at 4 clinics. It was determined that 48 patients were infected with hepatitis C.

In 2004, a nurse anesthetist was investigated in connection with a hepatitis C outbreak in a Texas hospital, as well as infections in Virginia and Washington, DC. Of 543 people notified of possible exposure, approximately 16 were found to have been infected.

In 2009, there were two hepatitis C outbreaks in Colorado associated with hospital technicians who diverted narcotics. One technician was linked to 24

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[8] Shepard CW, Finelli L, Alter MJ, Global epidemiology of hepatitis C infection, *Lancet Infectious Diseases*, 5 (9), 2005 Sept: 558-567.

[9] Hellinger WC, Bacalis LP, Key RS, et al. "Health Care-Associated Hepatitis C Virus Infections Attributed to Narcotic Diversion". *Ann Int Med*, April 3, 2012, 156 (7), pp. 477-483.

[10] Berge KH, et al, "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention", Mayo Clin Proc., July 2012:87(7):674-682

[11] Meg Heckman, concordmonitor.com, New Hampshire hep C cluster not the first: stealing syringes in hospitals and infecting patients with HCV, July 29, 2012.

infections and the other to 18 infections. Both technicians received 30-year sentences.

A radiographer who worked from 2006 to 2010 in the interventional radiology lab at The Mayo Clinic in Florida, was determined to be the source of another hepatitis C outbreak. Several patients with no risk factors for hepatitis C were identified as having the virus. Interventional radiology procedures and injectable fentanyl were the common epidemiologic links. An extensive search of patient records, employee schedules, and narcotic dispensing logs was performed. Of 21 employees tested, only one tested positive for hepatitis C. The same employee admittedly diverted injectable fentanyl, potentially exposing nearly 4,000 patients. The employee was sentenced to 30 years in prison for infecting 5 patients, causing one death to date.

2. Benefits and Risks of Injectable Narcotics

Fentanyl and other narcotics such as morphine and hydromorphone are administered for pain during uncomfortable invasive procedures, such as cardiac catheterizations. Fentanyl is generally given intravenously at the start of the procedure, along with short acting sedation such as midazolam or propofol. The drugs provide short-term relief of pain and anxiety, often sedate the patient, and may have an amnestic effect. The medications are typically drawn up from a multi-dose vial or ampule in separate syringes, labeled, and given by an authorized clinician (nurse, physician) with the dose and administration timing determined by the physician within some standard parameters.

The products used to deliver injectable narcotics (vial/syringe/needle) do not evidence prior use and substitutes for the narcotic are easily obtainable. As a result, a drug diverter can surreptitiously substitute the narcotic and return the needle for reuse. Additionally, drugs may be diverted in the hospital or clinical environment, because a single authorized clinician is able to obtain the drug from central supply, prepare the drug, administer the drug to patients, and dispose of any excess drug (referred to as “wasting”) with minimal supervision.

When a healthcare worker diverts pain medication, the patient for whom the medication was prescribed may suffer from both substandard anesthesia and insufficient pain management. The patient may receive care from an impaired clinician. In addition, if diversion has involved contamination of medication or equipment with these pathogens, patients are at risk of infection with blood borne

pathogens such as hepatitis B, hepatitis C and HIV. A medical expert on healthcare worker drug diversion has noted:

> No data is available quantifying the extent of drug diversion occurring in healthcare facilities. While the majority of the nation's drug supply is administered outside of a healthcare facility, the manner in which medications are dispensed inside the hospital provides numerous opportunities for drug diversion. Drug diversion occurring in hospitals can be associated with many adverse consequences, including harm to the patient, harm to the diverting healthcare worker, and harm to his/her colleagues and employers. Anesthesiologists have frequent access to highly addictive psychotropic medications and are reported to have a higher rate of addiction to narcotics than physicians in other specialties. When anesthesiologists are addicted, it is found that the drugs most commonly abused (opioids) are obtained through diversion. This suggests that access to narcotics is a crucial component of drug diversion in hospitals and other healthcare facilities.[12]

3. Drug Diversion Risk Mitigation in Healthcare Facilities

Medications classified as Schedule II under federal and state laws,[13] including narcotics like fentanyl and morphine, require special handling even with an automated system. These medications are usually supplied by pharmacies pre-packaged in single use, tamper-evident syringes or multi-dose vials and are sequestered in locked bins separate from the patient's other medications. Most hospitals use automated dispensing systems, such as the Pyxis machine, to manage access to all medications in use in each clinical area, including procedural areas such as the interventional radiology or catheterization suites. These automated systems consist of locked bins assigned either to each patient (on an inpatient med-surgical unit) or each medication (in procedure areas) and provide continuous inventory and medication-use tracking. Access to the medications in the automated system is limited by the staff person's rights, which are programmed into the system. Staff can

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[12] Berge KH, et al, "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention", Mayo Clin Proc., July 2012:87(7):674-682

[13] 18 USC §§ 801 et seq.; Md. Criminal Law Code Ann. § 5-101 et seq

obtain access by inputting their personal log-on code or through biometrics, such as a fingerprint.

Most commonly, a registered nurse logs into the automated system, enters the patient information, and selects the appropriate medication. The system verifies that there is a current physician order for the medication, and the appropriate drawer opens. The nurse must then verify the opening count and specify how many syringes or vials were removed. Unused, un-opened vials may be returned to the system in a separate, usually witnessed, transaction. If a patient is given a dose that is less than the dose in the pre-filled syringe or vial, the remaining medication has to be wasted by shooting it into the sharps container or another designated, approved site. Maryland regulations provide that narcotics wasting may be done only by registered nurses, and that the wasting must be witnessed. The prevalent practice in Maryland is for two nurses to waste and witness.

A discrepancy occurs whenever the amount of medication in the medication storage device does not match the amount that the system notes is in the inventory. For example, when, according to the dispensing system, there should be nine syringes, but the nurse, after entering the system, counts only eight, the nurse must run a discrepancy report. Most hospitals require the nurse to report the discrepancy to the charge nurse and the pharmacy and complete an incident report. Discrepancy reports can be printed whenever necessary, but are usually printed no less often than once a shift. The discrepancy report includes the name of the patient and the last person to access that medication. Any discrepancies must be resolved before the next oncoming shift.

In most hospitals, unit managers randomly audit the Schedule II usage of two to three nurses every month as part of the hospital's quality assurance program. The audit consists of running a usage report for specific time frames, for example: two consecutive shifts and comparing the amount of medication used according to the dispensing system with the medical records. These audits should ensure that the medical records documentation and dispensing records match and are compliant with policy and with the standard of care. Either the pharmacy or any nurse executive may run a usage report, for any nurse at any time, if there is any suspicion of misuse.

Once a medication is removed from the automated dispensing system, the nurse is ultimately responsible for its security and use. The nurse must maintain custody of the medication or secure the medication properly. However, nurse's normal activities in the procedure areas, such as caring for patients who develop

complications or even assisting in the positioning of a patient, may leave Schedule II medication temporarily unsecured and unmonitored, creating an opportunity for diversion.

Also, the patient may be given increments of doses several times during a procedure. Most hospital policies require the nurse to keep the medication at the bedside and to maintain control over the vial or syringe at all times. Most hospital policies also provide that medication left over at the end of the procedure must be wasted with a witness. At no time should the nurse allow an unlicensed person to draw up a dose or touch the syringe or vial. Likewise, any medication vials or syringes that show evidence of tampering must be locked on the unit until they can be sent back to the pharmacy. Most hospitals require an incident report in any case involving evidence of tampering.

METHODS

The Secretary of Health and Mental Hygiene requested this review in September 2012. The review was conducted by: Renee Webster, R.E.H.S., Assistant Director of the Department's Office of Health Care Quality; Lucy Wilson, M.D., Sc.M., Chief of the Department's Center for Surveillance, Infection Prevention and Outbreak Response (Chair); and Patricia O'Connor, J.D., Assistant Attorney General. The Secretary directed the review team to gain a comprehensive understanding of Mr. Kwiatkowski's employment as a healthcare worker in Maryland from 2008 to 2010, and of his interaction with public and private systems designed to prevent and respond to drug diversion by healthcare workers and to protect patients against the transmission of infection.

The review team sought to identify weaknesses in these systems and to make recommendations for improvement. The team investigated credentialing, licensing and hiring of healthcare workers; licensing and hiring practices of staffing agencies; and narcotics delivery systems within regulated facilities. The team's focus was on preventing blood borne pathogen transmission resulting from healthcare worker diversion of injectable narcotics.

The team consulted with multiple hospital administrators who had expertise in human resources, risk management, drug diversion and infection control, representing seventeen Maryland hospitals, including the four hospitals where Mr. Kwiatkowski worked. The team also consulted with patient safety experts from the federal Centers for Disease Control and Prevention, the Drug Enforcement Agency,

the Joint Commission, and the Veterans Health Administration. Staff at Maryland regulatory agencies, including the Board of Physicians, the Board of Nursing, and the Office of Health Care Quality, were also consulted. The team met with the Maryland Hospital Association and the Chesapeake Registry Program. Subpoenas for records related to Mr. Kwiatkowski were issued to hospitals, staffing agencies, and credentialing and licensing authorities.[14] The team also reviewed relevant medical and patient safety literature.

This report cites directly publicly available information and records produced in response to the Department's subpoenas. Information obtained from discussions with stakeholders is not attributed to a specific hospital or individual.

FINDINGS AND RECOMMENDATIONS

The review team found that the hepatitis C outbreak at issue did not result from a single critical gap or deficiency, but was, instead, the result of multiple, system-wide gaps in regulations, allied health credentialing and licensing procedures, and human resources and risk management practices at staffing agencies and healthcare facilities.

Through this review, DHMH identified vulnerabilities in Maryland's public health and healthcare systems that might expose future patients to the risk of infection by blood borne pathogens, such as hepatitis C infection, via contaminated injectables. The team made findings in five areas.

1. Licensing and Regulatory Oversight of Staffing Agencies

The review finds that insufficient regulatory oversight of staffing agencies facilitated Mr. Kwiatkowski's employment in and movement among Maryland hospitals.

[14] As discussed in greater detail in Appendix C to the report, one of the staffing agencies to whom the Department issued a subpoena, Maxim Healthcare Services, indicated in February 2013 that it could no longer confirm the authenticity of two documents that it had earlier produced in response to the Department's subpoena. None of the findings in this report are based on these documents.

Context

In the 1970s, healthcare facilities began to make increasing use of temporary staffing, mainly to fill nurse staffing shortages. Now, staffing agencies are used by hospitals and other healthcare facilities to fill temporary needs for various health professionals. The business model of temporary staffing is similar in the healthcare, business and industrial sectors: an agency vets the worker and reportedly retains twenty five percent, or more, of the worker's wages. The worker nets a higher wage per hour than a permanent employee would earn. The contracts are typically 13 weeks in duration. Traveling healthcare workers like Mr. Kwiatkowski are provided with agency-paid housing and transportation. There is financial incentive for staffing agencies to make referrals because they are only paid by healthcare providers for successful placements.

In interviews with the review team, hospital representatives indicated that that they prefer to use permanent staff. The hospitals further indicated that they try to develop "staffing or float pools" of permanent staff, through the use of overtime and other incentives and that they use staffing agencies only when necessary, because of the additional expense.

Presently, Florida is the only state that regulates the placement of allied health professionals by staffing agencies, according to the Association of Health Care Facilities Survey Agencies and The Joint Commission. Maryland licenses and regulates staffing agency placements of nurses, but not allied health professionals. *See* Md. Code Ann., Health-Gen. §§ 19-2001 and 19-2002; COMAR 10.07.03. Under Maryland law, staffing agencies that place nurses (registered nurses, licensed practical nurses, and nursing assistants) must be licensed by the Department of Health and Mental Hygiene. Licenses are issued to agencies after completion of an application process and must be renewed annually.

The regulations for nurse staffing agencies allow for licensing inspections but do not impose inspection requirements; the Department's budget does not include resources for annual inspections, but the Office of Health Care Quality is equipped to respond to complaints and other concerns.

The regulations focus on ensuring that qualified and properly licensed nurses are provided under any contract between a staffing agency and a healthcare facility. The regulations require that a staffing agency verify a nurse's past employment, perform reference checks, and verify the nurse applicant's health status. The

statutes and regulations do not specify the scope of information an agency must obtain from a past employer, or how many past employers an agency must contact.

There is no legal requirement that a staffing agency obtain a written evaluation from the facility at the end of each contract. However, the law does require a nurse staffing agency to notify the Maryland Board of Nursing of any actions or inactions on the part of the nurse that may violate the Health Occupations Article.

Maryland currently licenses more than 400 nurse staffing agencies. Most are out-of-state companies. One of the agencies that placed Mr. Kwiatkowski as a radiological technologist in Maryland, Maxim, is a Maryland company and has a Maryland license as a nurse staffing agency. Again, however, the regulations for nurse staffing do not apply to the staffing of positions for allied health professionals, like Mr. Kwiatkowski.

There are two national accreditation organizations that certify healthcare staffing agencies, the Community Health Accreditation Program and the Joint Commission. These organizations certify staffing agencies in connection with their placement of all types of healthcare professionals, including allied health professionals. There are no Maryland licensed staffing agencies that are certified by the Community Health Accreditation Program in Maryland. Eleven nurse staffing agencies licensed in Maryland are certified by The Joint Commission under its Healthcare Staffing Certification program.

The review team studied the standards of The Joint Commission for Healthcare Staffing Certification. These standards are comparable to the Department's regulations but are broader in scope because they encompass additional healthcare staffing categories, such as allied health professionals. The regulations of the Joint Commission and the state are both process oriented standards that focus on the development of systems for verifying credentialing, licensure, health status, employment history and references.

Findings

The review team found both a lack of regulatory oversight for staffing agencies that place allied health professionals and a lack of accountability when an agency knowingly places staff with dangerous behaviors in hospitals and other healthcare facilities.

The review found that, before making a placement, staffing agencies do not routinely ask previous employers specific questions regarding patient safety violations or risk factors for drug diversion. In cases where unfavorable references are obtained, staffing agencies may continue to place the employee while failing to disclose the behaviors to the hospital contracting for his or her services.

The review found insufficient regulatory oversight of staffing agencies. As noted above, in Maryland, staffing agency placement of allied health professionals, as opposed to nurses, is not regulated by the State. Nurse staffing agencies are required to report to the Board of Nursing when a nurse is suspected to pose a safety risk to patients. However, in the absence of regulatory oversight, there are no statutes or regulations in place that require disclosures of allied health professionals' conduct posing a patient safety risk, including related to drug abuse and drug diversion. Staffing agencies themselves do not appear to have a process whereby evaluation and references regarding performance and patient safety risks are documented and available for future reference requests.

In the case of Mr. Kwiatkowski, staffing agencies failed on at least two occasions to disclose adverse information from prior hospitals placements before placing him in a new hospital. After having been placed by the staffing agency Maxim at the University of Pittsburgh Medical Center-Presbyterian, a coworker at the hospital allegedly observed Mr. Kwiatkowski putting a fentanyl syringe down his scrub pants. Mr. Kwiatkowski allegedly tested positive for fentanyl and/or other opiates, and the hospital terminated his placement.[15]

Maxim's records contain an internal "termination notice," dated May 8, 2008, stating that the University of Pittsburgh Medical Center-Presbyterian terminated Mr. Kwiatkowski "for cause, reason-misconduct."Maxim has also indicated that a UPMC employee informed it that the termination was related to "narcotics." Maxim questioned Mr. Kwiatkowski and conducted its own drug tests of Mr. Kwiatkowski, which reportedly came back negative, as a result of which Maxim determined that UPMC's allegations were "unsubstantiated." Maxim's internal "termination notice" states that Mr. Kwiatkowski is able to work for Maxim again, and that Maxim is looking to place him. Six months after University of Pittsburgh Medical Center-Presbyterian terminated Mr. Kwiatkowski's placement, for cause, Maxim placed Mr.

[15] Patricia Wen, Boston Globe, As risk grew, hospitals turned a blind eye, November 11, 2012.

Kwiatkowski at Southern Maryland Hospital, where he was eventually terminated for forgery and falsifying time records.

In between these two placements by Maxim, Mr. Kwiatkowski then worked in two other Maryland hospitals, placed by other staffing agencies. Molecular testing has linked Mr. Kwiatkowski to hepatitis C infections in 5 patients in 2 Maryland hospitals.

Approximately three months after terminating Mr. Kwiatkowski for stealing and using fentanyl on assignment at Arizona Heart Hospital, the staffing agency SpringBoard informed another staffing agency, Medical Solutions, that SpringBoard would not rehire Mr. Kwiatkowski. This unfavorable information was reported by Mr. Kwiatkowski's placement specialist at Medical Solutions to her superior via email: "Springboard on his employment came back as non rehirable… I just need your approval on this." A response came thirty five minutes later: "Approved ☺!" Medical Solutions then placed Mr. Kwiatkowski at Hays Medical Center in Kansas. Records produced by Medical Solutions in response to a subpoena contain no indication that Medical Solutions followed up on SpringBoard's negative reference, or informed Hays Medical Center of the negative reference before placing him there.

At the end of Mr. Kwiatkowski's placement at Hays Medical Center, a cardiac catheter lab manager filled out a performance evaluation form with low marks across the board and said Kwiatkowski was not eligible for rehire there. The manager also commented:

> David has several issues, but the main issue is integrity. Unfortunately, this affects his job performance. [Procedures associated with Mr. Kwiatkowski were noted to have higher rates of medical complications] and missed supplies, causing missed supply charges (in the tens of thousands of dollar range that I had to correct manually). David did what he wanted and disregarded our policy and procedures. I think he lies so much he doesn't remember what the truth is. He has potential but I think until he gets his lying under control he will not be successful. Feel free to contact me for any questions or comments.

Molecular testing has linked Mr. Kwiatkowski to hepatitis C infections in six patients at Hays Medical Center.

Recommendation

Recommendation 1: Staffing agencies that place allied health professionals in Maryland facilities should be required by law to obtain a license.

Maryland law requires licensure for nurse staffing agencies. *See* Md. Code Ann., Health-Gen. §§ 19-2001 and 19-2002; COMAR 10.07.03. The review team recommends that the law be amended to provide for the regulation of staffing agency placement of allied health professionals.

In addition, § 19-2302 of the Health-General Article should be amended so staffing agencies can be "deemed" for licensure if certified by a Department-approved accreditation organization, such as The Joint Commission.

Should such a law be enacted, the Department should consider imposing specific requirements on staffing agencies to obtain from facilities information pre- and post- placement about drug diversion and other patient safety risks.

Because the details of these issues are complex, the review team recommends further discussion with interested parties on the best approach to regulation in this area.

2. Licensing of Allied Health Professionals

The review finds that weaknesses in professional oversight and licensure contributed to Mr. Kwiatkowski's ability to continue in practice despite multiple problems over time.

Context

With the growing utilization of ancillary healthcare services such as imaging, respiratory, pharmacy and surgical services over the past 50 years, there has been a greater need for the services and expertise of allied health professionals, and the role of allied health professionals has expanded and evolved. The scope of practice and the number of allied health professionals will continue to expand with the delegation of duties that were once solely under the scope of practice of nurses or physicians. By 2018 the U. S. Bureau of Labor Statistics projects national employment demand will increase by 17% for radiographers and 18% for diagnostic medical sonographers. For other allied health professionals, the predicted increase in demand is 39% for physician assistants, 30% for physical

therapists, and 14% for clinical laboratory scientists. Together, these projections translate to an additional need of over 152,000 allied health professionals in these five professions alone.[16] As a result of these changes, many allied health professionals now work in settings that present opportunities for drug diversion.

The Maryland Board of Physicians licenses certain allied health professionals, including radiographers. Certification and registration by the American Registry of Radiologic Technologists (referred to here as "the national registry" or ARRT) are prerequisites to Maryland licensure for radiographers. To become certified, applicants must graduate from an approved program, satisfy ARRT's ethical standards, and pass an ARRT-administered exam. A certified radiographer becomes registered by paying an initial fee to the national registry. Registration is renewable every year by submitting an application for approval and proof of compliance with continuing education requirements, and paying a fee.

In Maryland, the Board of Physicians licenses radiographers who are certified by and registered with ARRT after submission of an application and payment of a fee. A Maryland license is renewable every two years after the initial licensing period expires.

Findings

The review team found that both the certification process at ARRT and the licensure process at the Board of Physicians rely on self-reporting of negative information, without reliable means of verification. In addition, the national registry failed to conduct an appropriate investigation of a complaint it received about Mr. Kwiatkowski.

Mr. Kwiatkowski applied to the Board of Physicians for a Maryland license on September 25, 2008. The Board issued a license on October 28, 2008, which expired on April 30, 2009. After allowing his license to lapse, Mr. Kwiatkowski applied for renewal on June 17, 2009, and the Board re-issued Mr. Kwiatkowski's license on July 8, 2009. The license again expired on April 30, 2011, and Mr. Kwiatkowski's national certification through ARRT was revoked in July 2012 as a result of criminal charges.

[16] Bureau of Labor Statistics (www.bls.gov) and (http://education-portal.com/articles/List_of_Health-Related_Careers_that_are_in_High_Demand.html

The review team found that Mr. Kwiatkowski made false statements on his initial and renewal applications for certification, registration and licensure that were not detected by ARRT or the Board. ARRT required Mr. Kwiatkowski to disclose criminal convictions or charges resulting in withheld adjudication or a plea of guilty in both his certification application and in his annual registration renewal applications. On all of the materials he submitted to ARRT from 2003 to 2011, Mr. Kwiatkowski failed to disclose either his 2000 conviction for driving under the influence or his 2005 conviction for driving while intoxicated. The ARRT website states[17]:

> When ARRT finds a charge or conviction that has not been reported, the non-disclosure is a violation of Ethics Rules 1 and 19. The non-disclosure often can be more serious than the nature of the conviction because it involves falsifying an Application for Certification or for Renewal of Registration. More and more, employers are conducting criminal background checks as part of the regular employee hiring process. When employers find unreported charges or convictions, they may contact ARRT to determine if these had been reported to the ARRT. Such reports are often the basis for initiating an inquiry into an individual's ARRT records. ARRT may also conduct background checks.

Records produced by ARRT in response to a subpoena give no indication that it conducted a criminal background check on Mr. Kwiatkowski in connection with any registration, or even when ARRT was investigating Mr. Kwiatkowski's admitted fentanyl diversion at Arizona Heart Hospital in 2010. ARRT conducted no ethics review in connection with Mr. Kwiatkowski's registration.

In his 2008 application for a Maryland license from the Board of Physicians, Mr. Kwiatkowski failed to disclose his 2005 conviction for DWI. Moreover, although Mr. Kwiatkowski did inform the Board about his 2000 DUI, he falsely asserted in his accompanying letter of explanation that he had informed ARRT about this conviction. In this letter, Mr. Kwiatkowski also stated that, despite the conviction, ARRT had permitted him to sit for its 2003 examination, falsely implying that he had passed ARRT's ethics review. The letter states:

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[17] https://www.arrt.org/FAQ/Ethics.

> In the year of 2000, I was pulled over by the state of Michigan police department, for drive (sic) under the influence of alcohol. At this point I was arrested and put in jail for the night. The next morning however I was let go and still had my license. A couple months later I went to court to follow up on the charges, I got a lenient sentence I was to do some community service and also attend case (sic) on alcohol abuse. This was on (sic) of the biggest mistakes in my life, but for some reason I had someone looking out over me[.] It took 2 years of a clean record and weekly class that I maintained even as a college student and college baseball player. I surely learned my lesson. The ARRT was aware of the charge and they still allowed for me to take my exam. This is all I really know about the situation, because like I said before if I stayed out of trouble there would be no record of it ever happening.

Board staff did not contact ARRT to verify Mr. Kwiatkowski's claim that he had told ARRT about the 2000 DUI. Nor did the Board conduct a criminal background check, which would likely have revealed the 2005 DWI.

Under the Board's procedures, licensure analysts are required to refer alcohol-related convictions, occurring within three years of an application, for further investigation by Board staff. Older offenses must be explained by letter, and the analyst decides whether the explanation is sufficient or requires referral to Board investigators. Under this policy, even if Mr. Kwiatkowski had disclosed his then-three-year-old 2005 conviction for DWI, an explanatory letter like the first one could possibly have been deemed sufficient.

Presently, the Board has assigned 1.5 full-time equivalent employees to process applications submitted by allied health professionals. Mr. Kwiatkowski's initial and renewal applications were handled by the same analyst. An analyst typically spends about 20 minutes processing a radiographer application, but, in the case of Mr. Kwiatkowski, the assigned analyst indicated that she may have spent more time on the initial application in 2008 because of the need to request and evaluate the letter explaining the 2000 DUI.

For a typical radiographer application, an analyst verifies education by mailed correspondence, verifies national registry certification and registration online, and checks the Healthcare Integrity & Protection Data Bank online.

In 2008, applicants to the Board were required to list all employers since 1995. Renewal applicants were required to list all employers since the last renewal.

Board analysts reported that the volume of applications does not afford them time to contact employers. Consequently none of the employers listed by Mr. Kwiatkowski were contacted for either of his applications to the Board.

Board policy requires an analyst only to communicate with employers identified in affirmative answers to question 14(D):

> Has your employment by any healthcare employer been affected by disciplinary actions including probation, suspension, loss of privileges, transfer to other duties, or termination of employment or contract? (e.g., provide name of institution, correspondence received or sent, related documents.)

The instructions require an applicant to "provide a signed and dated, detailed explanation" with supporting documents for an affirmative answer. Because Mr. Kwiatkowski falsely answered "no" to this question in the application he filed in 2008, the Board analyst did not know of his suspension by the University of Michigan Hospital in 2006, or the for-cause termination of his employment by the University of Pittsburgh Medical Center-Presbyterian in May 2008. It appears that the analyst did not communicate with either hospital before the Board issued a license to Mr. Kwiatkowski in October 2008.

Mr. Kwiatkowski was terminated for cause by Southern Maryland Hospital in February 2009. Mr. Kwiatkowski's license then expired on April 30, 2009. Six weeks later, on June 17, 2009, Mr. Kwiatkowski applied to renew his license. Because Mr. Kwiatkowski falsely answered "no" to question 14(D) again, the analyst did not know that Southern Maryland had terminated Mr. Kwiatkowski in March 2009 for falsifying time records and forgery. The Board reinstated Mr. Kwiatkowski's license on July 8, 2009.

Our review also identified weaknesses in ARRT's review of a complaint it received about Mr. Kwiatkowski in 2010. Specifically, in April 2010, the healthcare staffing agency then employing Mr. Kwiatkowski reported both to Arizona's licensing authority for radiographers and to ARRT that Mr. Kwiatkowski had been found unconscious at an Arizona hospital after an apparent episode of fentanyl diversion. Specifically, according to the statement of a co-worker that was submitted to the Arizona licensing authority, Mr. Kwiatkowski was found unresponsive in a bathroom stall. The co-worker wrote:

> We opened his [Mr. Kwiatkowski's] eye lids and saw his pupils were dilated. I then noticed he was bleeding from his right AC (antecubital). I looked in the toilet and spotted a 5cc syringe and a needle floating in the water….I then noticed the label on the syringe. The label was a blue fentanyl label. Dave slowly regained consciousness and the first word he uttered was "!&*$." He then said "!&*$…I am going to jail." I told Dave not to worry about that right now. He answered "How can I not worry about it?" He then sat up and threw something into the toilet and flushed it, syringe and needle both getting flushed also.

The nurse corroborated these observations in her separate statement. About three hours later, Mr. Kwiatkowski was interviewed by hospital staff and a police officer. Hospital staff records state in part:

> When asked what happened, David stated he had come in that morning and was doing his usual preparation for the case and went to the circular rack for "community lead" …put on one of the lead aprons…[and found] a filled, labeled syringe in the chest pocket of the lead. I asked what the label said, he replied it was "Fentanyl 100%". He said it was a 5 cc syringe and had "about 2 cc's" in the syringe. I asked why he did not inform someone about this syringe he found, and he did not give a direct answer …he went to the men's locker room and injected himself with the fentanyl in his right antecubital area….

The review team sought records from ARRT to understand how it responded to the information it received about this incident in Arizona. We found that the national registry did not request critical information from the Arizona board, including the facts described above. Nor did the registry obtain from the Arizona board a faxed, hand-written letter dated May 7, 2010 from Mr. Kwiatkowski, surrendering his license.

ARRT decided on January 26, 2011 to take no action against Mr. Kwiatkowski, apparently based on his explanatory letter received July 2, 2010, which stated in part:

> [T]he allegations of me being found semi-conscious in a bathroom stall at Arizona Heart Hospital are somewhat true to some extent. I wasn't feeling well all day, I was on my lunch break when I passed out, and when I came to I was on a stretcher on the way to the ER. At his (sic) point I was so confused and not myself I was bombarded with questions about what I took. They told

me they found drugs on me which was not true and I asked for a drug test than (sic). At this point I called a friend who told me to just go along with what they have to say and the test will show its truth. My employer is Springboard Inc. I than (sic) talked with them and arrange (sic) another drug test with them which I took and it was negative, I have enclosed that. To this day I'm still able to work with Springboard; there wasn't a fall out with this company. … To this day I'm still licensed in AZ and no decision has been made, I have called the committee there and haven't received any answers also I just renewed my license again.

Records produced in this review failed to show that ARRT staff spoke with staff at the Arizona board, the hospital where the incident occurred, or the staffing agency responsible for Mr. Kwiatkowski's placement there to verify Mr. Kwiatkowski's contentions in this letter.

In July 2012, the national registry defended its response to the Arizona incident by saying it "did not have first-hand evidence" and "[t]he filing of federal criminal charges in New Hampshire was the first information [it] received about Mr. Kwiatkowski that met the standard of evidence enabling the organization to remove his [national] credential."[18]

However, evidence gathered in our review appears to contradict that contention. There are weaknesses in the national registry's systems that have state and national implications. Thirty-nine states require radiographers to be certified and/or licensed.[19] Of those, thirty-seven states use the national registry's examination for state licensing purposes. [20]

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[18]CNN Wire Staff, Group: We had no evidence to punish man now accused in hepatitis C case, August 2, 2012.

[19] http://www.asrt.org/main/standards-regulations/state-legislative-affairs/states-with-licensure-or-certification-laws.

[20] https://www.arrt.org/State-Licensing/Licensing-vs-Certification-Registration.

Recommendation

Recommendation 2: The Board of Physicians should review and revise its procedures for licensing allied health professionals.

The Maryland Board of Physicians should undertake a thorough review of the processes by which allied health professionals are licensed, and the role, if any, a credentialing authority like the American Registry of Radiologic Technologists should play.

The Board and credentialing authorities should refine their initial and renewal application processes, based on a better understanding of the profiles of healthcare workers who engage in drug diversion. The Board and credentialing authorities should incorporate into their procedures a national criminal background check; should validate past employment experiences and thoroughly investigate any suspicions of drug abuse and diversion; and should have robust processes for complaint intake, investigation, resolution, and interstate reporting, when appropriate. In addition, in terms of scope of practice issues for allied health professionals, the Board should examine the statutes governing the licensure and practice of the allied health professions and clarify any ambiguity regarding supervisory responsibilities they may impose on physicians, particularly relating to medication administration and handling.

3. Employment References and Reporting of Patient Safety Violations and Risks

The failure of hospitals and temporary staffing agencies to properly screen Mr. Kwiatkowski before hiring him contributed significantly to the multi-state hepatitis C outbreak. Our review also revealed that hospitals and staffing agencies either did not disclose Mr. Kwiatkowski's conduct to one another, or favorably represented his job performance to one another, despite evidence of risky conduct, thereby obscuring the risks that Mr. Kwiatkowski posed.

Context

For each of Mr. Kwiatkowski's temporary placements in Maryland, the staffing agency and the hospital likely would be considered joint employers under

Maryland's joint employer doctrine,[21] qualifying their employment references for protection under *See* Md. Code Ann., Cts. & Jud. Proc. § 5-423. [22]

In providing references to prospective employers, current or former employers must evaluate the job performance and weigh potential tort duties of disclosure[23] against the risk of defamation claims, [24] and must do so in the context of the protections offered by Maryland's reference immunity statute. The review team found that healthcare employers do not disclose risky conduct in references for fear of defamation claims, despite the statute's strong protections.

Maryland's reference immunity statute, at § 5-423 of the Courts and Judicial Proceedings Article, provides that an employer who discloses adverse information in good faith is immune, and:

> shall be presumed to be acting in good faith unless it is shown by clear and convincing evidence that the employer (a)cted with actual malice or (i)ntentionally or recklessly disclosed false information about the employee or former employee[.]

(emphasis added). The ordinary standard of proof in a civil action is a preponderance of the evidence. The clear and convincing evidence standard set forth in the statute is a higher standard of proof, and like the presumption of good faith, increases a disclosing employer's likelihood of pretrial dismissal if sued.

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[21] *Whitehead v. Safway Steel Products*, 304 Md. 67, (1985); Maryland Employment Law § 2.04 Joint Employer Doctrine.

[22] *See also* Frank v. Home Depot, U.S.A., Inc., 481 F. Supp. 2d 439, 443-444 (D. Md. 2007).

[23] *See*, *e.g.,Kadlec Med. Ctr. v. Lakeview Anesthesia Assocs*., 527 F.3d 412 (5th Cir. 2008); *see also* Candor After Kadlec: Why, Despite the Fifth Circuit's Decision, Hospitals Should Anticipate an Expanded Obligation to Disclose Risky Physician Behavior, 1 Drexel L. Rev. 383, 405-407(2009).

[24] *Shapiro v. Massengill*, 105 Md.App. 743, 770-778 (1995); *see generally* Maryland Employment Law, Ch. 5, §5.02.

In the wake of the interstate outbreak associated with Mr. Kwiatkowski, some hospital executives are advocating for laws that would require health care employers to make certain disclosures to prospective employers.[25]

Findings

None of the individuals interviewed in connection with this review indicated that they were aware of Maryland's reference immunity statute, or the fact that the majority of states have enacted reference immunity statutes. Lack of such awareness is evidently an issue nationwide.[26]

Seventeen years after Maryland's reference immunity statute was enacted, healthcare employers' fears of defamation lawsuits persist. When asked about hiring practices, hospital administrators described essentially the same practice: when contacted by others to be a reference, hospitals confirm the fact and dates of employment for former employees, and receive the same limited information when inquiring about prospective employees. Those interviewed indicated this practice serves to prevent defamation lawsuits.

Our review found that, in the case of Mr. Kwiatkowski, there was not strict adherence to this practice of simply confirming the fact and dates of employment was not universally followed. At one Maryland hospital, for example, Mr. Kwiatkowski was among employees under suspicion when two or three fentanyl vials were found to be missing in the cardiac catheter lab. Minutes of a staff meeting attended by his manager state in part:

> Concerns have arisen regarding David K and his employment. Many concerns have come to light from current staff members about his accountability, performance, attitude, and other issues/lies.

At the same hospital, the same manager expressed specific concerns to colleagues that Mr. Kwiatkowski was "going through our sharps containers" to look for narcotics, and supervisors expressed mock surprise to one another ("take a wild

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[25] Kevin Callahan, UnionLeader, Opinion, Aug. 10, 2012.

[26] Bruce Elder, Sara Gerdes, Is a Job Reference Really a Reference? Addressing Employer Name, Rank, and Serial Number Policies through Job Reference Immunity Legislation, Journal of Business Inquiry: Research, Education and Application, Volume 6 (2006-2007); Markita D. Cooper, Job Reference Immunity Statutes: Prevalent but Irrelevant, 11 Cornell J. L. & Pub. Pol'y 1 (2001).

guess"), via email, when it was discovered that fentanyl was missing in the treatment room to which Mr. Kwiatkowski was assigned.

A staffing agency later contacted the hospital for a reference on Mr. Kwiatkowski. In an email message to the staffing agency, the manager -- who had expressed and was personally aware of concerns about Mr. Kwiatkowski's performance, honesty and apparent scavenging for narcotics -- stated in part:

> Just trying to follow up with you after our phone call. I am glad we caught up regarding Dave Kwiatkowski and his skill sets seen here …. David is very professional and worked very hard...

During his placements in Pennsylvania, Maryland, and Arizona, there were clear indications that Mr. Kwiatkowski was diverting fentanyl and engaging in other behaviors that posed risks to patients. Yet Maryland hospitals were not made aware of what occurred in Pennsylvania, the Arizona hospital was not made aware of what occurred in Pennsylvania and Maryland, and hospitals in Kansas and New Hampshire were not made aware of what occurred in Arizona, Maryland or Pennsylvania. Hepatitis C infections have been attributed to Mr. Kwiatkowski in New Hampshire, Kansas and Maryland. Required reference disclosure statutes might have broken this chain of non-disclosure and precluded Mr. Kwiatkowski from continuing to work, divert fentanyl and infect patients with hepatitis C.

Recommendation

Recommendation 3: There should be consideration of additional legislation related to disclosure of negative employment references.

While there are existing statutes conferring immunity on those who report potential disciplinary violations to the health occupations boards, the review team recommends there be consideration of a single immunity statute that would apply to reports and references made to any licensing board and to other prospective employers.

Consideration should also be given to broadening the obligation to report to require that employers make concerns about patient safety known to prospective employers during reference checks.

Because the details of these issues are complex, the review team recommends further discussion with interested parties on the best approach to legislation in this area.

4. Drug Diversion Prevention and Response Processes in Hospitals and Other Healthcare Facilities

The review found that Mr. Kwiatkowski thwarted the drug diversion prevention and response processes in hospitals.

Context

A key tenet of patient safety is to perform assessments of processes where errors can occur and develop improved systems and processes to eliminate the risk of error. Maryland hospitals are required by law to perform root cause analysis (RCA) and healthcare failure mode effect analysis (HFMEA) for serious adverse events and sentinel events. *See* Md. Code Ann., Health-Gen. § 19-304; COMAR 10.07.06. The Joint Commission imposes similar requirements for accreditation. The failure to secure medication and the subsequent reuse of syringes and vials are serious adverse events/ sentinel events. Hospitals should begin to analyze lost medications (especially injectable medications, given the infection risk) as they would a potentially lethal near miss, deem such loss as a reportable adverse event, requiring both immediate investigation and subsequent Root Cause Analysis to be reported to the state regulatory body (DHMH Office of Health Care Quality).

According to a survey conducted by the New Hampshire health department in response to Kwiatkowski's actions at Exeter Hospital, momentary lapses in procedures may have contributed to Mr. Kwiatkowski's access to controlled medications.[27] Exeter Hospital staff was asked by the surveyors to prepare to perform a catheterization procedure while surveyors observed. One example of such a lapse was noted during this observation, when a registered nurse was noted by surveyors to have left medication unattended as she put on a protective lead apron. The surveyors believed that, in the time needed for the nurse to put on a lead apron, there would have been sufficient opportunity for a drug-diverting healthcare worker to switch needles or vials.

Hospitals and healthcare facilities must change their view of drug diversion and elevate it to the level of both a patient safety violation and an infection prevention event. Anecdotal evidence repeatedly demonstrated that highly educated and well-trained staff failed to recognize or overlooked behaviors

[27] Exeter Hospital, CMS 2567 for the survey dated July 13, 2012.

indicative of addiction and/or failed to follow established policies to address staff with substance abuse problems. Healthcare culture must change for hospital staff to accept and understand that the patient is the primary victim of diversion.

Findings

The review has focused on systemic weaknesses that contributed to the hepatitis C outbreak. Even when there are reasonable systems to prevent drug diversion, the nature of healthcare procedures and the products used for patient care can provide for a healthcare worker to quickly steal medications and devices without detection, substituting used contaminated devices that subsequently can be used on an unsuspecting patient. Healthcare workers may be required to multitask or to address the emergency needs of a patient, giving rise to momentary lapses in medication security.

The exact means by which Mr. Kwiatkowski infected patients in Maryland and elsewhere has not been determined. But those who worked with him have postulated, in review interviews and in public accounts about his work in other states, that his drug diversion may have involved the following acts:

- Switching the intended syringe/vial/ampule with a syringe/vial/ampule containing saline-type solution but labeled as the intended narcotic medication (thus, medication containers at risk for contamination)
- Accessing a multi-dose vial by withdrawing, substituting or diluting the contents and returning the vial back to the procedure area(using a contaminated syringe/needle could contaminate the vial)
- Intervening with the procedural "wasting" of unused narcotic
- Salvaging discarded vials and lids from waste containers
- Stealing syringe or vial during brief moments of inattention by other clinical staff during busy or distracting times, such as medical emergencies or setting up/cleaning up procedure areas
- Accessing locked drawers or containers where medications were temporarily stored
- Befriending and assisting nurses while finding innovative ways to obtain medications
- Entering, exiting and taking frequent breaks during procedures
- Coming in to work off hours, visiting procedure and patient care areas
- Acting as a witness for the "wasting" of narcotics in the procedure suite

- Assisting with clean up after procedures (where partially used vials may have been left)
- Pocketing filled syringes, leaving syringes in toilet bowls and leaving empty syringe wrappers in common areas
- Tampering with an automated medication dispensing system

Many hospitals have drug diversion monitoring programs, but these programs are not currently mandated or standardized, and their scope and efficacy vary. Critical aspects of such a program include surveillance, a rapid response to diversions suspicion, referral to treatment for substance use disorders, and strong institutional support.

To enhance patient protection, healthcare facilities should assign drug diversion prevention and response to their patient safety teams and regard any incident of drug diversion as an adverse event. Prevention of adverse events is often implemented in hospitals by such means as pre-procedural checklists or tool kits, or with post-procedural events such as post-operative sponge counts or surgery tray equipment counts. However, mechanisms do not exist to facilitate the reporting of injectable narcotic loss via Root Cause Analysis to regulatory authorities. This is a missed opportunity for evaluation, remediation and oversight. The Maryland Department of Health and Mental Hygiene, Office of Health Care Quality has an existing system for receiving and responding to adverse event reporting.

Another vulnerability identified in the review was the failure of co-workers and supervisors to report missing injectable narcotics and suspicions about possible diversion up the chain of command and to licensing boards. The team heard anecdotes about anonymous calls from staff at one hospital warning staff at another hospital to "watch out" for Mr. Kwiatkowski, without details being given. The cardiac catheterization lab staff at different hospitals appeared to know one another and discuss employees like Mr. Kwiatkowski on a regular basis. But the review found no evidence that fellow staff reported Mr. Kwiatkowski's patient safety violations to the Maryland Board of Physicians or the national registry.

Environmental controls can minimize drug theft. State and national experts in risk management, pharmacy and radiology recommend placing automated medication dispensing systems in the procedure room closest to where the medications will be administered by the nurse. This is considered the best arrangement to minimize the likelihood of diversion. When Mr. Kwiatkowski worked in Maryland, all four hospitals used automated dispensing systems in the suites containing the procedure rooms where Mr. Kwiatkowski participated in

procedures, but not all hospitals had automated dispensing systems in each individual procedure room. While all the hospitals currently have medication dispensing systems directly in each procedure room, this was not the case when Mr. Kwiatkowski was working in Maryland.

Scope of practice restrictions can limit access to narcotics. In Maryland, radiographers are expressly prohibited from giving "narcotic or sedating medication," *see* Code of Maryland Regulation 10.32.10.07(B)(2), but they are not prohibited from witnessing narcotics wasting. Some Maryland hospitals, citing staffing shortages, indicated that they allow radiographers or other licensed personnel to witness narcotics wasting by a nurse. This was identified as a potential opportunity for injectable narcotics diversion, as it involves additional hospital staff who are not authorized to administer or access medication.

Clear supervisory roles may safeguard against unauthorized behaviors by allied health professionals. The review team observed deficits in awareness that, under Maryland law, a radiographer "may only practice under the supervision of a licensed physician" and that "the failure of a licensed physician to properly supervise a licensee is unprofessional conduct in the practice of medicine". *See* Md. Code Ann. § 14-5B-07(a)(1)-(2). As a radiographer, Kwiatkowski should never have had unsupervised access to narcotics. But it appears that physicians are not consistently aware of their supervisory duties regarding allied health professionals, nor has substantial consideration been given to ensuring the effectiveness of such supervision.

There are numerous barriers to reporting drug loss or suspected drug diversion and other unethical or criminal behavior among healthcare workers. The review found that the perception of the negative consequences of reporting drug loss can create a barrier to such reporting. In some clinical situations, the nurse or pharmacist may face fines or disciplinary action if a controlled substance is missing that has been dispensed under his or her supervision. There is also a lack of clarity on protections offered by the Maryland legal system to the reporting person. In interviews, some healthcare workers expressed concerns both about risks to their own personal safety after reporting suspicions and about the possibility that fellow workers might abuse a reporting mechanism by making false reports for personal gain. Finally, many health care workers interviewed for this review expressed a lack of confidence that personnel action would be taken in response to a report of drug diversion or that risks to patient safety would be investigated. Healthcare workers are more likely to report adverse information about co-workers if facilities address

and communicate an understanding of the possible outcomes and ramifications of such reporting.

There is no standardization of the definition of "significant loss" of an injectable narcotic, making reporting of such a loss subjective. In the case of Mr. Kwiatkowski, no Maryland facility reported a "significant loss" of narcotics to the federal Drug Enforcement Agency (DEA). According to federal and state statutes, any instance of theft or "significant loss" of any Schedule II-V controlled dangerous substance must be reported to the DEA within one business day. *See* 18 USC §§ 801 et seq.; Md. Code Ann., Crim. Law § 5-101 *et seq*. In the facilities that discussed their policies with the review team, the most common way of handling the "significant loss" issue is to detect and report a "pattern" of loss. Additionally, in discussions with the review team, local DEA officials acknowledged the serious nature and consequences of drug diversion/theft in healthcare facilities, but stated that DEA must focus its resources on larger scale drug theft and abuse. Small scale theft is more frequently handled by individual hospital risk management and pharmacy teams, who investigate the loss at their discretion and often do not report to DEA.

At present, hospitals may not adequately educate their staff about their internal policies on identifying and reporting substance abuse, drug loss and drug diversion. Regularly training staff regarding the signs and symptoms of substance abuse and drug diversion would improve the detection of such activities. One Maryland facility reported that it has incorporated such training into its routine patient safety training for staff, in order to raise awareness. It may be possible for facilities to develop expertise in identifying sentinel behaviors associated with substance abuse and diversion. Such behaviors might well include many of those attributed to Mr. Kwiatkowski, such as volunteering for extra shifts, volunteering to help clean up and witness medication wasting, cultivating friendships with dispensing clinicians, taking frequent breaks during procedures and coming into work when not scheduled, as well as physical signs of active drug use and withdrawal.

Anonymous reporting mechanisms for patient safety concerns are not uniformly available in the hospital setting, but many Maryland hospitals do have an anonymous reporting hotline or a system for reporting concerns to the administration. Increasing awareness of substance abuse issues and creating mechanisms for anonymous reporting would have the added benefit of potentially increase referrals for treatment for substance use disorders in healthcare workers.

Recommendation

Recommendation 4: Hospitals and other healthcare facilities should develop processes to prevent and respond to drug diversion.

The review team recommends that hospitals and healthcare facilities regard drug diversion as a patient safety issue and standardize their prevention and response efforts. Such efforts should include:

- the formation of drug diversion and response teams at each facility;
- staff education regarding substance abuse, drug diversion and patient safety;
- the development of a standard definition of "significant loss" of controlled substances, with a special focus on injectable narcotics;
- staff empowerment to report suspected diversion, including education about applicable legal protections and immunities;
- placement of medication storage units in procedure areas, such as electronic medication dispensing systems;
- limiting staff witnessing of drug wasting to only those licensed to handle controlled dangerous substances;
- implementing injectable narcotics count " time outs" after procedures, in order to tally the amount dispensed and wasted before staff leave the procedure area;
- instituting a "stop work" or "lockdown" if there is any missing narcotic post-procedure;
- mandatory staff testing for the presence of narcotics immediately following a discrepancy occurrence;
- internal reporting protocols for diversion events;
- posting of an internal and external hotline for anonymous reporting of suspected drug diversion;
- clarification of supervisory responsibility over allied health professionals, including temporary employees;

- the development of a system to identify, refer to treatment, and assist employees with substance use disorders;
- requiring drug diversion to be a reportable adverse event; and
- discrepancy reporting via "root cause analysis" to regulatory authorities.

Surveillance for drug diversion and theft should be strengthened and standardized. Medical experts from the Centers for Disease Control and Prevention and the Mayo Clinic support the formation of a team for drug diversion review and response in hospital settings. Such multidisciplinary teams design and oversee surveillance for drug abuse and diversion, including: pharmacy data and inventory analysis, narcotic waste collection analysis, audits of pharmacy use, camera surveillance, DEA reporting; and employee evaluation, drug testing, and discipline. Important elements of such a team would include: strong active multidisciplinary leadership, adequate resources and financing, an initial focus on high risk situations, a robust surveillance system, optimization of supportive technology, and rapid response.[28] While aspects of such programs have been implemented in various forms in Maryland hospitals, even well-developed ones have proven fallible.

Finally, facilities should explore new technologies that may improve products and protocols related to narcotic use. These technologies should include changes in drug administration, such as minimizing intravenous administration of narcotics or improved dosing to negate the need for the risky practice of "drug wasting." Also, product changes could include single-use and/or tamper-proof syringes or the addition of inert dyes in all injectable narcotics that would make substitution by other substances evident.

To accomplish these objectives, the review team recommends that the Office of Health Care Quality, the Maryland Patient Safety Center, or similar organization convene hospitals and develop a best practices approach appropriate for statewide adoption.

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[28]Berge KH, Perz JF, Dillon KR, Pugliese G, "Preventing theft of drugs and controlled substances - A patient safety imperative". Premier Safety Institute, Sept. 26, 2012. at: https://www.premierinc.com/safety/safety-share/bulletin-preventing-drug-theft-081712.jsp

5. Interstate Information Sharing about Allied Health Professional Conduct Posing Patient Safety Risk

The federal government has established a registry, called the Data Bank, to enable state licensing boards, hospitals, and professional societies to report unprofessional behavior, prevent incompetent providers from ongoing practice if they move between states, and decrease fraud and abuse.

However, there are limitations on the usefulness of the Data Bank for addressing ongoing misconduct by allied health professionals.

There are two main areas of reporting to the Data Bank that may be monitored by hiring entities and licensing bodies.

Licensure actions: Licensure actions have historically been reported to two separate entities, the National Practitioner Data Bank and the Healthcare Integrity & Protection Data Bank, which under the Affordable Care Act have been consolidated into one entity, the Data Bank. Before 2010, licensure actions against allied health professionals were only accessible to health plans and to federal and state governments. Starting in 2010, these licensure actions became available to hospitals, other health care entities, and professional organizations.

Administrative actions: Reporting of administrative actions—such as termination for activity that compromises patient care or illegal activity—to the Data Bank is mandated for physicians and dentists. Such reporting is permitted (but not required) for some other health care practitioners with clinical privileges—for example, nurse practitioners or physician assistants. However, the Data Bank cannot receive reports of administrative actions against health care practitioners without clinical privileges, such as radiographers

Recommendation

Recommendation 5: The federal government should expand the Data Bank to capture additional information about allied health professionals who may pose risks to patient safety.

Medical licensing boards and health care employers should utilize the Data Bank's existing capabilities and run queries on licensure actions when licensing and hiring allied health practitioners.

The federal Data Bank should be configured to support reporting of adverse administrative actions against all health care practitioners and to allow for routine queries for all hiring and licensure of health care practitioners. This step may require federal regulatory action.

When such capacity is available, health care facilities should be required to report to the Data Bank administrative actions against all health care practitioners.

APPENDIX A: REFERENCES

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APPENDIX B: STATUTES/REGULATIONS/STANDARDS

Annotated Code of Maryland

Hospitals and Related Institutions, Reporting unexpected occurrences or incidents; analysis. Annotated Code of Maryland Health General Article §19-304 (2012)

Nursing Staff Agencies, Annotated Code of Maryland Health General Articles §19-2001 to §19-2002 (2012).

Radiation Oncology/Therapy Medical Radiation Nuclear Medicine Technologist.

Annotated Code of Maryland Health Occupations § 14-5B-03(2012)

Accreditation of Health Care Facilities. Annotated Code of Maryland Health General Articles § 19-2301 and § 19-2302 (2012).

Joint Employer Doctrine. Maryland Employment Law § 2.04 (2012)

Misrepresentation. Maryland Tort Law Handbook § 11.8, Direct and Indirect Employer Liability and §§ 17.0-17.6, Risk of defamation § 6.4, Defamation *Per Se (2012).*

Maryland Reference Immunity Statute. Annotated Code of Maryland Courts and Judicial Proceedings§ 5-423 (2012).

Code of Maryland Regulations

Licensure of Radiation Technologists, Radiographers, Nuclear Medicine Technologists, and Radiologist Assistants Technologists. Code of Maryland Regulations 10.32.10

Maryland Hospital Patient Safety. Code of Maryland Regulations 10.07.06

Acute General and Special Hospitals. Code of Maryland Regulations 10.07.01

Nursing Staff Agencies. Code of Maryland Regulations 10.07.03

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American Registry of Radiologic Technologists (ARRT) https://www.arrt.org (2012)

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Federal Statutes

Controlled Substance Act of 1970. 21 Code of Federal Register 801

Medicare Conditions of Participation for Acute General Hospitals. 42Code of Federal Register 82.

APPENDIX C: FABRICATION OF MAXIM DOCUMENTS

In October 2012, the Secretary of Health and Mental Hygiene issued a subpoena, pursuant to § 2-104(k) of the Health-General Article, to Maxim HealthCare Services, Maxim Staffing Solutions and Travel Max (collectively, "Maxim"), for all documents related to Maxim's employment or placement of David Kwiatkowski. Maxim's businesses include temporary healthcare staffing, and Maxim was responsible for placing Mr. Kwiatkowski at the University of Pittsburgh Medical Center in March 2008 and then, after UPMC's termination of that placement for reasons related to "narcotics," which Maxim found to be "unsubstantiated," for placing Mr. Kwiatkowski at Southern Maryland Hospital in November 2008. Southern Maryland terminated Mr. Kwiatkowski's placement in February 2009 after it found that he was falsifying time records and forging his supervisor's signature.

In response to the Secretary's October 2012 subpoena, Maxim produced, among other things, an email message (attached) dated "March 11, 2009 3:21 PM" from the "Maryland Board of Physicians (mpbmail@rcn.com)" to Maxim's then Regional Director of Clinical Services, stating:

> Please let this serve as notification that we received your report of unprofessional and unethical conduct on David Kwiatkowski, License #R090107 on March 9, 2009. We take these matters very seriously and assure you that we will investigate this issue to the fullest extent possible and may require further investigation from you. Thank you for your report and supporting our commitment to patient safety. Should you have any questions, you may email us at mbpmail@rcn.com.

Upon reviewing this document, the review team conducted extensive investigation of the Board of Physicians' then-seemingly deficient response to Maxim's purported March 9, 2009 complaint about Mr. Kwiatkowski, making repeated inquiries of both the Board and Maxim. On February 12, 2013, in response to inquiries by the review team, a lawyer for Maxim contacted the Office of the Attorney General to indicate that Maxim could not confirm the authenticity of the "March 11, 2009 3:21 PM" email message that it had produced three months earlier. On February 22, 2013, counsel for Maxim indicated that the email message was a fabrication.

Through counsel, Maxim indicated that it has conducted an internal investigation of this matter, and it has concluded that, in July 2012, after Mr.

Kwiatkowski was arrested, Maxim's former Regional Director of Clinical Services fabricated the "March 11, 2009 3:21 PM" email message, as well as one other document produced in response to the Secretary's subpoena. According to Maxim, there is no evidence that anyone other than the former Regional Director of Clinical Services participated in the fabrication of these documents. Maxim has further acknowledged that the former Regional Director of Clinical Services, who had specific responsibility within Maxim for placement of radiographers and other allied health professionals in Maryland, did not contact the Maryland Board of Physicians on March 9, 2009. Instead, according to cell phone records that Maxim has provided, at 4:57pm on that date, the former Regional Director of Clinical Services made a 36-second phone call to the Maryland Board of Physical Therapy Examiners, which does not regulate radiographers. Maxim states that the former Regional Director of Clinical Services heard a recorded message when she called the Board of Physical Therapy Examiners, and that, during the brief call, she left a voicemail message. She fabricated the "March 11, 2009 3:21 PM" email in 2012 in an apparent attempt to document this phone call.

Since September 2011, Maxim has been operating under a Deferred Prosecution Agreement with the U.S. Attorney for the District of New Jersey. In connection with that agreement, Maxim admitted that, from 2003 to 2009, it had "conspired to defraud government health care programs," by, among other things, "submit[ting] materially false and fraudulent billings to government health care programs." Maxim further admitted that, "to conceal [its] submission of materially false and fraudulent billings," it "falsely and fraudulently creat[ed] or modif[ied] timesheets," "falsely and fraudulently submit[ted] billings," and "falsely and fraudulently creat[ed] or modif[ied] documentation related to required administrative functions."

In the September 2011 Deferred Prosecution Agreement, Maxim "commit[ted] itself to exemplary corporate citizenship, best practices of effective corporate governance, the highest principles of honesty and professionalism, the integrity of the operation of federal health care programs . . . , and a culture of openness, accountability, and compliance throughout the Company."

The Department has advised the U.S. Attorney's Office in New Jersey of this matter, as well as the Criminal Division of the Office of the Attorney General of Maryland. Separately, the Department's Office of Health Care Quality is reviewing the matter to determine whether any action should be taken with respect to Maxim's license to operate as a nurse staffing agency in Maryland.

[redacted]

From: [redacted]
Sent: Friday, July 13, 2012 1:30 PM
To: [redacted]
Subject: FW: David Kwiatowski

[redacted]

MSS Regional Director of Clinical Services
TravelMax/Reflectx Staffing
Maxim Government Services/Maxim Physician Resources
[redacted]/PPOR/Orbis Clinical

[redacted]

Confidentiality Statement: "The information contained in this facsimile/email transmission is privileged and confidential and is intended only for the use of the recipient listed above. If you are neither the intended recipient or an employee or agent of the intended recipient responsible for the delivery of this information, you are hereby notified that the disclosure, copying, use or distribution of this information is strictly prohibited. If you have received this transmission in error, please notify us immediately to arrange for the return of the transmitted documents or to verify their destruction."

Confidential Health Information Attached: "Health care information is personal and sensitive. It is being forwarded to you after appropriate authorization from the patient/employee or under circumstances that do not require patient authorization. You, the recipient, are obligated to maintain this information in a safe, secure and confidential manner. Re-disclosure without additional patient consent or authorization or as permitted by law is prohibited. Unauthorized re-disclosure or failure to maintain the confidentiality of this information could subject you to penalties under Federal and/or State law." Thank you.

From: Maryland Board of Physicians (mpbmail@rcn.com)
Sent: Wednesday, March 11, 2009 3:21 PM
[redacted]
Subject: David Kwiatowski

[redacted]

Please let this serve as notification that we received your report of unprofessional and unethical conduct on David Kwiatkowski, License #R09107 on March 9, 2009. We take these matters very seriously and assure you that we will investigate this issue to the fullest extent possible and may require further information from you. Thank you for your report and supporting our commitment to patient safety. Should you have any questions, you may email us at mbpmail@rcn.com .

Maryland Board of Physicians